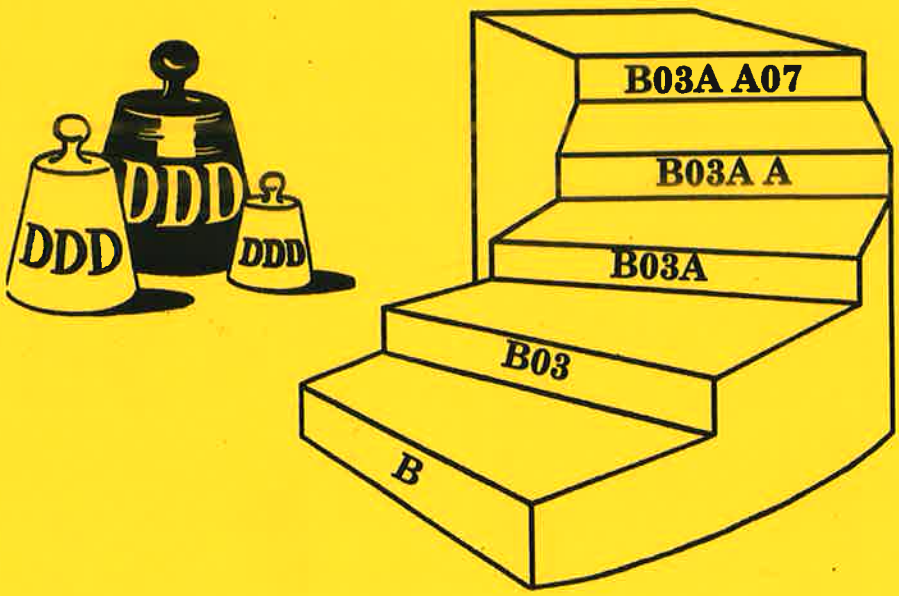
Guidelines for

ATC classification and DDD assignment



WHO Collaborating Centre
for Drug Statistics Methodology

Oslo 1996

Guidelines for ATC classification and DDD assignment

ISSN 0802-8753
ISBN 82-90312-23-7

Guidelines for ATC classification and DDD assignment

1st edition[1]

WHO Collaborating Centre
for Drug Statistics Methodology
c/o Norsk Medisinaldepot AS
P.O.Box 100, Veitvet
N-0518 Oslo
Norway
Telephone: (47) 22169810/22169801
Telefax: (47) 22169818

---

[1] 1st edition of the combined publication. Previously published: *Guidelines for ATC classification* (4 editions), *Guidelines for DDD* (2 editions)

PREFACE

The Anatomical Therapeutic Chemical (ATC) classification system and the Defined Daily Dose (DDD) as a measuring unit in drug utilization studies are now widely used internationally and the number of users is gradually increasing. The purpose of preparing guidelines is to make information about the ATC classification system and the DDD methodology available to the users.

This new edition is a combined edition including the two previous publications, *Guidelines for ATC classification* and *Guidelines for DDD*. Since DDDs are closely connected to the ATC classification system we have considered it most appropriate to prepare one combined publication covering the two previous books.

This new edition of the *Guidelines for ATC classification and DDD assignment* is built up similarly to the previous separate editions and will replace the 4th edition of the *Guidelines for ATC classification* and the 2nd edition of the *Guidelines for DDD*. All text connected to the assignment of DDDs are given in shadowed boxes in the various chapters to each ATC group.

The members of the WHO Technical Working Group have given expert advice and comments on the work with these guidelines

Complete ATC indices including DDDs, which will be useful when reading these guidelines, are available on request from the WHO Collaborating Centre for Drug Statistics Methodology.

We hope this book will prove helpful to the users of the ATC/DDD system. Suggested improvements can be addressed to the WHO Centre in Oslo.

Oslo, December 1995

Marit Rønning, Solveig Sakshaug and Irene Litleskare
WHO Collaborating Centre for Drug Statistics Methodology
c/o Norsk Medisinaldepot AS
P.O. Box 100, Veitvet
N-0518 Oslo
Norway
Telephone: (47) 22169810/22169801
Telefax : (47) 22169818

CONTENTS

Preface 5

Introduction 9

Who Collaborating Centre for Drug Statistics Methodology 10

The Anatomical Therapeutic Chemical (ATC) Classification System 12

Main principles for the classification of medicinal substances according to the ATC system 14

Classification of plain preparations 15

Classification of combined preparations 16

New entries in the ATC classification 17

Nomenclature in the ATC system 18

Principles for making alterations in the ATC system 19

Units of measurement in drug utilization studies 21

Cost 21

Volume 21

Prescribed daily dose 22

Defined Daily Dose 22

Main principles for the establishment of DDDs 23

Principles for expressing defined daily doses 27

Procedure for establishment of new DDDs 28

DDD time schedule 29

Principles for reviewing and changing DDDs 29

Reporting 31

Uses of the ATC/DDD system 32

ATCvet classification 34

ATCherbal classification 35

ATC system main groups 36

A Alimentary tract and metabolism 37

B Blood and blood forming organs 69

C Cardiovascular system 81

D Dermatologicals 107

G Genito urinary system and sex hormones 123

H Systemic hormonal preparations, excl. sex hormones 137

J General antiinfectives for systemic use 145

L Antineoplastic and immunomodulating agents 163

M Musculo-skeletal system 169

N Nervous system 179

P Antiparasitic products, insecticides and repellents 201

R Respiratory system 209

S Sensory organs 223

V Various 233

Order form - ATC index 249

INTRODUCTION

Many new potent, effective, and expensive drugs have been introduced during the recent decades. This has led to a steady increase in drug consumption, as reflected in increased drug costs.

Research into drug utilization has been attracting increasing interest, both in scientific and in government circles.

The pioneering work, done by two consultants at the WHO Regional Office for Europe, Engel and Siderius, was a study of drug consumption in six European countries in the period 1966 - 1967, which showed great differences in drug utilization. This study was followed by a symposium entitled *The Consumption of Drugs* in Oslo in 1969, organized by the WHO Regional Office for Europe. On the basis of the findings in the study, this symposium clearly confirmed that an internationally accepted classification system was needed for presenting data on drug consumption.

The most important result of this symposium was the formation of the Drug Utilization Research Group (DURG). Its main task was to develop and establish an international method for drug utilization studies.

By modifying and extending the European Pharmaceutical Market Research Association (EPhMRA) classification system, the Norwegian Medicinal Depot (NMD) developed a system known as the Anatomical Therapeutic Chemical (ATC) classification. NMD also introduced the defined daily dose (DDD) as a unit of measurement in drug utilization studies. The ATC/DDD system has been used in Norway since the early seventies for presenting drug consumption data.

The DURG members recommended the ATC/DDD methodology for international drug utilization studies.

The Nordic Council on Medicines (NLN) was established in 1975. In 1976 the NLN decided to publish *Nordic Statistics on Medicines* using the ATC/DDD methodology. The ATC classification was as a result of this, further developed in collaboration with the NLN, and a DDD was established for most drugs on the Nordic market.

In 1981, the WHO Regional Office for Europe recommended the ATC/DDD

system for international drug utilization studies. In connection with this, and to make the methodology more widely used, there was a need for a central body responsible for coordinating the use of the methodology. The WHO Collaborating Centre for Drug Statistics Methodology was accordingly established in Oslo in 1982.

It should be emphasized that the inclusion of a substance in the ATC system and the assigned DDD is not to be considered a recommendation for use, nor does it confer any status (i.e. related to efficacy) on the substance.

The main purpose of the ATC/DDD system is to be a useful tool for presenting drug consumption statistics. The decision to adopt the methodology for other purposes is the responsibility of the users (e.g. health authorities). Accordingly the WHO does not have any legal responsibility as to how the ATC/DDD system is adopted.

This book includes all ATC headings down to the 4th level assigned by the Centre in Oslo.

The comments included vary from one ATC group to another. No comments are given if the establishment of ATC codes and DDDs is considered to cause no special problems.

Comments related to the assignment of DDDs are given in shadowed boxes.

WHO COLLABORATING CENTRE FOR DRUG STATISTICS METHODOLOGY

The Anatomical Therapeutic Chemical (ATC) classification system and the defined daily dose (DDD) as a unit of measurement are recommended by the World Health Organization Regional Office for Europe (WHO-Euro) for use in drug utilization studies.

In 1982, the WHO Regional Office for Europe (WHO-Euro) established a WHO Collaborating Centre for Drug Statistics Methodology to ensure the broader international dissemination of the ATC/DDD methodology. The Centre is situated at the Norwegian Medicinal Depot (NMD), which has long experience in the use of this methodology.

According to the agreement between WHO-Euro and NMD, the Centre's main tasks are:

- to classify drugs according to the ATC system,
- to establish DDDs for drugs which have been assigned an ATC code,
- to review and revise as necessary the ATC classification system and DDDs.

Priority will be given to the classification of single substances, while combination products available internationally (i.e. important fixed combinations) will be dealt with as far as possible.

The agreement between WHO-Euro and NMD is reviewed every fourth year.

The WHO Collaborating Centre for Drug Statistics Methodology receives expert advice from a WHO Technical Working Group. The Working Group is responsible for the scientific development of the ATC/DDD system. The Working Group is consulted when questions of principle character arise concerning the ATC/DDD system (e.g. various difficulties concerning where to classify a certain drug and which DDD should be assigned). Decisions concerning ATC and DDD alterations are discussed and approved by the members of the Working Group.

The members of the WHO Technical Working Group represent different users of the ATC/DDD system and different nationalities.

The members pr. 1 September 1995 are:

Giuseppe Battaglino	Ministry of Health, Pharmaceutical dept., Rome, Italy
Vladimir Bíba	State Institute for Drug Control, Prague, The Czech Republic
Rainer Lasek	Drug Commission of the German Medical Profession, Cologne, Germany

Marie Lindquist	WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden
Steffen Loft	Dept. Pharmacology, University of Copenhagen, Denmark
Joost E. de Metz	Ministry of Health,Welfare and Sport, Rijswijk, The Netherlands
Dave Roberts	Prescribing Research Unit, The University of Leeds, United Kingdom
Peter A.G.M. de Smet	Drug Information Center, Royal Dutch Association for the Advancement of Pharmacy The Hague, The Netherlands
Ingrid Trolin	Medical Products Agency, Uppsala, Sweden
Cees M. de Vos	Ministry of Health,Welfare and Sport, Rijswijk, The Netherlands

The Working Group has two meetings annually. The Collaborating Centre in Oslo coordinates its work.

All requests for new ATC codes and new DDDs should be addressed to the Centre in Oslo. Comments on the present ATC classification and suggestions for alterations should be forwarded to the Centre in Oslo. Such inquiries should also include the reasons for the proposed alterations and any relevant background information.

THE ANATOMICAL THERAPEUTIC CHEMICAL (ATC) CLASSIFICATION SYSTEM

Structure of the ATC system

In the Anatomical Therapeutic Chemical (ATC) classification system, the drugs are divided into different groups according to the organ or system on which

they act and/or therapeutic and chemical characteristics.

In the ATC system drugs are classified in groups at 5 different levels. The drugs are divided into 14 main groups (1st level), with two therapeutic/pharmacological subgroups (2nd and 3rd levels). Level 4 is a therapeutic/pharmacological/chemical subgroup and level 5 is the chemical substance. The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups.

The complete classification of ferrous sulfate preparations illustrates the structure of the code:

B	Blood and blood forming organs (1st level, anatomical main group)
B03	Antianemic preparations (2nd level, therapeutic main group)
B03A	Iron preparations (3rd level, therapeutic/pharmacological subgroup)
B03A A	Iron, bivalent, oral preparations (4th level, chemical/therapeutic/pharmacological subgroup)
B03A A07	Ferrous sulphate (5th level, subgroup for chemical substance)

Thus, in the ATC system all plain ferrous sulphate preparations are given the code B03A A07.

The ATC classification system was originally based on the same main principles as the *Anatomical Classification* (AC-system) developed by the European Pharmaceutical Market Research Association (EPhMRA) and the Pharmaceutical Business Intelligence and Research Group (PBIRG)[1].

In the EPhMRA system drugs are classified in groups at 3 different levels. This EPhMRA system was modified and extended by the Norwegian Medicinal

---

1 Formerly called International Pharmaceutical Market Research Group (IPMRG).

Depot by the addition of a therapeutic/pharmacological/chemical subgroup as level 4 and a chemical substance subgroup as level 5.

In connection with the introduction of the ATC system in all the Nordic countries, the system was further developed in collaboration with the Nordic Council on Medicines. The Centre in Oslo now has the responsibility for the updating and further development of the ATC/DDD system.

Since 1991 there has been a consultation between the EPhMRA classification committee and the WHO Collaborating Centre for Drug Statistics Methodology in order to achieve a better harmonization between the two systems. The aim of this harmonization process is to make the systems harmonized down to the ATC 3rd level, where this is possible, and to describe the differences (i.e. show the differences by giving bridges) and similarities in groups where a harmonization is not achieved. The harmonization process was initiated in order to minimize the confusion of having two very similar classification systems.

It should be emphasized that there are many differences between the EPhMRA classification and the ATC classification. This means that figures prepared by using the ATC classification cannot be directly compared with figures prepared by using the EPhMRA system. The abbreviation ATC is unfortunately also used for the EPhMRA classification, which can cause confusion.

The EPhMRA classification system is used by IMS (Intercontinental Medical Statistics) in marketing research statistics for the pharmaceutical industry.

Main principles for the classification of medicinal substances according to the ATC system

Medicinal products are classified according to their main therapeutic use (i.e. based on main active ingredient), on the basic principle of only one ATC code for each pharmaceutical formulation (i.e. similar ingredients, strength and pharmaceutical form).

A medicinal product can be given more than one ATC code if it is available in two or more strengths or formulations with clearly different therapeutic uses. E.g.: Sex hormones in certain dosage forms or strengths are only used in the treatment of cancer and are thus classified under L02 - Endocrine therapy. Remaining dosage forms/strengths are classified under G03 - Sex hormones and modulators of the genital system.

Correspondingly, clonidine is available in two different strengths. One strength, which is used in hypertension, is classified under C02 - Antihypertensives. Another strength is used in migraine and classified under N02C - Antimigraine preparations.

Different formulations for topical and systemic use are also given separate ATC codes, e.g. prednisolone is given several ATC codes due to different local application formulations.

A medicinal product may be used on two or more equally important indications, and the main therapeutic use of a drug may differ from one country to another. This will often give different classification alternatives. Such drugs are usually only given one code, the main indication being decided on the basis of the available literature. Problems are discussed in the WHO Technical Working Group where the final classification is decided. Cross-references will be given in the guidelines to indicate the various uses of such drugs.

Some ATC levels are assigned according to the mechanism of action of the various substances. Such subdivision will, however, often be rather rough, since a too detailed classification according to mode of action often will result in having one substance per subgroup which as far as possible should be avoided.

Substances classified in the same ATC 4th level cannot always be considered pharmacotherapeutically equivalent since the mode of action, therapeutic effect and adverse drug reaction profile may differ for the various substances.

Normally, different stereoisomeric forms will have separate ATC codes. Exceptions will be described in the guidelines of the respective ATC groups.

The same ATC code should usually be assigned for prodrugs and the active drug if the dosages used and the therapeutic aspects are similar. If the dosages used are different and/or the nonproprietary name of the prodrug and the active drug are different, the ATC code should normally be different.

Classification of plain preparations

Plain preparations are defined as:

Drugs containing one active component (including stereoisomeric mixtures).

Medicinal products which in addition to one active component contain auxiliary substances intended to increase the stability of the preparations (e.g. vaccines containing small amounts of antibacterials increase the duration (e.g. depot formulations) and/or increase the absorption (e.g. different solvents in various dermatologicals) are also considered as plain products.

Classification of combined preparations

Preparations containing two or more active ingredients are regarded as combined preparations. Combined preparations are classified according to two main principles.

1. Combined preparations containing two or more active ingredients belonging to the same therapeutic 4th level are normally classified using the 5th level codes 20 or 30. E.g.:

   J01C A02 Pivampicillin
   J01C A08 Pivmecillinam
   J01C A20 Combinations (e.g. pivampicillin and pivmecillinam)

2. Two or more active components not belonging to the same therapeutic group (i.e. 4th level) are classified by using the 50-series. E.g.:

   N02B A01 Acetylsalicylic acid (plain)
   N02B A51 Acetylsalicylic acid, combinations, excl. psycholeptics

   Different combined preparations sharing the same main active ingredient are usually given the same ATC code. Thus preparations containing phenylpropanolamine + brompheniramine and phenylpropanolamine + cinnarizine are both given the code R01B A51

   Combined preparations which contain psycholeptic drugs, which are not classified under N05 - Psycholeptics and or N06 - Psychoanaleptics, are classified at separate 5th levels using the 70 series. E.g.:

   N02B A71 Acetylsalicylic acid, combinations with psycholeptics

(Preparations containing other substances in addition to a psycholeptic are also classified here.)

Some of the combined preparations containing psycholeptics have been classified at a separate third or fourth level (e.g. A03C Antispasmodics in combination with psycholeptics).

There are some exceptions to the main rules and these will be explained in the guidelines.

Separate ATC 3rd or 4th levels have been assigned for some important combinations, e.g. beta blocking agents and diuretics.

It may be difficult to decide where a certain combination should be classified. The main therapeutic use often decides these classification problems. A medicinal product containing an analgesic and a tranquillizer, and used primarily to ease pain, should be classified as an analgesic. Likewise a preparation used as an antispasmodic will be classified under A03 *Antispasmodic and anticholinergic agents and propulsives* even if it contains small amounts of analgesics and/or psycholeptics. Similar examples are described in detail in the guidelines.

In some ATC groups a ranking is introduced to help in the classification of combination products (e.g. combinations of different antihypertensives and combinations of different analgesics). This ranking shows which drugs take precedence over others when the classification is decided.

New entries in the ATC classification
The WHO Collaborating Centre in Oslo establish new entries in the ATC classification on requests from the users.

The Centre gives priority to plain preparations and only to a limited extent assigns official ATC codes to combined preparations. Fixed combinations likely to be widely used internationally, however, are given an ATC code (e.g. diuretics + beta blocking agents).

It is left to the national user of the ATC system to classify combined preparations based on the principles given in the guidelines. These guidelines are prepared in order to facilitate this work and to ensure that different users of the ATC system classify in a consistent way. If the content of these guidelines is not sufficient to decide a classification of a specific combination, or if it is

necessary to establish a new ATC entry, such problems should be addressed to the WHO Centre in Oslo.

Requests for classification of a medicinal substance should be addressed to the Centre in Oslo. These requests should contain some basic information about the new substance, such as its therapeutic use, main indication and chemical structure, which will be used in its classification.

A new medicinal substance is normally not included in the ATC system before an application for marketing authorization is ready for submission in at least one country. In some cases it may be necessary to await a classification until the new substance has been approved in at least one country (i.e. especially substances where it is considered difficult to establish a new ATC 4th level). These conditions are set to avoid too many substances in the ATC system which never become marketed.

A new medicinal substance not clearly belonging to any existing ATC 4th level group of related substances will as a main rule be placed in an X group ("other" group). To avoid a situation of several 4th levels with only one single substance in each, new 4th levels are as a general rule only assigned when more than one substance fits in. As a result of this rule, new and innovative drugs will be classified in an other group (X group). However, if it is assumed that more than one substance will be marketed in the near future, a new ATC 4th level may be established.

Nomenclature in the ATC system

- International nonproprietary names (INN) should be preferred.
  If INN names are not assigned, USAN or names are usually chosen.

- The same headings for different ATC levels should be avoided.
  (Exception: when the chemical category appears in different groups e.g. benzodiazepines)

ATC time schedule

- A new ATC code is assigned during 1995

- The assigned ATC code is valid from January 1996

- The ATC code is reviewed in 1998 only if WHO Centre in Oslo has

received comments to the classification. If an ATC alteration is decided by the WHO Technical Working Group, it will be valid from January 1999.

- The ATC code will then remain unchanged for a period of two years (irrespective of whether a change was decided or not from January 1999). The ATC code will after this two year period be reconsidered only if the WHO Centre in Oslo has received new information about or written objections to the assigned ATC code. If an ATC alteration is then decided by the WHO Technical Working Group, it will be valid from January 2001.

- The ATC code will then remain unchanged for at least a five years period, until January 2006 (irrespective of whether a change was decided or not from January 2001). Based on received comments to the assigned ATC codes, the WHO Technical Working Group will decide the priority of the ATC groups that should be reviewed.

The ATC classification will also be considered in connection with DDD revisions. When there is a total ATC revision of a group some exceptions from the general ATC time schedule will occur.

PRINCIPLES FOR MAKING ALTERATIONS IN THE ATC SYSTEM

As the drug assortment and uses are continually changing and expanding, regular revisions of the ATC system will always be necessary. This work is coordinated by the WHO Centre in Oslo in close collaboration with the WHO Technical Working Group.

Principles for ATC alterations

Changes in the ATC classification should be kept at a minimum. Before alterations are made, difficulties arising for the users of the ATC system should be considered and related to the benefits achieved by the alteration.

Alterations in the ATC system are made if more subgroups are needed, a better specificity is to be achieved and a new therapeutic grouping is considered necessary.

When an alteration is decided the following principles are used:

- Space should be provided for possible future extensions of an ATC group.

- The sequence of combined preparations should as far as possible agree with the order of classification of the single substances in question.

- Previous ATC codes for deleted preparations should not be used for new substances.

- Obsolete drugs or drugs withdrawn from the market are kept in the ATC system, since exclusion of substances from the ATC system may create difficulties for the users of the system when considering historical data.

- Changes of currently valid codes should be kept to a minimum. A gap in the sequence should be preferred to changing codes. An alteration which does not result in a logical construction should be explained in a footnote.

In connection with ATC alterations the defined daily dose (DDD) will also be reviewed. E.g. when the classification of chloroquine was changed from ATC group M to P (i.e. classified only as an antimalarial), the DDD was changed since the dosages used for treatment of malaria are different from the dosages used for rheumatic disorders.

All alterations should be presented for the EPhMRA (European Pharmaceutical Market Research Association) committee as a result of the present consultation concerning a better harmonization of the two systems.

Procedure for alterations

A change in the ATC system should be proposed and explained in writing, and addressed to the WHO Collaborating Centre for Drug Statistics Methodology.

All proposals for changes should be discussed in the WHO Technical Working Group before a decision is made.

Deadline for submitting proposals for alterations is 1 September. Alterations decided during a year are valid from the first of January the following year.

UNITS OF MEASUREMENT IN DRUG UTILIZATION STUDIES

In order to measure drug use, it is important to have both a classification system and a unit of measurement.

It is important to have a stable and consistent method which makes it possible to compare drug statistics and study long term trends in drug exposure, both nationally and internationally.

There are different ways of expressing drug consumption.

Cost

Drug use can be expressed in terms of costs (e.g. national currency). Cost figures are suitable for an overall cost analysis of drug expenditure. Cost analyses are also applicable for prescription studies of one single substance.

National and international comparisons based on cost parameters are often misleading and of limited value in the evaluation of drug use. Price differences between alternative preparations and different national cost levels make the evaluation difficult. Long-term studies are also difficult due to fluctuations in currency and changes in prices. When cost data are used, an increase in the use of cheaper drugs may have little influence on the total level, while a shift to more expensive drugs is more readily noticed.

Volume

Common physical units (e.g. grams, kilos, litres), numbers of packages or tablets and numbers of prescriptions are also used for quantifying drug consumption. These units can be applied only when the use of one drug or of well defined products is evaluated. Problems arise, however, when the consumption of whole drug groups is considered.

If consumption is given in terms of grams of active ingredients, drugs with low potency will have a larger fraction of the total than drugs with high potency. Combined products may also contain different amounts of active ingredients from plain products, which will not be reflected in the figures.

Counting numbers of tablets also has disadvantages, because strengths of tablets vary, with the result that low strength preparations relatively contribute more than high strength preparations. Also, short-acting preparations will often

contribute more than long-acting preparations.

Numbers of prescriptions do not give a good expression of total use, unless total amounts of drugs per prescription are also being considered. Counting of prescriptions, however, is of great value in measuring the frequency of prescriptions and in evaluating the clinical use of drugs (e.g. diagnosis and dosages used).

Prescribed daily dose

The prescribed daily dose (PDD) can be determined from prescription studies, medical- or pharmacy records and patient interviews. It is important to relate the PDD to the diagnosis on which the dosage is based. The PDD will give the average daily amount of a drug that is actually prescribed. When there is a substantial discrepancy between the PDD and the defined daily dose (DDD), it is important to take this into consideration when evaluating and interpreting drug consumption figures.

For drugs where the recommended dosage differs from one indication to another (e.g. the antipsychotics) it is important that diagnosis is linked to the prescribed daily dose given. Pharmacoepidemiological information (e.g. sex, age and mono/combined therapy) is also important in order to interpret a PDD.

The PDD can vary according to both the illness treated and national therapy traditions. For the antiinfectives, for instance, PDDs vary according to the severity of the infection. The DDDs for most antiinfectives are based on treatment of moderately severe infections. In hospital care, much higher doses are frequently used and this must be considered when using the DDD as a unit of measurement.

The fact that PDDs may differ from one country to another should always be considered when making international comparisons.

Defined Daily Dose

To deal with the objections against traditional units of measurement, a technical unit of measurement was developed called the *Defined Daily Dose (DDD)*.

The basic definition of this unit is:

The DDD is the assumed average maintenance dose per day for a drug used on its main indication in adults.

It should be emphasized that the defined daily dose is a unit of measurement and does not necessarily reflect the recommended or actual used dose. The individual dosages used will often differ from the DDD and will necessarily have to be based on individual characteristics (e.g. age and weight) and pharmacokinetic considerations.

Since many drugs are used in different dosages on different indications, this must be taken into consideration when evaluating drug consumption figures. For drugs used in short courses, e.g. antiinfectives, agents for treatment of peptic ulcer etc., the duration of treatment may differ from one drug to another and this is important to take into consideration when comparing the use of the different drugs. Sales or prescription data monitored and presented in DDDs will thus give only a rough estimate of consumption and not an exact picture of actual use.

With the defined daily dose as a fixed unit of measurement, an improved basis for comparisons, independent of price differences and different preparations, has been established. Long-term studies, both national and international can be carried out by using the DDD as a unit of measurement. Comparison between different countries has also been made possible.

For some types of drugs, DDDs have not been established. Examples are preparations for topical use, i.v. solutions, sera and vaccines, antineoplastic drugs, allergen extracts, general and local anesthetics, and contrast media. For some of these drug groups, alternative ways of presenting data have been recommended. Consumption of dermatological preparations (ointments etc.) is often presented in grams of preparations regardless of strength.

MAIN PRINCIPLES FOR THE ESTABLISHMENT OF DDDs

All DDDs for plain substances are based on monotherapy treatment. Exception from this rule will be given in the guidelines.

Plain preparations
Plain products are preparations containing one active ingredient (including stereoisomeric mixtures).

When a new DDD is assigned, various sources are used in order to get the best

overview of the actual or expected use of a substance. The assigned DDD should be based on the following principles:

- The average adult dose used for the main indication as reflected by the ATC code. When the recommended dose refers to body weight an adult is considered to be a person of 70 kg. It should be emphasized that even special pharmaceutical forms mainly intended for children (e.g. mixtures, suppositories) will receive the DDD used for adults. Exception: preparations used by children only, e.g. growth hormones and fluoride tablets.

- The maintenance dose is usually preferred when establishing the DDD. Some drugs are used in different doses initially but this will not be reflected in the DDD. Parenteral preparations are often used initially in doses that differ from those of oral formulations. When the use of parenteral formulations represents only a minor fraction of the total use (i.e. nearly no impact on the figures), these preparations will not receive a separate DDD even if the bioavailability is substantially different.

- The therapeutic dose is generally chosen. If, however, prophylaxis is the main indication, this dose is used, e.g. for fluoride tablets (A01A A01) and some antimalarials.

- A DDD is usually established according to the declared content (strength) of the product. Various salts of a substance will not usually be given different DDDs. Exceptions will be described in the guidelines for the different ATC groups. E.g. for antimalarials the DDDs are expressed as the base.

- Normally, different stereoisomeric forms will have separate DDDs and ATC codes. The DDDs for stereoisomeric forms are described in the respective ATC groups.

- Prodrugs which have not been given a separate ATC code will normally not be given a separate DDD.

- The DDD is usually identical for various dosage forms of the same drug. Different DDDs may be established when the bioavailability is substantially different for various routes of administration (e.g. oral and parenteral administration of morphine) or if the dosage forms are used on

different indications. Parenteral preparations intended for i.v. and i.m. administration will have the same DDD.

When a DDD is assigned the following sources of information are used:

- Dose recommendations approved by national drug control authorities. These will indicate the dosages which most probably will be used in clinical practice. The dose recommendations do not necessarily reflect the results retrieved from equipotency studies.

- Information showing the prescribed daily dose (PDD) is also considered when a DDD is assigned. PDDs add valuable information on the actual use of a drug.

- When assigning a DDD for a new drug belonging to an existing pharmacological group, e.g. ACE inhibitors, the new DDD will be compared with the DDDs assigned for the other substances within the same group. In such cases, data concerning equipotency are evaluated together with information regarding the actual use of a drug (i.e. dose recommendations and PDD data).

Accordingly, when a DDD is assigned, a total evaluation of the dose recommendations, prescribed daily dose data and equipotency data is necessary in order to achieve the best approximated value of a DDD.

In some instances the assigned DDD will be an almost never prescribed average of two or more widely prescribed dosages.

The DDD should therefore not be considered as an "exact value" but as an international compromise based on a review of available documentation.

Combined preparations

The DDDs assigned for combined preparations should, as a main principle, be at the same level as for plain preparations in the same therapeutic ATC group. The DDDs for combined preparations should not exceed the DDDs assigned for the different active ingredients in mono-component preparations.

The DDD for a combined preparation that contains auxiliary substances intended to reduce gastrointestinal discomfort, or modify untoward effects of the drug, will normally be the same as the DDD for the plain preparation.

For a combined preparation with a few active ingredients (two or three), the DDD should relate closely to the contribution of the different substances to the therapeutic effect.

For some of the frequently used combinations of cardiovascular drugs it has been considered most appropriate to assign fixed DDDs based on the average use of the different combinations without considering and comparing the strengths of the different products. A description on how these DDDs are assigned are given in the chapter covering ATC group C.

If a preparation contains many active ingredients (more than three), the defined daily dose should primarily reflect the total therapeutic effect and should mainly be based on the dose recommendations in different drug textbooks.

For some groups of preparations it has been considered most appropriate to estimate the average use for preparations within a group instead of establishing accurate doses for every single preparation, e.g. cough mixtures in ATC group R05 and multivitamins in ATC group A11. For the multivitamins the composition of various preparations may differ, but the average recommended dose is usually the same. Such DDDs are called "fixed dose".

For eye drops used in glaucoma therapy, a fixed dose regardless of strength has been established in the different subgroups. This is based on the assumption that, per dosage given, only one drop is applied in each eye, regardless of strength.

When fixed doses are assigned, this will be further described in the guidelines for the different ATC groups.

Depot formulations

Depot formulations (e.g. sustained release formulations) are usually assigned the same DDD as the ordinary dosage forms. Exceptions to this main rule will be described in the guidelines to the different ATC groups.

Intermittent doses

In certain therapeutic groups, e.g. hormones, many of the preparations are administered intermittently. In such cases, the dose administered should be divided by the number of days in the treatment period to obtain the average daily dose. This also applies to such drugs as depot antipsychotics and contraceptive pills which are given intermittently.

Duration of treatment
The duration of treatment is normally not considered when assigning a DDD, even if the drugs are used mainly in short periods. Exceptions from this main rule are explained in the respective ATC groups.

PRINCIPLES FOR EXPRESSING DEFINED DAILY DOSES

Plain preparations
DDDs are as far as possible given in amounts of active ingredients, using the following units: g (gram), mg (milligram), µg (microgram), mmol (millimol), E (unit), TE (thousand units) and ME (million units). The abbreviation E for unit is used for international as well as other units.

Combined preparations
For combined preparations or preparations where a DDD for various reasons cannot be given in amount of active ingredient, the unit UD (unit dose) is used:

- Tablets, suppositories, pessaries, etc:
  1 UD equals 1 tablet, 1 suppository, 1 pessary etc.

- Powder for oral use:
  1 UD equals 1 gram of powder. If the DDD for an oral powder is given in grams, this refers to the content of active ingredient.

- Powder in single dose units for oral use:
  1 UD equals 1 dose powder.

- Powder for injection:
  1 UD equals 1 gram of powder. If the DDD for powder for injection is given in grams, this refers to the content of active ingredient.

- Liquid preparations for oral use (mixtures, syrups etc.):
  1 UD equals 5 ml of the preparation.

- Liquid preparations for parenteral use (injections):
  1 UD equals 1 ml of the preparation.

- Liquid preparations for rectal use:
  1 UD equals 1 ml of the preparation.

- Enemas:
  1 UD equals 1 enema.

- Plaster for transdermal application:
  1 UD equals 1 plaster.

- Vaginal cream:
  1 UD equals 1 dose, 1 application.

Route of administration
The route of administration is indicated by the following codes:

Inhal	= Inhalation	R	= Rectal
N	= Nasal	SL	= Sublingual/buccal
O	= Oral	TD	= Transdermal
P	= Parenteral	V	= Vaginal

PROCEDURE FOR ESTABLISHMENT OF NEW DDDs

New DDDs are assigned by the WHO Collaborating Centre for Drug Statistics Methodology, and requests for new DDDs should be addressed to the Centre. The Centre has prepared a form to be filled in when asking for a DDD. When standard information concerning main indication, maintenance dose, etc.has been filled in, the form should be sent to Centre together with copies of references relevant for the DDD assignment.

As a basis for assigning DDDs international textbooks, peer reviewed scientific journals and documentation used as a basis for approval of drugs by drug control authorities are used.

All new DDDs are discussed and approved by the WHO Technical Working Group.

For many substances in the ATC index no DDDs are listed, as no requests for a DDD have been made. In some drug groups no DDDs are established as it is difficult to find appropriate DDDs, e.g. dermatologicals.

A DDD will normally not be assigned for a substance before a product is

approved and marketed in at least one country.

DDD time schedule

- A new DDD is assigned during 1995
- The assigned DDD is valid from January 1996
- The DDD is reviewed in 1998. If a DDD alteration is decided by the WHO Technical Working Group, it will be valid from January 1999.
- The DDD will then remain unchanged for a period of two years (irrespective of whether a change was decided or not from January 1999). The DDD will after this two year period be reconsidered only if the WHO Collaborating Centre for Drug Statistics Methodology has received new information about or written objections to the assigned DDD. If a DDD alteration is decided by the WHO Technical Working Group, it will be valid from January 2001.
- The DDD will then remain unchanged for at least a five year period, until January 2006 (irrespective of whether a change was decided or not from January 2001). Based on received comments to the assigned DDDs, the WHO Technical Working Group will decide the priority of the ATC groups in which the DDDs should be reviewed. As a general rule all DDDs in important ATC groups (i.e. ATC groups including drugs with a major consumption) should be reviewed at 5 years intervals.

When there is a total revision of all DDDs in an ATC group, some exceptions from the general DDD time schedule will occur.

PRINCIPLES FOR REVIEWING AND CHANGING DDDs

Reviewing of new DDDs after 3 years
All new assigned DDDs are reviewed after 3 years. The ATC classification is also reevaluated at the same time.

Plain preparations
The following should be considered:

- Received written complaints or objections to the DDD
- Existing DDDs in the ATC group
- Established main indication and therapy tradition of the preparation (i.e. has the main indication changed?)
- Recommended dosages as listed in drug catalogues in different countries and/or published in peer reviewed scientific journals or major international textbooks:
  a) varying dosages (i.e.in different countries)
  b) stable dosage regimen - or changing dosage regimens.

Figures showing the prescribed daily dose (PDD) are important when validating an assigned DDD. Usually more data concerning PDDs are available after a three years period than at the time of marketing.

The mentioned principles (see page ¤) for the assignment of DDDs are also used when DDDs are reviewed.

Suggestions for alterations should always be forwarded to the WHO Centre in Oslo together with documentation containing relevant information concerning the reason for the proposed alteration.

Combined preparations
It should be considered if the DDDs for the different active ingredients have changed. The revision is, otherwise, made as for plain preparations.

Reviewing of DDDs after 5, 10, 15 and 20 years etc. after the assignment
Based on new information or written objections concerning a DDD received by the WHO Centre in Oslo in the two year period after the first 3 year revision, this DDD will be reconsidered again. Revision will be carried out as described above for new DDDs.

After the first five years period the DDD will remain unchanged for at least five years unless the WHO Technical Working Group decides to make a total revision of all DDDs assigned in an ATC group. Such a total revision may result in some alterations which are not in accordance with the normal DDD time schedule.

All DDDs in important ATC groups (i.e. groups containing drugs with a major consumption) should be reviewed at five years intervals.

Principles for alteration of a DDD

As the dosages used may change over time, it will always be necessary to make some alterations. Results from postmarketing studies are a valuable tool to indicate the doses actually used.

Changes of DDDs should be kept to a minimum and be avoided as far as possible. Too many alterations will always be disadvantageous for long-term studies on drug utilization. Before alterations are made, difficulties arising for the users should be weighed against the benefits achieved by the alteration.

- The given principles when assigning new DDDs also apply when DDDs are reviewed.

- Any change should be at least of the order of 50%. For important drugs which are frequently used, however, a minor alteration should be allowed (e.g. the DDD for cimetidine was changed from 1.0 g to 0.8 g).

REPORTING

The WHO Collaborating Centre for Drug Statistics Methodology publish a new issue of the complete ATC index annually. The complete ATC index consists of one list sorted according to ATC codes, including all the established ATC codes and DDDs for plain substances, and one list alphabetically sorted according to nonproprietary drug names, including all ATC 5th levels. The index can be ordered as a paper copy or on diskette from the Centre (order form, see page 249).

The DDDs which are to be reviewed during the year are marked in the ATC index with an asterisk.

The Centre is responsible for reporting all alterations of the ATC classification and DDDs to the users of the ATC/DDD system.

Lists of the annual ATC/DDD alterations are in November/December each year distributed free of charge to the users of the ATC/DDD system according to a mailing list, together with an order form for the new index.

Cumulative lists of alterations are available from the WHO Centre in Oslo on request.

USES OF THE ATC/DDD SYSTEM

Drug utilization

The ATC/DDD system was developed as a tool for presenting drug consumption figures. The system has been used for many years in drug utilization studies where it has shown itself to be suitable for both national and international comparisons of drug consumption and for the evaluation of long-term trends in drug use. The main purpose of the system is to be a tool for presenting drug consumption statistics. Figures presenting drug consumption should always be a basis for evaluation in order to study the factors that may influence the level of drug use.

Drug consumption figures should preferably be presented as numbers of DDDs/1000 inhabitants/day or, when in-hospital drug use is considered, as DDDs per 100 bed days. Sales or prescription data presented in DDD/1000 inhabitants/day provide a rough estimate of the proportion of the population within a defined area treated daily with certain drugs. E.g. the figure 10 DDDs/ 1000 inhabitants/day indicates that 1% of the population on average gets a certain treatment daily.

For antiinfectives (or other drugs normally used in short periods) it is often considered most appropriate to present the figures as numbers of DDDs per inhabitant per year, which will give an estimate of the number of days for which each inhabitant is, on average, treated annually. E.g. 5 DDDs/inhabitant/year indicates that the consumption is equivalent to the treatment of every inhabitant with a 5 days course during a year. Alternatively, if the standard treatment period is known, e.g. 5, 7 or 10 days, the total number of DDDs can be calculated as the number of treatment courses, and the number of treatment courses can then be related to the total population.

Drug consumption figures are often based on sales data, such as wholesale data, which will not reflect the actual use of drugs, whereas data based on prescription or dispensing surveys will give more information on the actual use of drugs. However, for the purpose of comparing regions (or countries), and looking for trends, sales statistics provide reliable and meaningful information.

The WHO Collaborating Centre for Drug Statistics Methodology has prepared a *Drug Utilization Bibliography* containing a survey of references published on the subject drug utilization (latest issue covering 1989-1992). Copies of this bibliography can be ordered from the Centre.

Cost-containment
Information from the ATC/DDD system can be used as a tool for cost analysis when comparing different brand names or generic preparations (e.g. same substance, formulation, strength and package size). The ATC/DDD system is also used to follow the cost increases in various groups and to compare costs between different groups (e.g diuretics compared to ACE inhibitors).

Detailed price comparisons between different medicinal substances are more complicated and should be made with caution. When comparing different medicinal substances it is important to define and decide which drugs should be considered pharmacotherapeutically equivalent (i.e. similar efficacy, adverse drug reactions profile, and formulations) and which should not be considered equivalent. The decision to adopt the DDD as a measuring unit for cost-containment purposes should be based on a thorough evaluation by national experts, taking into consideration that this use is deviating from the main purpose of the system.

Basing reimbursement decisions indiscriminately on certain ATC groups is not recommended, since the indications for use of drugs often differ widely between countries, and the ATC code is decided according to what is considered to be the main international use. The grouping of pharmacotherapeutically equivalent drugs should always be based on review by national clinical experts.

It is important to emphasize that the main purpose of the ATC/DDD system is to be a tool for presenting drug consumption figures. This will influence the basis for assignment of both ATC codes and DDDs and may make it less suitable for other purposes.

Marketing purposes
It is important to emphasize that the ATC classification does not necessarily reflect the recommended therapeutic use in all respects. Therefore, the ATC system should not be used as a tool for marketing purposes i.e. an ATC code should thus not be used as a marketing tool concerning efficacy.

WHO International Drug Monitoring Programme
Spontaneously reported cases of suspected adverse reactions are sent from national centres (45 countries are included in the programme, January 1995) to the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden. Information on all medicinal products appearing in these reports is stored in a drug register, linked to the reports database. All single and multiple ingredient preparations are given an ATC code on the substance level, which

allows flexible searches comprising different drug categories or groups of drugs. The ATC system is also used for the grouping of drugs in output documents.

"Double medication" and "pseudo-double medication"
"Double medication" can be defined as using two identical drugs simultaneously (e.g. two different diazepam preparations) whereas "pseudo-double medication" can be defined as using two chemically different substances but with similar pharmacodynamic properties simultaneously (e.g. a diazepam preparation plus an oxazepam preparation).

The objective of checking these situations, by using phycisian or pharmacy patient computer records, is to prevent unnecessary medication which may increase the risk of side effects.

The ATC classification can be used as a tool for screening of "double"- and "pseudo-double medication". In the case of plain preparations, the ATC 5th level codes can be used; while the level to which monitoring must be made depends on the ATC group concerned. For combined preparations the ATC 5th level code is not always sufficient to identify all active ingredients. It is therefore recommended to connect all ATC codes given for each of the different active ingredients to each combined preparation. A detailed description of this ATC application of the classification system is published in: De Smet P.A.G.M., New applications of the ATC/DDD methodology in The Netherlands, Part I, ATC/ DDD principles and computerized medication surveillance (International Pharmacy Journal 1993; Vol 7, No 5, p 196-199.

Drug catalogues
ATC codes are included in some international drug catalogues (e.g. the European Drug Index) and in several national drug catalogues.

ATCvet CLASSIFICATION

The Anatomical Therapeutic Chemical classification for veterinary medicinal products, ATCvet, is based on the same main principles as the ATC system for medicines for human use, i.e. a medicinal substance both used in human and veterinary medicine will be classified in a way that makes it easy to recognize that it is the same substance. The ATCvet classification was developed by the Nordic Council on Medicines and further information on the ATCvet classification can be received from its secretariate (address: Nordic Council on

Medicines, Box 1983, S-75149 Uppsala, Sweden, tlf. 46 18105800, fax 46 18105808)

ATCherbal CLASSIFICATION

A framework for ATC classification of herbal remedies has been developed. Further information about the Herbal ATC classification can be obtained from Peter de Smet (address: Drug Information Centre, Royal Dutch Assosication for the Advancement of Pharmacy, Alexanderstraat 11, 2514 IL The Hauge, The Netherlands)

ATC CLASSIFICATION

The main groups of the ATC classification system are listed below. A survey of each main group is given in the beginning of each of the following chapters.

ATC system main groups :

A	Alimentary tract and metabolism
B	Blood and blood forming organs
C	Cardiovascular system
D	Dermatologicals
G	Genito urinary system and sex hormones
H	Systemic hormonal preparations, excl. sex hormones
J	General antiinfectives for systemic use
L	Antineoplastic and immunomodulating agents
M	Musculo-skeletal system
N	Nervous system
P	Antiparasitic products, insecticides and repellents
R	Respiratory system
S	Sensory organs
V	Various

A ALIMENTARY TRACT AND METABOLISM

A01 STOMATOLOGICAL PREPARATIONS

A Stomatological preparations

A02 ANTACIDS, DRUGS FOR TREATMENT OF PEPTIC ULCER AND FLATULENCE

A Antacids
B Drugs for treatment of peptic ulcer
D Antiflatulents
E Antiregurgitants
X Other antacids, drugs for treatment of peptic ulcer and flatulence

A03 ANTISPASMODIC AND ANTICHOLINERGIC AGENTS AND PROPULSIVES

A Synthetic antispasmodic and anticholinergic agents
B Belladonna and derivatives, plain
C Antispasmodics in combination with psycholeptics
D Antispasmodics in combination with analgesics
E Antispasmodics and anticholinergics in combination with other drugs
F Propulsives

A04 ANTIEMETICS AND ANTINAUSEANTS

A Antiemetics and antinauseants

A05 BILE AND LIVER THERAPY

A Bile therapy
B Liver therapy, lipotropics
C Drugs for bile therapy and lipotropics in combination

A06 LAXATIVES

A Laxatives

A07 ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ ANTIINFECTIVE AGENTS

A Intestinal antiinfectives
B Intestinal adsorbents
C Electrolytes with carbohydrates
D Antipropulsives

E Intestinal antiinflammatory agents
F Antidiarrheal microorganisms
X Other antidiarrheals

A08 ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS
A Antiobesity preparations, excl. diet products

A09 DIGESTIVES, INCL. ENZYMES
A Digestives, incl. enzymes

A10 DRUGS USED IN DIABETES
A Insulins
B Oral blood glucose lowering drugs
X Other drugs used in diabetes

A11 VITAMINS
A Multivitamins, combinations
B Multivitamins, plain
C Vitamin A and D, incl. combinations of the two
D Vitamin B_1, plain and in combination with vitamin B_6 and B_{12}
E Vitamin B-complex, incl. combinations
G Ascorbic acid (vitamin C), incl. combinations
H Other plain vitamin preparations
J Other vitamin products, combinations

A12 MINERAL SUPPLEMENTS
A Calcium
B Potassium
C Other mineral supplements

A13 TONICS
A Tonics

A14 ANABOLIC AGENTS FOR SYSTEMIC USE
A Anabolic steroids
B Other anabolic agents

A15 APPETITE STIMULANTS

A16 OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS
A Other alimentary tract and metabolism products

A ALIMENTARY TRACT AND METABOLISM

A01 STOMATOLOGICAL PREPARATIONS

A01A STOMATOLOGICAL PREPARATIONS

This group comprises agents for treatment of conditions of mouth and teeth. It is difficult to differentiate between preparations for use in the mouth and preparations for use in the throat. Preparations mainly used in gingivitis, stomatitis etc. should be classified in this group.

Preparations for the treatment of throat infections, (lozenges for common cold conditions) are classified in R02 - Throat preparations.

Preparations containing local anesthetics, see N01B - Anesthetics, local, and R02A D - Anesthetics, local.

A01A A Caries prophylactic agents

This group comprises all types of fluoride preparations (tablets, gargles, toothpastes etc.).

Combinations of olaflur and dectaflur are classified at the 5th level of olaflur - A01A A03. Combinations of sodium fluoride and sodium monofluorophosphate are classified in A01A A30.

For caries prophylactic agents in A01A A, the DDDs are based on use in children. DDDs are only established for tablets.

A01A B Antiinfectives for local oral treatment

This group comprises all antiinfective agents, incl. antibiotics, for the treatment of stomatitis, gingivitis etc. Products used in common minor infections of mouth and throat are classified in R02, e.g. cetylpyridinium.

Other antibiotics for local use, see D - Dermatologicals.

The DDD for amphotericin in this group refers to lozenges.

A01A C *Corticosteroids for local oral treatment*

This group comprises corticosteroid preparations for the treatment of gingivitis, stomatitis etc., i.e. corticosteroid preparations for use in the oral cavity.

Other corticosteroids for local use, see D - Dermatologicals.

No DDDs have been established in this group. The dosage forms are mainly ointments and pastes.

A01A D *Other agents for local oral treatment*

This group comprises e.g. various gargles and hemostatic agents used in dentistry.

Other hemostatic agents, see B02B C - Local hemostatics.
E.g. combinations with local anesthetics for oral treatment are classified at the *various* level A01A D11.

See also N01B - Anesthetics, local.

No DDDs have been established in this group. The dosage forms are mainly ointments and pastes.

A02 ANTACIDS, DRUGS FOR TREATMENT OF PEPTIC ULCER AND FLATULENCE

A02A ANTACIDS

This group comprises plain antacid drugs, antacids in combination with antiflatulents and antacids in combination with other drugs.

Antacids in combination with liquorice root or linseed are classified in this group.

Plain antiflatulents, see A02D - Antiflatulents.

Agents for gastroesophageal reflux, see A02E A - Antiregurgitants.

The DDDs for antacids are based on treatment of hyperacidity and dyspepsia, not ulcus. One exception, however, is antacids in combination with antispasmodics in A02A G, where the DDDs are based on treatment of ulcus.

For ordinary salt combinations in A02A D, fixed doses are used instead of individual doses for every single preparation (10 tablets = 10 UD, or 50 ml mixture = 10 UD).

A02A A *Magnesium compounds*

This group comprises preparations with magnesium compounds.

Combinations of different magnesium compounds are classified in A02A A10 - Combinations.

A02A B *Aluminium compounds*

This group comprises preparations with aluminium compounds.

Combinations of different aluminium compounds are classified in A02A B10 - Combinations.

A02A C *Calcium compounds*

This group comprises preparations with calcium compounds.

Combinations of different calcium compounds are classified in A02A C10 - Combinations.

A02A D *Combinations and complexes of aluminium, calcium and magnesium compounds*

This group comprises antacids with combinations of aluminium, calcium and magnesium compounds. Antacids with two of the substances in combination are also classified here.

Ordinary salt combinations are classified at the same 5th level A02A D01 e.g. combinations of aluminium hydroxide, magnesium carbonate gel and attapulgite, while the various complexes with a

layer structure are classified at separate 5th levels e.g. magaldrate and almagate.

A02A F *Antacids with antiflatulents*

A02A G *Antacids with antispasmodics*

Preparations containing a combination of antacids and antispasmodics are classified in this group if the main use is as an antacid. See also A03 - Antispasmodic and anticholinergic agents.

A02A H *Antacids with sodium bicarbonate*

All antacids containing sodium bicarbonate are classified in this group.

No ATC 5th levels are assigned in this group.

Preparations containing sodium bicarbonate to be used only in connection with double-contrast radiography are classified in V07A Y.

A02A X *Antacids, other combinations*

A02B DRUGS FOR TREATMENT OF PEPTIC ULCER

This group comprises preparations with a specific action in ulcus, such as cimetidine. See also A03 - Antispasmodic and anticholinergic agents. Antacids in combination with liquorice root or linseed are classified in A02A - Antacids.

The DDDs are based on treatment of peptic ulcers.

A02B A *H2-receptor antagonists*

Ranitidine bismuth citrate is classified here, whereas other bismuth salts are classified in A02B X.

A02B B *Prostaglandins*

A02B C *Proton pump inhibitors*

A02B X *Other drugs for treatment of peptic ulcer*

This group comprises e.g. bismuth, carbenoxolone, sucralfate and pirenzepine.

Ranitidine bismuth citrate is classified in A02B A.

A02D ANTIFLATULENTS

This group comprises e.g. preparations containing silicones.

Combinations with antispasmodics are classified in this group if the main indication is flatulence.

Combinations with antacids are classified in A02A F.

A02D A *Antiflatulents*

A02E ANTIREGURGITANTS

A02E A *Antiregurgitants*

This group comprises preparations with effect on gastroesophageal reflux. Alginic acid and aluminium hydroxide in combinations are given the code A02E A01.

The DDDs for antiregurgitants in this group are given in fixed doses (10 tablets = 10 UD, or 50 ml mixture = 10 UD).

A02X OTHER ANTACIDS, DRUGS FOR TREATMENT OF PEPTIC ULCER AND FLATULENCE

This group comprises preparations which cannot be classified in the preceding groups.

A03 ANTISPASMODIC AND ANTICHOLINERGIC AGENTS AND PROPULSIVES

A major part of the preparations in this group are combined preparations. Preparations containing e.g. analgesics and antispasmodics could be classified either in this group or in N02 - Analgesics. Combinations of psycholeptics and antispasmodics could be classified in A03 or in N05 - Psycholeptics etc. The main indication for the use of the combination will, together with the relative effect of the active components, decide the classification. In the treatment of pain caused by spasms, the spasmolytic component must be judged as more important than the analgesic component. Accordingly, analgesic/antispasmodic combinations should be classified in A03 if the main effect of the agent is the antispasmodic action.

Combined preparations are classified in:

A03C - Antispasmodics in combination with psycholeptics
A03D - Antispasmodics in combination with analgesics
A03E - Antispasmodics and anticholinergics in combination with other drugs

Antispasmodics which are used specifically in the urogenital tractus, are classified in G04B D - Urinary antispasmodics.

The DDD is equal for different formulations (oral, parenteral or rectal) of the same compound and is based on the oral dose.

When establishing DDDs for combinations with psycholeptics or analgesics (A03C, A03D or A03E), the DDD assigned for the psycholeptic and the analgesic component should also be taken into considerations.

A03A SYNTHETIC ANTISPASMODIC AND ANTICHOLINERGIC AGENTS

Papaverine is included in this group. Semisynthetic derivatives such as butylscopolamine, are classified in A03B - Belladonna and derivatives.

A03A A *Synthetic anticholinergics, esters with tertiary amino group*

A03A B *Synthetic anticholinergics, quaternary ammonium compounds*

Combined preparations are classified at separate 5th levels using the corresponding 50-series.

Plain preparations containing glycopyrronium are classified in this group. Preparations containing glycopyrronium in combination with neostigmine are classified in N07A A51.

A03A C *Synthetic antispasmodics, amides with tertiary amines*

A03A D *Papaverine and derivatives*

Combined preparations are classified at separate 5th levels using the corresponding 50-series. Combinations with sterculia are classified here.

A03A X *Other synthetic anticholinergic agents*

This group comprises all other synthetic antispasmodic and anticholinergic agents which cannot be classified in the preceding groups.

A03B BELLADONNA AND DERIVATIVES, PLAIN

A03B A *Belladonna alkaloids, tertiary amines*

A03B B *Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

A03C ANTISPASMODICS IN COMBINATION WITH PSYCHOLEPTICS

Antispasmodics in combination with psycholeptics and other drugs (excl. analgesics) are classified in this group.

Antispasmodics in combination with psycholeptics and analgesics are classified in A03E A.

The classification at the 5th levels is based on the antispasmodic component. At each 5th level several psycholeptics may occur. When classifying such combined products, it is necessary to look at the main indication for use and the composition, to see if the preparation should be classified in A03 or in N05 - Psycholeptics (see comments under A03).

A03C A *Synthetic anticholinergic agents in combination with psycholeptics*

General comments, see A03C.

Combinations with more than one antispasmodic are classified in a ranking according to the ATC-code. A substance classified in A03C A01 takes precedence over a substance classified in A03C A02 etc.

A03C B *Belladonna and derivatives in combination with psycholeptics*

General comments, see A03C.

Combinations with more than one antispasmodic are classified in a ranking according to the ATC-code. A substance classified in A03C B01 takes precedence over a substance classified in A03C B02 etc.

A03C C *Other antispasmodics in combination with psycholeptics*

This group comprises combined preparations with psycholeptics which are not covered by A03C A and A03C B.

A03D ANTISPASMODICS IN COMBINATION WITH ANALGESICS

This group is completely parallel to A03C.

The classification at the 5th levels is based on the antispasmodic component. At each 5th level several analgesics may occur. Antispasmodics in combination with analgesics and other drugs (excl. psycholeptics) are classified in this group.

When classifying these combination products, it is necessary to look at the indications for use and the composition to see if the preparation should be classified in A03 or in N02 - Analgesics.

Opioid analgesics in combination with antispasmodics, see N02A G - Opioids in combination with antispasmodics. Ethylmorphine is not regarded as a narcotic in this context.

Antispasmodics in combination with psycholeptics and analgesics are classified in A03E A.

A03D A *Synthetic anticholinergic agents in combination with analgesics*

General comments, see A03D.

Combinations with more than one antispasmodic are classified in a ranking according to the ATC-code. A substance classified in A03D A01 takes precedence over a substance classified in A03D A02 etc.

A03D B *Belladonna and derivatives in combination with analgesics*

General comments, see A03D.

Combinations with more than one antispasmodic are classified in a ranking according to the ATC-code. A substance classified in A03D B01 takes precedence over a substance classified in A03D B02 etc.

A03D C *Other antispasmodics in combination with analgesics*

This group comprises combined preparations with analgesics which are not covered by A03D A and A03D B.

A03E ANTISPASMODICS AND ANTICHOLINERGICS IN COMBINATION WITH OTHER DRUGS

General comments, see A03.

This group comprises all combined preparations with antispasmodics and anticholinergics which are not covered by A03C or A03D.

A03E A *Antispasmodics, psycholeptics and analgesics in combination*

Antispasmodics in combination with psycholeptics, analgesics and other agents are classified in this group.

A03E D *Antispasmodics in combination with other drugs*

A03F PROPULSIVES

A03F A *Propulsives*

Agents stimulating gastro-intestinal motility are classified here, e.g. substituted benzamides.

Trimebutine is classified in A03A A.

A04 ANTIEMETICS AND ANTINAUSEANTS

A04A ANTIEMETICS AND ANTINAUSEANTS

Antihistamines which are often used as antiemetics, are classified in R06 - Antihistamines for systemic use.

Metoclopramide is classified in A03A C.

Antivertigo preparations, see N07C.

A04A A *Serotonin ($5HT_3$) antagonists*

The DDDs are based on antiemetic treatment.

A04A D *Other antiemetics*

E.g. scopolamine and metopimazine are classified in this group.

Combined preparations are classified at separate 5th levels using the corresponding 50-series.

The DDD for scopolamin plaster is one plaster (i.e. 1 UD). This DDD is based on prophylactic treatment of motion sickness.

DDDs for other substances classified in this group are based on antiemetic treatment.

A05 BILE AND LIVER THERAPY

A05A BILE THERAPY

A05A A Bile acid preparations

Preparations classified in this group are primarily bile acid preparations, but various combinations, e.g. with spasmolytics, are also included.

A05A B Preparations for biliary tract therapy

E.g. Nicotinyl methylamide is classified here.

A05A X Other drugs for bile therapy

This group comprises other drugs for bile therapy which cannot be classified in the preceding groups.

A05B LIVER THERAPY, LIPOTROPICS

A05B A Liver therapy

E.g. arginine glutamate and silymarin are classified here. Tioctic acid is classified in A16A X.

Preparations containing silibinin are classified at the same ATC 5th level as silymarin.

A05C DRUGS FOR BILE THERAPY AND LIPOTROPICS IN COMBINATION

A06 LAXATIVES

A06A LAXATIVES

Laxatives are mainly grouped according to their mode of action. All enemas are classified in A06A G, regardless of mode of action.

Some combination products are classified at separate levels. These are mentioned in the respective ATC group.

Otherwise combination products are classified at separate 5th levels using the corresponding 50-series.

Laxatives in combination with centrally acting antiobesity agents are classified in A08A - Antiobesity preparations, excl. diet products.

A06A A *Softeners, emollients*

This group comprises preparations containing liquid paraffin, docusate sodium etc.

Combinations with contact laxatives are classified in A06A B, except all liquid paraffin combinations which are classified in A06A A.

DDDs for e.g. liquid paraffin and castor oil are given using the following unit: g (gram), (1 g = 1 ml for all practical purposes). Preparations classified in A06A A51 - Liquid paraffin mixtures, combinations, are all given the same DDD = 3 UD (15 ml), independent of liquid paraffin concentration.

A06A B *Contact laxatives*

This group comprises agents which mainly inhibit the absorption of electrolytes and water through a specific pharmacological mechanism, e.g. bisacodyl and senna glycosides.

Combinations with bulk producing laxatives are classified in A06A C.

Gas producing rectal preparations and glycerol suppositories, see A06A X - Other laxatives.

Phenolphthalein in combination with liquid paraffin, see A06A A. Combined packages with tablets and enemas are classified in A06A G.

A major part of the products classified in this group are various combinations of two or more contact laxatives. These are classified

at separate 5th levels:

A06A B20 - Contact laxatives in combination
A06A B30 - Contact laxatives in comb. w/belladonna alkaloids

Otherwise combination products are classified at separate 5th levels using the corresponding 50-series.

A06A C *Bulk producers*

This group comprises linseed and psylla seed products, methyl cellulose etc.

Lactulose, see A06A D.

Products containing linseed in combination with antacids are classified in A02A.

Products containing sterculia in combination with alverine are classified in A03A X.

Combined products are classified at separate 5th levels using the corresponding 50-series.

A06A D *Osmotically acting laxatives*

This group comprises various saline purgatives and e.g. lactulose which is primarily considered as an osmotically acting substance.

Combined products are classified at separate 5th levels using the corresponding 50-series. Combinations with contact laxatives are classified in A06A B.

Mineral salts in combinations are classified in A06A D10.

Magnesium hydroxide is classified as an antacid in A02A A.

A06A G *Enemas*

All enemas and laxative rectal solutions are classified in this group, regardless of mode of action.

Combined packages containing tablets and enemas are classified in this group.

Some 5th levels for plain substances includes also combinations, e.g.:

A06A G10 - Docusate - docusate and e.g. sorbitol or glycerol
A06A G11 - Laurilsulfate - laurilsulfate and e.g. sodium citrate

The DDDs for enemas classified in this group are 1 enema.

A06A X *Other laxatives*

This group comprises all laxatives which cannot be classified in A06A A-G, e.g. glycerol suppositories and carbon dioxide producing agents.

A07 **ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS**

A07A INTESTINAL ANTIINFECTIVES

This group comprises locally acting antiinfectives. Antiinfectives for systemic use, see J - General antiinfectives, systemic.

See also P - Antiparasitic products.

A07A A *Antibiotics*

Vancomycin and colistin for oral therapy are classified in this group as they are used in enterocolitis. Vancomycin injection/infusion is classified in J01X A - Glycopeptide antibacterials, and colistin injection/infusion in J01X B - Polymyxins.

Most of the combined products containing more than one antibiotic, contain neomycin. Neomycin is given classification priority, thus all combined products containing neomycin and other antibiotics should be classified in A07A A51 - Neomycin, combinations.

The DDDs are based on treatment of intestinal candidiasis.

A07A B *Sulfonamides*

The DDDs are based on prophylactic preoperative treatment of intestinal infections.

A07A C *Imidazole derivatives*

The DDDs are based on treatment of gastrointestinal mycosis.

A07A X *Other intestinal antiinfectives*

This group comprises antiinfectives which cannot be classified in A07A A-C, e.g. broxyquinoline.

A07B INTESTINAL ADSORBENTS

Combinations with intestinal antiinfectives are classified in A07A.

A07B A *Charcoal preparations*

The DDD for charcoal preparations is based on treatment of common diarrhea.

A07B B *Bismuth preparations*

See also A02B X - Other drugs for treatment of peptic ulcer.

No ATC 5th levels are assigned in this group.

A07B C *Other intestinal adsorbents*

This group comprises all other intestinal adsorbents, e.g. pectin.

A07C ELECTROLYTES WITH CARBOHYDRATES

A07C A *Oral rehydration salt formulations*

The DDDs are mainly based on use in children.

A07D ANTIPROPULSIVES

A07D A *Antipropulsives*

This group comprises agents which reduce gastrointestinal motility, e.g. diphenoxylate and loperamide. Loperamide oxide is classified at the same 5th level as loperamide.

A07D A01 - Diphenoxylate - includes combinations with atropine
A07D A02 - Opium - includes also combinations with belladonna and/or bismuth subgallate, albumin etc.

Otherwise combination products are classified at separate 5th levels by using the corresponding 50-series.

The DDDs are based on treatment of acute diarrhea and have been established according to diphenoxylate and opium compounds.

A07E INTESTINAL ANTIINFLAMMATORY AGENTS

A07E A *Corticosteroids for local use*

Enemas and rectal foams for treatment of e.g. ulcerative colitis are classified here.

The DDDs are given as 1 enema. The DDD for hydrocortison rectal foam is given in amount of active substance.

A07E B *Antiallergic agents, excl. corticosteroids*

Cromoglicic acid for oral use in food allergy is classified in this group.

The DDD is based on treatment of food allergy.

A07E C *Aminosalicylic acid and similar agents*

Some preparations classified in this group are also used for treatment of rheumatoid arthritis.

The DDDs are based on treatment of colitis ulcerosa and morbus Crohn.

A07F ANTIDIARRHEAL MICROORGANISMS

A07F A *Antidiarrheal microorganisms*

Preparations with e.g. lactic acid producing organisms are classified in this group.

The DDDs are given in UDs (e.g. numbers of tablets).

A07X OTHER ANTIDIARRHEALS

A07X A *Other antidiarrheals*

Preparations containing e.g. albumin tannate and semen ceratonia are classified here.

A08 ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

A08A ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

Low-energy diets, see V06A A.

A08A A *Centrally acting antiobesity products*

Centrally acting drugs mainly used to produce anorexia, e.g. phentermine, are classified in this group. Amfetamine which is commonly used in psychiatry is classified in N06B - Psychostimulants and nootropics.

A09 DIGESTIVES, INCL. ENZYMES

A09A DIGESTIVES, INCL. ENZYMES

A09A A *Enzyme preparations*

Only enzymes used in digestion disorders are classified in this group. Other enzymes, see B06A A - Enzymes, and D03B A - Proteolytic enzymes.

Enzyme preparations which are indicated to treat inflammatory conditions are classified in M09A B - Enzymes.

Combinations of digestive enzymes and other agents (e.g. silicone compounds and spasmolytics) are classified in this group if the main indication is digestion disorders.

Cholagogues are classified in A05 - Bile and liver therapy.

DDDs can be difficult to establish because of great variations in enzyme content. The DDDs are based on average recommended doses given in different drug catalogues. Most of the preparations are combinations of different enzymes, and the DDDs are therefore given in UDs.

A09A B *Acid preparations*

A09A C *Enzyme and acid preparations, combinations*

A10 **DRUGS USED IN DIABETES**

A10A INSULINS

This group comprises both human - and animal insulins.

Glucagon, see H04A - Glycogenolytic hormones.

A10A A *Insulins*

Insulin preparations are classified at 4 different 5th levels, according to onset and duration of action.

Combination products with fast-acting and intermediate-acting insulins are classified in A10A A03.

DDD for insulins is 40 units.

A10B ORAL BLOOD GLUCOSE LOWERING DRUGS

This group is subdivided according to the chemical structure.

A10B A *Biguanides*

A10B B *Sulfonamides, urea derivatives*

The DDD for micronized glibenclamide is lower compared to older non-micronized formulations, due to higher bioavailability.

A10B C *Sulfonamides (heterocyclic)*

A10B D *Biguanides and sulfonamides in combination*

A10B F *Alpha glucosidase inhibitors*

A10B X *Other oral blood glucose lowering drugs*

E.g. guar gum is classified here.

A10X OTHER DRUGS USED IN DIABETES

A10X A *Aldose reductase inhibitors*

A11 VITAMINS

Vitamins constitute a comprehensive group of therapeutic and prophylactic preparations, and before classifying any product it is important to be familiar with the main subdivision of the group.

It may be necessary to consider whether a product is a vitamin preparation with iron or an iron preparation with vitamins, a mineral preparation with vitamins or a vitamin preparation with minerals, or if the product should be regarded as a tonic etc. As an aid to such considerations, guidelines are given at each sublevel.

Vitamin B_{12} is classified in B03 - Antianemic preparations.

Vitamin K is classified in B02 - Antihemorrhagics.

Vitamins administered as I.V. solution additives, see B05X C.

Some definitions:

Multivitamins: Products containing minimum vitamins A, B, C and D. One B-vitamin is sufficient.

B-complex: Products containing minimum thiamine, riboflavine, pyridoxine, nicotinamide. The products may contain other B-vitamins.

A11A MULTIVITAMINS, COMBINATIONS

The DDDs are based on prophylactic use. For simplicity, the DDDs for oral formulations are given as fixed doses (1 tablet = 1 UD, or 30 ml mixture = 6 UD).

A11A A Multivitamins with minerals

The group is subdivided:

A11A A01 - Multivitamins and iron
A11A A02 - Multivitamins and calcium
A11A A03 - Multivitamins and other minerals, incl. combinations
A11A A04 - Multivitamins and trace elements

In A11A A01, 02 and 03, combinations with trace elements are allowed.

In A11A A04 only trace elements are allowed in addition to multivitamins.

Combinations with other substances, e.g. caffeine, are classified in A11A B.

Cholin, biotin, inositol and para-amino benzoic acid are regarded as vitamins and are allowed in preparations classified in A11A A.

A11A A01 Multivitamins and iron

Preparations containing multivitamins and sub-therapeutic doses of iron are classified in this group.

Sub-therapeutic doses of iron are defined as 5-30 mg of Fe^{2+} per defined daily dose, with corresponding limits for the various Fe^{3+} salts, if the main indication is not "iron deficiency". Preparations containing more than 30 mg Fe^{2+} (or corresponding doses of Fe^{3+}) are classified as iron preparations (B03A) regardless of therapeutic use.

See also A11A A.

A11A A02 Multivitamins and calcium

Preparations containing multivitamins and sub-therapeutic doses of calcium are classified in this group, e.g. a calcium content of up to 500 mg calcium carbonate per tablet have been allowed.

See also A11A A.

Calcium preparations, see A12A.

A11A A03 Multivitamins and other minerals, incl. combinations

Preparations containing multivitamins and sub-therapeutic doses of one or more mineral are classified in this group. Definitions of sub-therapeutic doses of calcium and iron, see A11A A01 and A11A A02. See also A11A A.

Mineral preparations, see A12.

A11A A04 Multivitamins and trace elements

Preparations containing multivitamins and trace elements are classified in this group. No other combinations may occur in this group.

A11A B Multivitamins, other combinations

This group comprises all combined preparations with multivitamins which are not classified in A11A A.

Preparations containing caffeine, strychnine etc. are classified in this group.

Preparations containing cholin, biotin, inositol, para-amino benzoic

acid etc. should be classified in A11A A.

A11B MULTIVITAMINS, PLAIN

A11B A Multivitamins, plain

Only plain multivitamin preparations are allowed.

The DDDs are based on prophylactic use. For simplicity, the DDDs are given as fixed doses (1 tablet = 1 UD, or 30 ml mixture = 6 UD).

A11C VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

Combinations with trace elements are allowed. Other combinations, see A11J - Other vitamin products, combinations.

See also A12 - Mineral supplements.

A11C A Vitamin A, plain

The DDD is based on therapeutic treatment of vitamin A deficiency.

A11C B Vitamin A and D in combination

Cod-liver oil products are classified in this group.

DDDs of the drops are based on prophylactic use in children.

A11C C Vitamin D and analogues

Vitamin D and analogues may be regarded as hormones, but are classified in this group. Calcium homeostasis, see H05.

The DDDs are based on therapeutic use. No DDDs are established for ergocalciferol and colecalciferol due to great differences between doses used for various indications.

A11D VITAMIN B_1, PLAIN AND IN COMBINATION WITH VITAMIN B_6 AND B_{12}

Combinations with trace elements are allowed. Other combinations see A11J - Other vitamin products, combinations.

A11D A Vitamin B_1 plain

DDDs are based on treatment of vitamin B_1 deficiency.

A11D B Vitamin B_1 in combination with vitamin B_6 and/or vitamin B_{12}

Combinations with vitamin B_2 are also allowed in this group.

For vitamin B_1 in combination with vitamin B_6 and/or vitamin B_{12}, DDDs are only established for parenteral preparations, based on the volume of one ampoule. The DDDs are given in UDs (1 UD = 1 ml).

A11E VITAMIN B-COMPLEX, INCL. COMBINATIONS

Definition of vitamin B-complex, see A11 - Vitamins.
The group is subdivided:

A11E A - Vitamin B-complex, plain
A11E B - Vitamin B-complex with vitamin C
A11E C - Vitamin B-complex with minerals
A11E D - Vitamin B-complex with anabolic steroids
A11E X - Vitamin B-complex, other combinations

Combinations with trace elements are allowed. Vitamin B-complex in combination with other vitamins than vitamin C, see A11J - Other vitamin products, combinations.

DDDs are based on prophylactic treatment. DDDs are given as fixed doses (1 tablet = 1 UD, or 30 ml mixture = 6 UD). DDDs for parenteral preparations are based on the volume of one ampoule. The DDDs for these preparations are given in UDs (1 UD = 1 ml).

A11E A *Vitamin B-complex, plain*

This group comprises plain vitamin B-complex preparations, also in combination with liver extract. Liver extract preparations, see also B03B A - Vitamin B_{12} (cyanocobalamine). See also A11E.

A11E B *Vitamin B-complex with vitamin C*

This group comprises all combinations of vitamin B-complex and vitamin C. Combinations with anabolic steroids, see A11E D.

See also A11E, A11E D and A11E X.

A11E C *Vitamin B-complex with minerals*

Preparations containing vitamin B-complex and sub-therapeutic doses of one or more mineral are classified in this group.

See also A11E.

Mineral preparations, see A12.

A11E D *Vitamin B-complex with anabolic steroids*

Preparations containing vitamin B-complex and anabolic steroids are classified in this group. Even combinations containing vitamin C, minerals or other substances, e.g. caffeine are classified in this group.

A11E X *Vitamin B-complex, other combinations*

This group comprises preparations with vitamin B-complex (plain or in combination with vitamin C or minerals) and other substances, e.g. caffeine, strychnine.

A11G ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS

Other preparations with vitamin C, see A11E B - Vitamin B-complex with vitamin C, and A11J - Other vitamin products, combinations.

Combinations with analgesics are classified in N02B.

The DDD refers to the assumed daily requirement.
For combination products, the DDDs are given as fixed doses for all tablets (1 tablet = 1 UD).

A11G A *Ascorbic acid (vitamin C), plain*

Combinations with trace elements only, are allowed.

A11G B *Ascorbic acid (vitamin C), combinations*

This group comprises combinations with e.g. minerals.

Preparations containing ascorbic acid and calcium should be classified in A12A X - Calcium, combinations with other drugs - if they are used in calcium deficiency or osteoporosis.

A11H OTHER PLAIN VITAMIN PREPARATIONS

A11H A *Other plain vitamin preparations*

Vitamin B_{12}, see B03B A.

Vitamin K, see B02 - Antihemorrhagics.

This group comprises e.g. pantethine, nicotinamide, pyridoxine (vitamin B_6) and tocopherol (vitamin E).

Combinations with trace elements are allowed. Other combinations, see A11DB and A11J.

DDDs are established only for tocopherol, pyridoxine and nicotinamide, and refers to assumed daily requirement in vitamin deficiency.

A11J OTHER VITAMIN PRODUCTS, COMBINATIONS

The group is subdivided:

A11J A - Combinations of vitamins
A11J B - Vitamins with minerals

A11J C - Vitamins, other combinations

Combinations with trace elements are allowed.

The DDDs are given as fixed doses (1 tablet = 1 UD, or 30 ml mixture = 6 UD), except for concentrated ACD vitamin drops.

A11J A *Combinations of vitamins*

This group comprises all combinations of vitamins with no addition of other substances, not covered by the preceding groups.

A11J B *Vitamins with minerals*

This group comprises all combinations of vitamins with minerals in sub-therapeutic doses, not covered by the preceding groups.

See also A12 - Mineral supplements.

A11J C *Vitamins, other combinations*

This group comprises all products which contain vitamins (with or without minerals) and in addition other substances, e.g. caffeine and strychnine. Combinations with folic acid are classified in B03B B if "folic acid deficiency" is the main indication.

This group contains products which may also be regarded as tonics. No sharp line has been drawn between these two groups.

Tonics are classified in A13. The vitamin content of tonics should be rather low.

A12 MINERAL SUPPLEMENTS

This group contains mineral supplements used for treatment of mineral deficiency.

A12A CALCIUM

A12A A *Calcium*

All plain calcium preparations, incl. bone extracts are classified in this group. See also B05X - I.V. solution additives.

Combinations of different calcium salts are given the following ATC-code: A12A A20. Small amounts of calcium carbonate (i.e. 300 mg per tablet) are, however, allowed at each 5th level for plain calcium preparations.

See also:

A11A A02 - Multivitamins and calcium
A11E C - Vitamin B-complex with minerals
A11G B01 - Ascorbic acid and calcium
A11J B - Vitamins with minerals

The DDDs are based on treatment of calcium deficiency and osteoporosis.

A12A X *Calcium, combinations with other drugs*

This group comprises all combined calcium preparations used in the treatment of calcium deficiency conditions and osteoporosis. Many of these are combinations with vitamins, especially vitamin A and D. Combination packages of calcium and bisphosphonates are classified in M05B B.

A12B POTASSIUM

A12B A *Potassium*

This group comprises preparations used as potassium supplements.

This group comprises also all combined potassium preparations used in the treatment of potassium deficiency conditions.

Small non-therapeutic amounts of potassium hydrogencarbonate are allowed at each level of plain potassium salts.
Potassium, combinations with other drugs, are classified at separate 5th levels using the corresponding 50-series.

Diuretics and potassium in combination, see C03 - Diuretics.

See also B05 - Plasma substitutes and perfusion solutions.

The DDDs are based on treatment of potassium deficiency, and correspond to a potassium content of about 40 mmol potassium.

A12C OTHER MINERAL SUPPLEMENTS

This group comprises other minerals, such as sodium, zinc, magnesium and fluoride.

See also B05 - Plasma substitutes and perfusion solutions.

A12C A Sodium

The DDD has been set to 1 g NaCl.

A12C B Zinc

The DDD is based on treatment of zinc deficiency.

A12C C Magnesium

The DDDs for the various magnesium salts are equivalent to an assumed daily requirement of 300 mg Mg (oral dose). The DDD for some of the oral formulations are higher than the parenteral formulations due to lower bioavailability.

A12C D Fluoride

This group comprises preparations used e.g. in the treatment of osteoporosis. Fluoride used in caries prophylaxis, see A01A A - Caries prophylatic agents.

Bisphosphonates are classified in M05B.
Calcitonin is classified in H05B A.
Calcium preparations are classified in A12A.

The DDD is based on treatment of osteoporosis.

A12C E *Selenium*

The DDD is based on the assumed daily requirement of selenium.

A12C X *Other mineral products*

A13 **TONICS**

A13A TONICS

This group comprises preparations used as tonics etc., if preparations do not fill the requirements to be classified as iron preparations, vitamin preparations etc.

All mixtures classified in this group are given a fixed DDD (30 ml = 6 UD).

A14 **ANABOLIC AGENTS FOR SYSTEMIC USE**

A14A ANABOLIC STEROIDS

Anabolic steroids are subdivided in different 4th levels according to chemical structure.

Anabolic steroids used exclusively in cancer therapy, see L - Anti-neoplastic and immunomodulating agents.

The DDDs are based on e.g. treatment of anemia.

A14A A *Androstan derivatives*

A14A B *Estren derivatives*

A14B OTHER ANABOLIC AGENTS

This group comprises all other anabolic agents which cannot be

classified in the preceding groups.

A15 APPETITE STIMULANTS

This group comprises preparations only used as appetite stimulants. A number of drugs with other main actions may have appetite stimulating properties.

Cyproheptadine, also used as an appetite stimulant in children, is classified in R06A X. Pizotifen is classified in N02C X01.

No DDDs are established in this group.

A16 OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

A16A OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

This group comprises all products acting on the alimentary tract and metabolism which cannot be classified in the preceding groups. V03 - All other therapeutic products, should also be considered.

Nutrients are classified in V06.

A16A A Amino acids and derivatives

Agents used in various metabolic deficiency states are classified here, when this is considered to be the main indication e.g. levocarnitine. Tryptophan and oxitriptan, see N06.

The DDD of levocarnitine is based on treatment of primary carnitine deficiency.

A16A B Enzymes

E.g. alglucerase is classified here.

A16A X Various alimentary tract and metabolism products

E.g. tioctic acid is classified here.

B BLOOD AND BLOOD FORMING ORGANS

B01 ANTITHROMBOTIC AGENTS

A Antithrombotic agents

B02 ANTIHEMORRHAGICS

A Antifibrinolytics

B Vitamin K and other hemostatics

B03 ANTIANEMIC PREPARATIONS

A Iron preparations

B Vitamin B_{12} and folic acid

X Other antianemic preparations

B04 SERUM LIPID REDUCING AGENTS

A Cholesterol- and triglyceride reducers

B05 PLASMA SUBSTITUTES AND PERFUSION SOLUTIONS

A Blood and related products

B I.V. solutions

C Irrigating solutions

D Peritoneal dialytics

X I.V. solution additives

Z Hemodialytics and hemofiltrates

B06 OTHER HEMATOLOGICAL AGENTS

A Other hematological agents

B BLOOD AND BLOOD FORMING ORGANS

B01 ANTITHROMBOTIC AGENTS

B01A ANTITHROMBOTIC AGENTS

B01A A Vitamin K antagonists

This group comprises vitamin K antagonists such as dicoumarol, warfarin etc.

The DDDs are based on prophylactic treatment of thrombosis.

B01A B Heparin group

This group comprises heparin preparations, including products for non-therapeutic use, e.g. for rinsing of indwelling vein cannulas. The different fractions of the low molecular weight heparins are classified at separate 5th levels.

The DDDs of ordinary heparin and antithrombin are based on prophylactic use for the prevention of thrombosis and pulmonary emboli, and given in international units (E). The DDD for the low molecular weight heparins are based on prophylactic use in general surgery . Since the anti Xa activity is decisive for the antithrombotic effect, the DDDs for low molecular weight heparins are given in international units based on anti Xa activity.

The DDDs for combination products are given as the DDD of the substance of the heparin group.

B01A C Platelet aggregation inhibitors excl. heparin

E.g. ticlopidine is classified here.

Acetylsalicylic acid preparations specifically intended for use as antithrombotic agents are classified in this group. This exception from the basic principle of only one code for each pharmaceutical preparation (i.e. the same formulation and strength) is made because

of the extensive use of acetylsalicylic acid both as an antithrombotic agent and as an analgesic. Whether an acetylsalicylic acid product should be classified in this group or in N02BA, should be decided at the national level based on the main indication of the product.

Sulfinpyrazone is classified in M04A B. Alprostadil is classified in C01E A and G04B X.

The DDDs are based on prophylactic treatment of thrombosis. The DDDs of *acetylsalicylic acid* and *carbasalate calcium* are given as 1 tablet independent of tablet strength. This is due to the great variations between different countries in the dosages/ strengths recommended for prophylactic treatment of thrombosis. The DDD of iloprost is based on treatment of peripheral vascular disease.

B01A D *Enzymes*

The DDDs of *streptokinase, alteplase* and *anistreplase* are based on thrombolytic treatment in connection with acute myocardial infarction. The DDD of urokinase is based on treatment of acute lung emboli. The DDDs are either expressed in international units or gram.

B01A X *Other antithrombotic agents*

B02 **ANTIHEMORRHAGICS**

B02A ANTIFIBRINOLYTICS

This group comprises agents which inhibit fibrinolytic activity.

Combinations with vitamin K, see B02B - Vitamin K and other hemostatics.

The DDDs are based on treatment of hemorrhage associated with fibrinolysis.

B02A A *Amino acids*

B02A B *Proteinase inhibitors*

E.g. aprotinin is classified here.

B02B VITAMIN K AND OTHER HEMOSTATICS

The DDDs are based on treatment of hemorrhage associated with different deficiency states (e.g. vitamin K deficiency, deficiency of different blood coagulation factors etc.)

B02B A *Vitamin K*

B02B B *Fibrinogen*

B02B C *Local hemostatics*

This group comprises gauze, tampons etc. impregnated with hemostatic agents. Local hemostatics used in dentistry, see A01A D - Other agents for local oral treatment. Epinephrine injection, see R03C - Adrenergics for systemic use. Tissue adhesives are classified in V03A K.

No DDDs are established for local hemostatics classified in this group.

B02B D *Blood coagulation factors*

This group comprises all blood coagulation factors, thrombin etc., incl. preparations for local use, and their combinations. Fibrinogen (factor I), see - B02B B - Fibrinogen.

B02B X *Other systemic hemostatics*

This group comprises systemic hemostatics which cannot be classified elsewhere, e.g. etamsylate is classified here.

B03 ANTIANEMIC PREPARATIONS

B03A IRON PREPARATIONS

This group comprises all plain iron preparations and all combination products containing more than 30 mg Fe^{2+} (or corresponding amounts of Fe^{3+} salts) per defined daily dose (DDD), regardless of therapeutic use.

Combined preparations with less than 30 mg Fe^{2+} per DDD should be classified as vitamin preparations or tonics (see also B03A E10), if the main indication is not "iron deficiency". All iron preparations with "iron deficiency" as the main indication are classified here, regardless of the amount of iron salts.

See also A11A A01 - Multivitamins and iron.

Only plain preparations should be classified in the groups B03A A, B03A B and B03A C. Combinations with stabilizing agents (e.g. ascorbic acid) are allowed at each 5th level. Combinations with e.g. laxatives are classified at separate 5th levels by using the 50-series.

Other combinations, see B03A D and B03A E.

B03A A Iron bivalent, oral preparations

The DDDs are based on treatment of iron deficiency anemia. The DDDs are established according to amount of Fe^{2+} and are equal for all compounds (i.e. the DDD corresponds to 0.2 g Fe^{2+}).

B03A B Iron trivalent, oral preparations

The DDDs are based on treatment of iron deficiency anemia. Separate DDDs are established for the different trivalent iron salts.

B03A C Iron trivalent, parenteral preparations

The DDDs are based on treatment of iron deficiency anemia. The DDDs are established according to amount of Fe^{3+} and are equal for all compounds (i.e. the DDD corresponds to 0.1 g Fe^{3+}).

B03A D *Iron in combination with folic acid*

This group comprises iron in combination with folic acid.
Preparations containing additional substances, see B03A E.

The DDDs are based on prophylaxis of iron deficiency anemia and folic acid deficiency during pregnancy (i.e. about half the iron dose for therapeutic treatment).

B03A E *Iron in other combinations*

This group comprises preparations which in addition to iron or iron and folic acid contain other substances.

The group is subdivided:

B03A E01 - Iron, vitamin B_{12} and folic acid
Intrinsic factor and/or liver extract are also allowed in this group

B03A E02 - Iron, multivitamins and folic acid
B03A E03 - Iron and multivitamins
B03A E04 - Iron, multivitamins and minerals
B03A E10 - Various combinations
This group comprises some "borderline" combined iron preparations i.e. preparations with an iron content of approximately 30 mg Fe^{2+} per defined daily dose (DDD).

For combinations of iron, vitamin B_{12} and folic acid (B03A E01), the DDDs are based on prophylaxis of iron deficiency anemia and folic acid deficiency during pregnancy.

Various combinations, classified in B03A E10, contain very small amounts of iron. The DDDs for these combinations are based on catalogue doses, and can be as low as corresponding to 30 mg Fe^{2+}.

The DDDs for iron in other combinations are based on treatment of iron deficiency anemia, and correspond to a DDD of 0.2 g Fe^{2+}.

B03B VITAMIN B_{12} AND FOLIC ACID

B03B A Vitamin B_{12} (cyanocobalamin and derivatives)

Hydroxocobalamin for treatment of neuralgia is classified here. Combinations with liver extract are classified at separate 5th levels using the corresponding 50-series. Combinations with folic acid are classified in this group by using the 50-series.

Vitamin B_{12}, see also:

A11D -	Vitamin B_1, plain and in comb. with vitamin B_6 and B_{12}
A11E A -	Vitamin B-complex, plain
B03A -	Iron preparations

The DDDs are based on maintenance treatment of pernicious anemia. Different DDDs are assigned for oral and parenteral formulations of cyanocobalamin due to great differences in bio-availability. No DDDs are assigned for combination products.

B03B B Folic acid and derivatives

Folic acid and derivatives in combination with other substances are classified in this group at separate 5th levels using the corresponding 50-series, if "folic acid" deficiency is the main indication. Calcium folinate, antidote in high dose metothrexate treatment, is classified in V03A. Combinations with iron, see B03A D and B03A E. Combinations with vitamin B_{12} are classified in B03B A.

Two different DDDs are established for folic acid, based on prophylaxis and treatment of megaloblastic anemia. The dosages used for these two indications, are very different, and this will be reflected in the strength of the folic acid preparations.

B03X OTHER ANTIANEMIC PREPARATIONS

This group comprises antianemic preparations other than iron, vitamin B_{12} and folic acid.

B03X A *Other antianemic preparations*

E.g. erythropoietin is classified here.

The DDD for erythropoietin is based on treatment of renal anemia in patients maintained by hemodialysis.

B04 SERUM LIPID REDUCING AGENTS[1]

B04A CHOLESTEROL- AND TRIGLYCERIDE REDUCERS

Combinations of different cholesterol- and triglyceride reducers are classified at separate 5th levels using the corresponding 50-series. The following ranking according to the ATC-codes is used: Substances classified in ATC-group B04A B take precedence over B04A C etc.

Pantethine, which is also used in the treatment of hyperlipidemi, is classified as a vitamin in A11H A.

The DDDs are based on treatment of hypercholesterolemia.

B04A B *HMG CoA reductase inhibitors*

This group comprises agents which act as competitive inhibitors of 3-hydroxy-3-methylglutaryl coenzyme A reductase (HMG CoA reductase).

B04A C *Fibrates*

Clofibrate and analogues are classified here.

B04A D *Bile acid sequestrants*

This group comprises substances (such as colestyramine and colestipol) which reduces the cholesterol level by increasing the excretion of bile acid.

---

[1] The serum lipid reducing agents will be included in ATC group C from January 1997

B04A E *Nicotinic acid and derivatives*

This group comprises high strength preparations (e.g. nicotinic acid tab 500 mg) used as cholesterol reducers. Nicotinic acid or derivatives in low strength preparations (e.g. nicotinic acid tab 50 mg) are classified in C04A - Peripheral vasodilators.

B04A X *Other cholesterol- and triglyceride reducers*

This group comprises all cholesterol- and triglyceride reducers which cannot be classified in the preceding groups. E.g. dextrothyroxine, probucol, acipimox and omega-3-triglycerides are classified here.

Sulodexide is classified in B01A B.

B05 PLASMA SUBSTITUTES AND PERFUSION SOLUTIONS

See also:

V07A B - Solvents and diluting agents, incl. irrigating solutions
V07A C - Blood transfusion, auxiliary products

No DDDs are established in this group. It is considered difficult to establish DDDs, because of the great variations in dosages given.

B05A BLOOD AND RELATED PRODUCTS

B05A A *Plasma substitutes and plasma protein fractions*

This group comprises e.g. dextran, gelatin solutions and albumin.

B05B I.V. SOLUTIONS

This group comprises I.V. solutions used in parenteral administration of fluids, electrolytes and nutrients. Agents administered as I.V. solutions or additives, see the respective therapeutic groups, e.g. C01- Cardiac therapy (lidocaine, dopamine)

and various antibiotics. I.V. solution additives, see B05X.

B05B A *Solutions for parenteral nutrition*

This group comprises amino acids, carbohydrates, fat emulsions etc. for parenteral nutrition. Combinations with electrolytes are allowed. Combinations of sodium chloride and glucose are classified in B05B B - Solutions affecting the electrolyte balance. These and similar combinations are not primarily used as nutrients.

A method for establishing a DDD for *total parenteral nutrition (TPN)* is described in *Pharmacy World and Science, Volume 15 no 2, 1993, p. 68-72.*

B05B B *Solutions affecting the electrolyte balance*

This group comprises electrolyte solutions, incl. combinations with e.g. carbohydrates. Combinations with amino acids, fat etc. should be classified in B05B A.

B05B C *Solutions producing osmotic diuresis*

Mannitol and similar agents are classified in this group.

B05C IRRIGATING SOLUTIONS

In this group products used for bladder irrigation, surgical irrigation, incl. instruments etc. are classified. See also V07A B - Solvents and diluting agents, incl. irrigating solutions.

Combined preparations are classified by using 5th level - 10. Only plain preparations are classified at the other 5th levels.

B05C A *Antiinfectives*

B05C B *Salt solutions*

B05C X *Other irrigating solutions*

This group comprises e.g. glucose and sorbitol.

B05D PERITONEAL DIALYTICS

B05D A *Isotonic solutions*

B05D B *Hypertonic solutions*

B05X I.V. SOLUTION ADDITIVES

I.V. solution additives are concentrated preparations containing substances used for correcting fluid and electrolyte balance and nutritional status. Drugs administered as I.V. solutions or additives, see the respective groups, e.g. C01 - Cardiac therapy (lidocaine, dopamine) and J - General antiinfectives for systemic use.

B05X A *Electrolyte solutions*

This group comprises plain electrolyte solutions, combinations of electrolytes, and combinations of electrolytes and other substances (e.g. trace elements). Products containing only trace elements, are also classified here (in B05X A31).
See also A12 - Mineral supplements.

B05X B *Amino acids*

B05X C *Vitamins*

See also A11 - Vitamins

B05X X *Other I.V. solution additives*

This group comprises all I.V. additives which cannot be classified in the preceding groups.

B05Z HEMODIALYTICS AND HEMOFILTRATES

B05Z A *Hemodialytics, concentrates*

B05Z B *Hemofiltrates*

B06 OTHER HEMATOLOGICAL AGENTS

No DDDs are established in this group.

B06A OTHER HEMATOLOGICAL AGENTS

This group includes preparations for local and systemic use, and also some preparations used for dissolving coagles in catheters, hemodialysis coagles etc.

See also:

V07A -	All other non-therapeutic products
B01A B -	Heparin group

B06A A Enzymes

This group comprises enzymes with fibrinolytic properties. Enzymes with other well defined therapeutic use should be classified in the respective groups, see e.g.:

A09A -	Digestives, incl. enzymes
B01A D -	Enzymes
D03B A -	Proteolytic enzymes
S01K X -	Other surgical aids (chymotrypsin)

B06A B Other hem products

E.g. hematin is classified in this group.

C CARDIOVASCULAR SYSTEM

C01 CARDIAC THERAPY

A Cardiac glycosides
B Antiarrhythmics, class I and III
C Cardiac stimulants excl. cardiac glycosides
D Vasodilators used in cardiac diseases
E Other cardiac preparations

C02 ANTIHYPERTENSIVES

A Antiadrenergic agents, centrally acting
B Antiadrenergic agents, ganglion-blocking
C Antiadrenergic agents, peripherally acting
D Arteriolar smooth muscle, agents acting on
K Other antihypertensives
L Antihypertensives and diuretics in combination
N Combinations of antihypertensives in ATC-gr. C02

C03 DIURETICS

A Low-ceiling diuretics, thiazides
B Low-ceiling diuretics, excl. thiazides
C High-ceiling diuretics
D Potassium-sparing agents
E Diuretics and potassium-sparing agents in combination

C04 PERIPHERAL VASODILATORS

A Peripheral vasodilators

C05 VASOPROTECTIVES

A Antihemorrhoidals for topical use
B Antivaricose therapy
C Capillary stabilizing agents

C07 BETA BLOCKING AGENTS

A Beta blocking agents
B Beta blocking agents and thiazides
C Beta blocking agents and other diuretics
D Beta blocking agents, thiazides and other diuretics
E Beta blocking agents and vasodilators
F Beta blocking agents and other antihypertensives

C08 ***CALCIUM CHANNEL BLOCKERS***

C Selective calcium channel blockers with mainly vascular effects
D Selective calcium channel blockers with direct cardiac effects
E Non-selective calcium channel blockers
G Calcium channel blockers and diuretics

C09 ***AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM***

A Angiotensin-converting enzyme (ACE) inhibitors, plain
B Angiotensin-converting enzyme (ACE) inhibitors, combinations
C Angiotensin II antagonists
D Angiotensin II antagonists, combinations
X Other agents acting on the renin-angiotensin system

C CARDIOVASCULAR SYSTEM

C01 CARDIAC THERAPY

C01A CARDIAC GLYCOSIDES

This group comprises plain and combined preparations containing cardiac glycosides, incl. standardized herbal extracts. Includes cardiac glycosides in combination with substances in group C01D and C01E. Combinations with antihypertensives, beta blocking agents, calcium channel blockers and ACE inhibitors, see group C02, C07, C08 and C09 respectively.

The DDDs are based on the average maintenance dose for the treatment of cardiac failure. Exception: the DDD for deslanoside is for acute treatment.

The DDDs for preparations of cardiac glycosides in combination with other drugs are established mainly according to the content of the glycosides. The DDDs should, however, normally not exceed the DDDs assigned for each ingredient.

C01A A *Digitalis glycosides*

C01A B *Scilla glycosides*

C01A C *Strophantus glycosides*

C01A X *Other cardiac glycosides*

This group includes e.g. peruvoside convallaria glycosides.

C01B ANTIARRHYTHMICS, CLASS I AND III

This group comprises preparations used in the treatment of arrhythmias.

The agents are listed according to the Vaughan Williams classification of antiarrhythmics. The division of class I antiarrhythmics may vary, depending on the literature used. The 3rd ed. of Avery's

"Drug Treatment" (1987) and "Drugs" 31, 93 - 95, 1986 are used as a basis for the ATC classification. Class II antiarrhythmics see C07 and class IV , see C08 (e.g. verapamil).

Adenosine which is also used as an antiarrhythmic is classified in C01E B.

Combined preparations are classified at separate 5th levels using the corresponding 50-series. Combinations with psycholeptics are classified at separate 5th levels using the corresponding 70-series. Combinations with an antihypertensive e.g. reserpine are classified in C02A A.

The DDDs are based on the prophylactic and therapeutic treatment of supraventricular and ventricular arrhythmias. The DDDs are based on the maintenance dose. Preparations for parenteral administration are only used initially and are therefore given the same DDD as oral preparations.

The DDDs for preparations of antiarrhythmics and psycholeptics in combination are established according to the content of both components, using the general principles for the establishment of DDDs for combined preparations.

C01B A *Antiarrhythmics, class IA*

Includes e.g. quinidine, procainamide, disopyramide, ajmaline and sparteine.

Combinations containing quinidine and verapamil are classified in C08D A.

C01B B *Antiarrhythmics, class IB*

Includes e.g. lidocaine, mexiletine, tocainide and aprindine. Lidocaine used as a local anesthetic is classified in N01B B. Phenytoin, a class IB antiarrhythmic, is classified as an antiepileptic in N03.

C01B C *Antiarrhythmics, class IC*

Includes e.g. propafenone, flecainide and lorcainide.

C01B D *Antiarrhythmics, class III*

Includes e.g. amiodarone and bretylium tosilate.

Sotalol which has class III antiarrhythmic properties is classified in C07A A.

C01B G *Other class I antiarrhythmics*

This group includes substances which do not belong to the class a, b or c of the class I antiarrhythmics (e.g. moracizine).

C01C CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

This group comprises agents for the treatment of hypotension. Respiratory stimulants are classified in R07A B.

Dihydroergotamine, which is used in the treatment of migraine as well as hypotension, is classified in N02C A - Ergot alkaloids.

Combinations with peripheral vasodilators, see C04 - Peripheral vasodilators.

This group includes various drugs used on different indications. The DDDs are therefore established individually for each substance (i.e. each ATC 5th level).

C01C A *Adrenergic and dopaminergic agents*

This group comprises sympathomimetics used in the treatment of hypotension. Preparations used mainly as bronchodilators are classified in R03 - Anti-asthmatics, e.g. epinephrine preparations.

C01C E *Phosphodiesterase inhibitors*

E.g. amrinone is classified in this group.

Phosphodiesterase inhibitors such as theophylline which are used in asthma therapy, are classified in R03D.

C01C X *Other cardiac stimulants*

This group includes agents which cannot be classified in the preceding groups, e.g. angiotensinamide and xamoterol.

C01D VASODILATORS USED IN CARDIAC DISEASES

This group comprises preparations used in ischemic heart diseases. See also C02, C03, C04, C07, C08 and C09.

Combinations with cardiac glycosides, see C01A.

Combinations with rauwolfia alkaloids, see C02A A.

Combinations with beta blocking agents, see C07.

Combinations with calcium channel blockers, see C08.

C01D A *Organic nitrates*

This group comprises nitrates used on the indication angina pectoris, including transdermal preparations. Amyl nitrite is classified in V03A B - Antidotes.

Combinations of two or more organic nitrates are classified at a separate 5th level C01D A20.

Other combined preparations are classified at separate 5th levels using the corresponding 50-series. All nitrate preparations in combination with psycholeptics are classified in the ATC-code C01D A70. Nitrates in combination with psycholeptics and other agents are also given the code C01D A70.

The DDDs for the nitrates are mainly based on the treatment of angina pectoris attacks (3-4 times daily). The DDDs of preparations for oral and transdermal administration are higher than the DDDs for other routes of administration (e.g. sublingual) due to a lower bioavailability.

The DDDs for some preparations are mainly based on the prophylactic use, for instance the DDDs of isosorbide dinitrate and glyceryl trinitrate plaster.

No DDDs are established for parenteral preparations due to great differences in the dosages used.

The DDDs for combined preparations are established mainly according to the DDD for the nitrate component.

C01D B *Quinolone vasodilators*

C01D X *Other vasodilators used in cardiac diseases*

This group comprises vasodilators used in cardiac diseases which cannot be classified in in the preceding groups.

C01E OTHER CARDIAC PREPARATIONS

This group comprises various preparations used in the treatment of ischemic heart diseases, which cannot be classified in any of the preceding groups.

C01E A *Prostaglandins*

This group comprises e.g. alprostadil. Specific formulations of alprostadil for treatment of erectile dysfunction are classified in G04B X.

C01E B *Other cardiac preparations*

This group comprises plain preparations used in the treatment of ischemic heart diseases, which cannot be classified in the preceding groups (e.g. crataegus glycosides, and creatinolfosfate).

Adenosine which is also used as an antiarrhythmic is classified here. Antiarrhythmics, see C01B.

Preparations containing indometacin which are only used for closing the ductus arteriosus in premature infants, are classified here. Indometacin used as an antiinflammatory agent is classified in M01A B01 or S01B C01.

C01E X *Other cardiac combination products*

This group comprises combined preparations which cannot be classified in the preceding groups.

C02 ANTIHYPERTENSIVES

See also C03 - Diuretics, C07 - Beta blocking agents, C08 - Calcium channel blockers and C09 - Agents acting on the renin-angiotensin system.

Antihypertensives are mainly classified at 3rd levels according to the mechanism of action. Most headings are regarded as self-explanatory:

C02A - Antiadrenergic agents, centrally acting
C02B - Antiadrenergic agents, ganglion-blocking
C02C - Antiadrenergic agents, peripherally acting
C02D - Arteriolar smooth muscle, agents acting on
C02K - Other antihypertensives
C02L - Antihypertensives and diuretics in combination
C02N - Combinations of antihypertensives in ATC group C02

The oral DDDs are based on the average doses needed to reduce the blood pressure to a normal level in patients with mild-moderate hypertension.

Parenteral DDDs are based on the dosages used for the treatment of hypertensive crises and are based on the content of the active ingredient pr. vial (ampoule).

C02A ANTIADRENERGIC AGENTS, CENTRALLY ACTING

C02A A Rauwolfia alkaloids

This group comprises plain and combined rauwolfia preparations used in hypertension.

There are separate 5th levels for combinations of rauwolfia alkaloids (C02A A03) and for rauwolfia, whole root (C02A A04).

Combinations with beta blocking agents, see C07F - Beta blocking agents and other antihypertensives.

Combinations with diuretics, see C02L A - Rauwolfia alkaloids and diuretics in combination.

Combinations with other antihypertensives, see C02N - Combinations of antihypertensives in ATC group C02.

Combined products are otherwise classified at separate 5th levels using the corresponding 50-series.

C02A B Methyldopa

Combinations with diuretics, see C02L B - Methyldopa and diuretics in combination.

Combinations with Rauwolfia alkaloids and diuretics, see C02L A - Rauwolfia alkaloids and diuretics in combination.

Different DDDs have been established for the various stereoisomeric forms of methyldopa, because of different potency.

C02A C Imidazoline receptor agonists

E.g. guanfacine is classified in this group.

Low strength clonidine preparations used in the treatment of migraine are classified in N02C - Antimigraine preparations.

Combinations with diuretics, see C02L C - Imidazoline receptor agonists in combination with diuretics.

C02B ANTIADRENERGIC AGENTS, GANGLION-BLOCKING

C02B A *Sulfonium derivatives*

Includes e.g. trimetaphan.

C02B B *Secondary and tertiary amines*

Includes e.g. mecamylamine.

C02B C *Bisquaternary ammonium compounds*

C02C ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

Alpha- and beta-adrenoceptor blocking agents, see C07A G.

C02C A *Alpha-adrenoceptor blocking agents*

Combinations with diuretics, see C02L E - Alpha-adrenoceptor blocking agents and diuretics.

Alfuzosin is classified in G04B X.

C02C C *Guanidine derivatives*

Combinations with diuretics, see C02L F - Guanidine derivatives and diuretics.

C02D ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

See also C08 Calcium channel blockers.

C02D A *Thiazide derivatives*

Includes e.g. diazoxide.

Oral preparations containing diazoxide for treatment of hypoglycemia are classified in V03A H.

C02D B *Hydrazinophthalazine derivatives*

Combinations with diuretics, see C02L G - Hydrazinophthalazine derivatives and diuretics.

The oral and parenteral DDDs of dihydralazine are different. This is because the parenteral DDD is given as the chloride salt while the oral DDD is given as the mesylate salt.

C02D C *Pyrimidine derivatives*

Includes e.g. minoxidil.

Dermatological preparations containing minoxidil are classified in D11A X.

C02D D *Nitroferricyanide derivatives*

Includes e.g. nitroprusside.

C02D G *Guanidine derivatives*

Includes e.g. pinacidil.

C02K OTHER ANTIHYPERTENSIVES

This group comprises all antihypertensives which cannot be classified in groups C02A-D, C02L, C02N, C03 - Diuretics, C07 - Beta blocking agents, C08 - Calcium channel blockers and C09 - Agents acting on the renin-angiotensin system.

C02K A *Alkaloids, excl. rauwolfia*

Includes e.g. veratrum alkaloids.

C02K B *Tyrosine hydroxylase inhibitors*

Includes e.g. metirosine.

C02K C *MAO inhibitors*

Includes e.g. pargyline.

C02K D *Serotonin antagonists*

Includes e.g. ketanserin.

C02L ANTIHYPERTENSIVES AND DIURETICS IN COMBINATION

All substances classified in groups C02A-K, in combination with diuretics are classified in this group. At each 5th level, various combinations containing e.g. different diuretics, other antihypertensives and potassium may occur.

Combinations with beta blocking agents, see comments under C07.

Diuretics in combination with calcium channel blockers are classified in C08.

Diuretics in combination with ACE inhibitors, are classified in C09B A.

The need for a systematic approach to classify combinations of different antihypertensives has resulted in a ranking according to the ATC codes. Substances classified in ATC group C02A A take precedence over C02A B and substances in C02A take precedence over C02B etc.

Example: A combined preparation containing bietaserpine, hydralazine and hydrochlorothiazide will be given the code C02L A07 according to the above mentioned ranking.

Combinations with psycholeptics are classified at separate 5th levels using the corresponding 70-series.

It has been considered most appropriate to assign fixed DDDs based on the average use of the different combinations without considering and comparing the strengths of the various components. 1 tablet is the fixed DDD for products given once daily whereas the fixed DDD for products given twice daily and three times daily is respectively 2 tablets and 3 tablets. Since fixed DDDs are chosen, it should be emphasized that equipotency is not considered and that the assigned DDDs cannot always be compared with the DDDs assigned for plain preparations.

C02L A *Rauwolfia alkaloids and diuretics in combination*

C02L B *Methyldopa and diuretics in combination*

C02L C *Imidazoline receptor agonists in combination with diuretics*

C02L E *Alpha-adrenoceptor blocking agents and diuretics*

C02L F *Guanidine derivatives and diuretics*

C02L G *Hydrazinophtalazine derivatives and diuretics*

C02L K *Alkaloids, excl. rauwolfia, in combination with diuretics*

C02L L *MAO inhibitors and diuretics*

C02L N *Serotonin antagonists and diuretics*

C02L X *Other antihypertensives and diuretics*

C02N COMBINATIONS OF ANTIHYPERTENSIVES IN ATC-GR. C02

Comprises combinations of different antihypertensives classified in ATC-gr. C02.

Antihypertensives in combinations with diuretics are classified in C02L - Antihypertensives and diuretics in combination.

Combinations with beta blocking agents, see C07F - Beta blocking agents and other antihypertensives.

The DDDs for fixed combinations, containing many different drugs, are based on the average doses given in the drug catalogues.

C03 DIURETICS

This group comprises diuretics, plain and in combination with potassium or other agents. Potassium-sparing agents are classsified in C03D and C03E.

Combinations with antihypertensives, see C02L - Antihypertensives and diuretics in combination.

Combinations with beta blocking agents, see C07B - C07D.

Combinations with calcium channel blockers, see C08.

Combinations with agents acting on the renin angiotensin system, see C09B and C09D.

The DDDs for diuretics are based on monotherapy. Most diuretics are used both for the treatment of edema and hypertension in similar doses and the DDDs are therefore based on both indications.

For a preparation containing a diuretic and a psycholeptic and/or an analgesic in combination, the DDD is mainly based on the DDD for the diuretic component if the preparation contains minimal amounts of the psycholeptic/analgesic component. If the content is on a therapeutic level, the DDD of the psycholeptic/analgesic component should be considered..

C03A LOW-CEILING DIURETICS, THIAZIDES

Combinations with potassium-sparing agents, see C03E A.

The different lipid solubility of the thiazides should be considered when assigning DDDs.

C03A A Thiazides, plain

C03A B *Thiazides and potassium in combination*

The 5th levels correspond to those in C03A A:

C03A A01 - Bendroflumethiazide
C03A B01 - Bendroflumethiazide and potassium

The DDDs for preparations containing potassium in addition to the diuretic component, correspond to the DDDs established for the plain preparations containing only the diuretic component.

C03A H *Thiazides, combinations with psycholeptics and/or analgesics*

C03A X *Thiazides, combinations with other drugs*

C03B LOW-CEILING DIURETICS, EXCL. THIAZIDES

This group comprises all low-ceiling diuretics not classified in C03A.

Combinations with potassium-sparing agents, see C03E A.

C03B A *Sulfonamides, plain*

Includes e.g. chlortalidone.

C03B B *Sulfonamides and potassium in combination*

The 5th levels correspond to those in C03B A, see example in C03A B.

C03B C *Mercurial diuretics*

Includes e.g. mersalyl.

C03B D *Xanthine derivatives*

Includes e.g. theobromine. See also R03D A - Xanthines.

C03B K *Sulfonamides, combinations with other drugs*

Includes e.g. combination with psycholeptics.

C03B X *Other low-ceiling diuretics*

All low-ceiling diuretics which cannot be classified in the preceding groups are classified here, e.g. cicletanine.

C03C HIGH-CEILING DIURETICS

This group comprises high-ceiling diuretics (loop-diuretics) e.g. furosemide.

Combinations with potassium-sparing agents, see C03E B.

C03C A *Sulfonamides, plain*

C03C B *Sulfonamides and potassium in combination*

The 5th levels correpond to those in C03C A. See example in C03A B.

C03C C *Aryloxyacetic acid derivatives*

Includes e.g. etacrynic acid.

C03C D *Pyrazolone derivatives*

C03C X *Other high-ceiling diuretics*

All high-ceiling diuretics which cannot be classified in the preceding groups are classified here, e.g. etozolin.

C03D POTASSIUM-SPARING AGENTS

C03D A *Aldosterone antagonists*

C03D B *Other potassium-sparing agents*

E.g. amiloride and triamterene are classified here.

C03E DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

C03E A *Low-ceiling diuretics and potassium-sparing agents*

Fixed DDDs are assigned for combinations in this group. E.g. 1 tablet regardless of strengths is the DDD assigned for hydrochlorothiazide and amiloride in combinations. See comments to C02L also.

C03E B *High-ceiling diuretics and potassium-sparing agents*

C04 PERIPHERAL VASODILATORS

C04A PERIPHERAL VASODILATORS

This group comprises plain and combined preparations used in the treatment of cerebrovascular og peripheral circulatory disorders.

Combinations with Antihypertensives, see C02 - Antihypertensives.

Combinations with vasodilators used in cardiac diseases, see C01D A.

The DDDs are based on the doses used for the treatment of cerebral and peripheral vascular disorders.

C04A A *2-amino-1-phenylethanol derivatives*

C04A B *Imidazoline derivatives*

The DDD for phentolamine is based on the treatment of acute heart failure and is based on parenteral use.

C04A C *Nicotinic acid and derivatives*

Includes low strength preparations (e.g. nicotinic acid tablets 50 mg). Nicotinic acid preparations in high strength (e.g nicotinic acid tablets 500 mg) is used as a cholesterol reducer and is classified in B04A E.

C04A D *Purine derivatives*

Include e.g. xantinol nicotinate and pentoxifylline. Combinations with nicotinic acid and derivatives are allowed at each 5th level.

C04A E *Ergot alkaloids*

Includes combinations with other peripheral vasodilators.

Combinations with calcium channel blockers (i.e. nifedipine) are classified in C08C A.

See also G02A B and N02C A.

C04A F *Enzymes*

Includes e.g. kallidinogenase.

C04A X *Other peripheral vasodilators*

Includes e.g. cyclandelate and phenoxybenzamine.

Betahistine, cinnarizine and flunarizine are classified as antivertigo preparations in N07C A.

Papaverine preparations, see A03A D - Papaverine and derivatives.

C05 VASOPROTECTIVES

No DDDs are established in this group, since most of the drugs in this group are for topical use.

C05A ANTIHEMORRHOIDALS FOR TOPICAL USE

This group comprises antihemorrhoidals for local use, such as suppositories, ointments etc.

C05A A Products containing corticosteroids

All antihemorrhoidal products which contain corticosteroids are classified in this group, including both plain products and combinations with e.g. antiinfectives, local anesthetics etc.

C05A B Products containing antibiotics

All antihemorrhoidal products which contain antibiotics, excl. combinations with corticosteroids, are classified in this group.

C05A D Products containing local anesthetics

All antihemorrhoidal products which contain anesthetics, excl. combinations with corticosteroids and/or antibiotics, are classified in this group.

See also D04A B - Anesthetics for topical use and N01B - Local anesthetics.

C05A X Other antihemorrhoidals for topical use

Antihemorrhoidals which cannot be classified in the preceding groups, are classified in this group, e.g. bismuth/zinc oxide-preparations

C05B ANTIVARICOSE THERAPY

This group comprises all products for topical treatment of varices, I.V. infusion induced thrombophlebitis etc.

Zinc bandages, see D09A - Medicated dressings.

C05B A Preparations with heparin for topical use

Heparin in combination with e.g. dexpanthenol and allantoin is

classified i C05B A53.

C05B B *Sclerosing agents for local injection*

C05B X *Other sclerosing agents*

C05C CAPILLARY STABILIZING AGENTS

C05C A *Bioflavonoids*

Rutoside is classified in this group.

Combinations with other capillary stabilizing agents are classified at separate 5th levels using the corresponding 50-series.

C05C X *Other capillary stabilizing agents*

C07 BETA BLOCKING AGENTS

C07A BETA BLOCKING AGENTS

All plain beta blocking agents are classified in this group. Combination packages containing two different products (e.g. sotalol tablets and aspirin tablets in a combination package) are also classified in this group.

Labetalol, and carvedilol are classified in C07A G - Alpha- and beta blocking agents.

The DDDs are based on the treatment of mild-moderate hypertension.

The DDDs for oral and parenteral formulations are equal, even if the parenteral preparations are used initially for treatment of arrhythmias. Exception: practolol.

C07A A *Beta blocking agents, non-selective*

All plain non-selective beta blocking agents are classified in this group.

Combined packages containing sotalol tablets and aspirin tablets are classified in C07A A57

C07A B *Beta blocking agents, selective*

All plain beta-selective blocking agents are classified in this group.

The s-enantiomer and the racemate of atenolol are classified at separate 5th levels.

Different DDDs have been assigned for the two stereoisomeric forms of atenolol due to different potency.

C07A G *Alpha and beta blocking agents*

Labetalol and carvedilol are classified in this group.

C07B BETA BLOCKING AGENTS AND THIAZIDES

This group comprises combinations of beta blocking agents and thiazides. Different thiazides may occur at each 5th level.

Combinations ot beta blocking agents, thiazides and other agents are classified at separate 5th levels using the 50-series.

See comments to C02L concerning the principles for assignment of DDDs for the combined preparations

C07B A *Beta blocking agents, non selective, and thiazides*

C07B B *Beta blocking agents, selective, and thiazides*

C07B G *Alpha and beta blocking agents and thiazides*

C07C BETA BLOCKING AGENTS AND OTHER DIURETICS

This group comprises combinations of beta blocking agents and diuretics excl. thiazides. Different diuretics except thiazides, may occur at each 5th level.

Combinations with other agents in addition, are classified at separate 5th levels using the 50-series.

See comments to C02L concerning the principles for assignment of DDDs for the combined preparations.

C07C A *Beta blocking agents, non-selective and other diuretics*

C07C B *Beta blocking agents, selective, and other diuretics*

C07C G *Alpha and beta blocking agents and other diuretics*

C07D BETA BLOCKING AGENTS, THIAZIDES AND OTHER DIURETICS

This group comprises combinations of beta blocking agents, thiazides and other diuretics. Different thiazides and diuretics may occur at each 5th level.

Combinations with other agents in addition, are classified at separate 5th levels using the 50-series.

See comments to C02L concerning the principles for assignment of DDDs for the combined preparations.

C07D A *Beta blocking agents, non-selective, thiazides and other diuretics*

C07D B *Beta blocking agents, selective, thiazides and other diuretics*

C07E BETA BLOCKING AGENTS AND VASODILATORS

This group comprises beta blocking agents and vasodilators (excl. calcium channel blockers) in combination.

Different vasodilators may occur at each 5th level.

Combinations with calcium channel blockers are classified in C07F.

See comments to C02L concerning the principles for assignment of DDDs for the combined preparations.

C07E A *Beta blocking agents, non-selective, and vasodilators*

C07E B *Beta blocking agents, selective, and vasodilators*

C07F BETA BLOCKING AGENTS AND OTHER ANTIHYPERTENSIVES

This group comprises combinations of beta blocking agents and antihypertensives. Different antihypertensives may occur at each 5th level.

Beta blocking agents in combination with calcium channel blockers are classified in this group.

See comments to C02L concerning the principles for assignment of DDDs for the combined preparations.

C07F A *Beta blocking agents, non-selective, and other antihypertensives*

C07F B *Beta blocking agents, selective, and other antihypertensives*

C08 CALCIUM CHANNEL BLOCKERS

The calcium channel blockers are classified according to selectivity of calcium channel activity and direct cardiac effects. The ATC 4th levels are subdivided according to chemical structure.

Combinations with ergot alkaloids (C04A E) are classified in this group by using the 50 series.

Combinations with diuretics are classified in C08G.

Combinations with ACE inhibitors are classified in C09B B.

Combinations with beta blocking agents are classified in C07F.

The DDDs for calcium channel blockers are based on the treatment of mild-moderate hypertension although some are used for other indications (e.g. angina pectoris).

The DDDs for oral and parenteral preparations are equal and are based on the oral dose since oral preparations represent the major fraction of the total consumption.

C08C SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

C08C A *Dihydropyridine derivatives*

Preparations containing nifedipine in combination with ergot alkaloids are classified in C08C A55.

Combinations with diuretics are classified in C08G.

C08D SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

C08D A *Phenylalkylamine derivatives*

Combinations containing verapamil and quinidine are classified in C08D A51.

C08D B *Benzothiazepine derivatives*

C08E NON-SELECTIVE CALCIUM CHANNEL BLOCKERS

C08E A *Phenylalkylamine derivatives*

C08E X *Other non-selective calcium channel blockers*

C08G CALCIUM CHANNEL BLOCKERS AND DIURETICS

C08G A *Calcium channel blockers and diuretics*

C09 AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

C09A ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS, PLAIN

All plain ACE inhibitors are classified in this group.

Combinations with diuretics, see C09B A - Angiotensin converting enzyme inhibitors and diuretics.

Combinations with calcium channel blockers, see C09B B- Angiotensin-converting enzyme (ACE) inhibitors and calcium channel blockers.

The DDDs are based on the treatment of mild-moderate hypertension.

See comments to C02L concerning the principles for assignment of DDDs for the combined preparations

C09A A Angiotensin-converting enzyme inhibitors, plain

C09B ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS, COMBINATIONS

C09B A Angiotensin-converting enzyme (ACE) inhibitors and diuretics

C09B B Angiotensin-converting enzyme (ACE) inhibitors and calcium channel blockers

C09C ANGIOTENSIN II ANTAGONISTS

C09C A Angiotensin II antagonists, plain

Losartan is classified in this group.

The DDD is based on treatment of mild-moderate hypertension.

C09D ANGIOTENSIN II ANTAGONISTS, COMBINATIONS

C09D A Angiotensin II antagonists and diuretics

Losartan in combinations with diuretics are classified here.

See comments to C02L concerning the principles for assignment of DDDs for the combined preparations.

C09X OTHER AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

C09X A Renin-inhibitors

Remikeren is classified here.

D DERMATOLOGICALS

D01 ANTIFUNGALS FOR DERMATOLOGICAL USE

A Antifungals for topical use
B Antifungals for systemic use

D02 EMOLLIENTS AND PROTECTIVES

A Emollients and protectives
B Protectives against UV-radiation

D03 PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS

A Cicatrizants
B Enzymes

D04 ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

A Antipruritics, incl. antihistamines, anesthetics, etc.

D05 ANTIPSORIATICS

A Antipsoriatics for topical use
B Antipsoriatics for systemic use

D06 ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

A Antibiotics for topical use
B Chemotherapeutics for topical use
C Antibiotics and chemotherapeutics, combinations

D07 CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

A Corticosteroids, plain
B Corticosteroids, combinations with antiseptics
C Corticosteroids, combinations with antibiotics
X Corticosteroids, other combinations

D08 ANTISEPTICS AND DISINFECTANTS

A Antiseptics and disinfectants

D09 MEDICATED DRESSINGS

A Medicated dressings

D10 ***ANTI-ACNE PREPARATIONS***

A Anti-acne preparations for topical use

B Anti-acne preparations for systemic use

D11 ***OTHER DERMATOLOGICAL PREPARATIONS***

A Other dermatological preparations

D DERMATOLOGICALS

Most of the drugs in this group are preparations for topical use. Some few preparations for systemic use with clear dermatological applications, e.g. griseofulvin (antimycotic), retinoids (for treatment of acne) and psoralens and retinoids (for treatment of psoriasis) are classified in this group.

Only oral preparations in ATC group D are given DDDs. Most products in this group are for topical use, and no DDDs are assigned because the amount given per day can vary very much according to the intensity and distribution of the disease. Consumption figures of these dermatological preparations can be expressed in grams of preparations regardless of strength.

D01 ANTIFUNGALS FOR DERMATOLOGICAL USE

This group comprises preparations for topical and systemic treatment of dermatological mycoses. Preparations with systemic antimycotic effect, see also J02A - Antimycotics for systemic use.

Topical preparations used especially in gynecological infections are classified in G01B - Antiinfectives/antiseptics in combination with corticosteroids. Preparations for local treatment of fungal infections in the mouth, see A01A B - Antiinfectives for local oral treatment.

D01A ANTIFUNGALS FOR TOPICAL USE

Combined preparations are classified at separate 5th levels, D01A A20, D01A C20 and D01A E20, if mycosis is regarded as the primary indication.

D01A A Antibiotics

Preparations used in the treatment of bacterial dermatological infections, see D06A - Antibiotics for topical use.

D01A C *Imidazole derivatives*

This group comprises e.g. clotrimazole and miconazole. Shampoos containing imidazoles are classified here. Topical metronidazole is mainly used in rosacea and is classified in D06B X - Other chemotherapeutics. Combinations with e.g. corticosteroids are classified in D01A C20.

D01A E *Other antifungals for topical use*

See also D08A H - Quinoline derivatives (chlorquinaldol, clioquinol etc).

Combined preparations containing salicylic acid which are used as antifungals (e.g. dusting powders), are classified in this group in D01A E20. See also D02A F - Salicylic acid preparations.

D01B ANTIFUNGALS FOR SYSTEMIC USE

This group comprises preparations used in the systemic treatment of dermatological mycoses. See also J02A - Antimycotics for systemic use.

D01B A *Antifungals for systemic use*

E.g. griseofulvin is classified in this group.

The DDDs for griseofulvin and terbinafine are based on treatment of dermatophyte infections in skin, hair or nails.

D02 EMOLLIENTS AND PROTECTIVES

D02A EMOLLIENTS AND PROTECTIVES

This group comprises all types of emollients and protectives with no specific therapeutic effect or use, and also preparations for use in wounds which are not classified in D09 - Medicated dressings.

Some similar products are classified in D03A - Cicatrizants, e.g. cod-liver oil ointments.

D02A A *Silicone products*

D02A B *Zinc products*

D02A C *Soft paraffin and fat products*

Some similar products with a higher water content (creams) are classified in D02A X - Other emollients and protectives. Soft paraffin dressings, see D09A X.

D02A D *Liquid plasters*

D02A E *Carbamide products*

D02A F *Salicylic acid preparations*

Some combined preparations containing salicylic acid used for the treatment of mycosis are classified in D01A E - Other antifungals for topical use.

D02A X *Other emollients and protectives*

Soft paraffin and fat products with a high water content (creams) are classified in this group. See also D02A C - Soft paraffin and fat products.

D02B PROTECTIVES AGAINST UV-RADIATION

This group comprises special protectives against UV-radiation.

D02B A *Protectives against UV-radiation for topical use*

E.g. aminobenzoic acid is classified here.

D02B B *Protectives against UV-radiation for systemic use*

E.g. betacarotene is classified here.

The DDD of betacarotene are based on treatment of patients with erythropoietic protoporphyria.

D03 PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS

Topical preparations used in the treatment of wounds and ulcers, e.g. leg ulcers, are classified in this group. Protective ointments are classified in D02A - Emollients and protectives.

Antiinfectives, see D06.
Antiseptics and disinfectants, see D08.
Medicated dressings, see D09.

D03A CICATRIZANTS

Topical vitamin preparations etc. are classified in this group if they cannot be classified in other groups.

D03A A Cod-liver oil ointments

D03A X Other cicatrizants

Includes e.g. dextranomer powders with and without antiseptics. Preparations containing dextranomer iodine are classified in D08A G - Iodine products.

Medicated dressings containing hyaluronic acid are classified here.

D03B ENZYMES

Proteolytic enzymes for topical treatment of ulcers are classified here.

D03B A Proteolytic enzymes

E.g. trypsin and clostridiopeptidase are classified here.

D04 ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

D04A ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

This group comprises antipruritics, anesthetics etc. for topical use in the treatment of pruritus, minor burns, insect stings, herpes zoster etc.

Corticosteroid preparations, see D07.

D04A A Antihistamines for topical use

At each 5th level, antiseptics, siccants etc. may occur in combination with the antihistamines. Combinations with corticosteroids, see D07.

D04A B Anesthetics for topical use

At each 5th level, antiseptics, siccants etc. may occur in combination with the anesthetics. Combinations with corticosteroids, see D07.

See also C05A - Antihemorrhoidals for topical use, and N01B - Anesthetics, local.

D04A X Other antipruritics

This group comprises ointments, creams, liniments etc. containing e.g. camphora, menthol, calamine. Crotamiton is classified here. When classifying products in this group, alternative groups should be given consideration, e.g.:

D02 - Emollients and protectives
D08 - Antiseptics and disinfectants
M02 - Topical products for joint and muscular pain

D05 ANTIPSORIATICS

D05A ANTIPSORIATICS FOR TOPICAL USE

This group comprises products for topical use mainly for the treatment of psoriasis. All corticosteroids for topical use are classified in D07.

D05A A *Tars*

D05A C *Antracen derivatives*

E.g. dithranol is classified here.

D05A D *Psoralens for topical use*

D05A X *Other antipsoriatics for topical use*

E.g. fumaric acid is classified here.

D05B ANTIPSORIATICS FOR SYSTEMIC USE

This group comprises drugs for systemic use against psoriasis. Antineoplastic agents, sometimes used in severe psoriasis, are classified in group L.

D05B A *Psoralens for systemic use*

The DDDs for psoralens for systemic use are based on the combined treatment with drug and UV-A irradiation.

D05B B *Retinoids for treatment of psoriasis*

E.g. etretinate is classified here. Retinoids for the treatment of acne are classified in D10B A.

D06 ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

This group comprises products for topical use in skin infections etc.

D06A ANTIBIOTICS FOR TOPICAL USE

This group comprises antibiotics for dermatological use, except

Antibiotics with antimycotic properties - D01A

Combinations with chemotherapeutics - D06C

Combinations with corticosteroids - D07C

Antiinfectives for treatment for acne - D10A F

D06A A *Tetracycline and derivatives*

Combined peparations which contain oxytetracycline and other antibiotics are classified in D06A A03 - Oxytetracycline.

D06A X *Other antibiotics for topical use*

Combined preparations which contain neomycin and other antibiotics are classified in D06A X04 - Neomycin.

D06B CHEMOTHERAPEUTICS FOR TOPICAL USE

This group includes chemotherapeutics for dermatological use, except:

Combinations with antibiotics - D06C

Combinations with corticosteroids - D07C

D06B A *Sulfonamides*

D06B B *Antivirals*

E.g. aciclovir and podophyllotoxin are classified in this group. Podophyllin preparations are classified at the 5th level for podophyllotoxin.

D06B X *Other chemotherapeutics*

This group comprises chemotherapeutics used in different skin disorders which cannot be classified in the preceding groups, e.g. metronidazole for the treatment of rosacea.

D06C ANTIBIOTICS AND CHEMOTHERAPEUTICS, COMBINATIONS

D07 CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

As a main rule, all topical corticosteroid preparations should be classified in this group. There are, however, some few exceptions:

Combinations of corticosteroids and antiinfectives for gynecological use, see G01B.

Corticosteroids for local oral treatment, see A01A C.

Anti-acne preparations, see D10A.

Antihemorrhoidals with corticosteroids, see C05A A.

Corticosteroids for ophthalmological or otological use, see S - Sensory organs.

D07A CORTICOSTEROIDS, PLAIN

The group is subdivided according to clinical potency of the steroids as such. Additional agents meant to enhance the penetration and increase the potency of the product do not influence the classification, neither do the strength of the preparations or the vehicle.

D07A A *Corticosteroids, weak (group I)*

D07A B *Corticosteroids, moderately potent (group II)*

D07A C *Corticosteroids, potent (group III)*

D07A D *Corticosteroids, very potent (group IV)*

D07B CORTICOSTEROIDS, COMBINATIONS WITH ANTISEPTICS

This group comprises combined corticosteroid/antiseptic preparations for dermatological use.

For most antifungal preparations with corticosteroids, the primary indication is mycosis and not inflammation. These products should be classified in D01A - Antifungals for topical use. Corticosteroids, antiseptics and salicylic acid in combination are classified in D07X.

The group is subdivided according to clinical potency, see D07A. Exceptions, see D07. At each 5th level various antiseptics may occur.

D07B A *Corticosteroids, weak, combinations with antiseptics*

D07B B *Corticosteroids, moderately potent, combinations with antiseptics*

D07B C *Corticosteroids, potent, combinations with antiseptics*

D07B D *Corticosteroids, very potent, combinations with antiseptics*

D07C CORTICOSTEROIDS, COMBINATIONS WITH ANTIBIOTICS

This group comprises combined corticosteroid/antibiotic preparations for dermatological use. The group is subdivided according to clinical potency, see D07A. Exceptions, see D07.

At each 5th level various antibiotics may occur.

D07C A *Corticosteroids, weak, combinations with antibiotics*

D07C B *Corticosteroids, moderately potent, combinations with antibiotics*

D07C C *Corticosteroids, potent, combinations with antibiotics*

D07C D *Corticosteroids, very potent, combinations with antibiotics*

D07X CORTICOSTEROIDS, OTHER COMBINATIONS

This group comprises most other combined corticosteroid preparations for dermatological use, e.g. combinations with coal tar, carbamide and salicylic acid. Salicylic acid is regarded as a keratolytic agent. Preparations with salicylic acid and antiseptics are classified in this group, as salicylic acid is regarded as being more important in relation to the therapeutic use of these products (psoriasis, seborrhea).

The group is subdivided according to clinical potency, see D07A. Exceptions, see D07.

D07X A *Corticosteroids, weak, other combinations*

D07X B *Corticosteroids, moderately potent, other combinations*

D07X C *Corticosteroids, potent, other combinations*

D07X D *Corticosteroids, very potent, other combinations*

D08 ANTISEPTICS AND DISINFECTANTS

D08A ANTISEPTICS AND DISINFECTANTS

This group comprises all dermatological antiinfective preparations which are not classified in any of the following groups:

D01 - Antifungals for dermatological use
D03A - Cicatrizants
D06 - Antibiotics and chemotherapeutics for dermatological use
D07B - Corticosteroids, combinations with antiseptics
D07X - Corticosteroids, other combinations
D09A - Medicated dressings
D10A - Anti-acne preparations for topical use
D11A C - Medicated shampoos
P03A - Ectoparasiticides, incl. scabicides

Chloroquinaldol and clioquinol are classified in this group and not in D01 - Antifungals for dermatological use.

Antiviral agents, see D06B B.

Non-therapeutic auxiliary products, such as exploration creams and lubricants, are classified in V07A Y. Lubricants which contain antiseptics are, however, classified in this group.

The group is subdivided according to chemical structure.

D08A A *Acridine derivatives*

D08A B *Aluminium agents*

D08A C *Biguanides and amidines*

D08A D *Boric acid products*

Weak boric acid vaseline is classified in D02A X.

D08A E *Phenol and derivatives*

D08A F *Furan derivatives*

D08A G *Iodine products*

D08A H *Quinoline derivatives*

D08A J *Quaternary ammonium compounds*

D08A K *Mercurial products*

Combined products which also contain silver compounds, are classified in this group.

D08A L *Silver compounds*

Combined products which also contain mercury compounds, see D08A K.

D08A X *Other antiseptics and disinfectants*

D09 MEDICATED DRESSINGS

D09A MEDICATED DRESSINGS

This group comprises medicated dressings, ointment dressings etc. Liquid wound protectives are classified in D02A D - Liquid plasters. Local hemostatics, e.g. gauze, tampons etc. are classified in B02B C - Local hemostatics. Medicated dressings containing hyaluronic acid are classified in D03A X - Other cicatrizants.

D09A A *Ointment dressings with antiinfectives*

D09A B *Zinc bandages*

Zinc bandages with and without supplements are classified in this group.

D09A X *Soft paraffin dressings*

Dressings with antiinfectives, see D09A A.

D10 ANTI-ACNE PREPARATIONS

The DDDs are based on treatment of severe acne.

D10A ANTI-ACNE PREPARATIONS FOR TOPICAL USE

This group comprises all topical preparations used specifically in the treatment of acne, incl. preparations with antibiotics, corticosteroids etc.

D10A A *Corticosteroids, combinations for treatment of acne*

Only combined corticosteroid preparations specifically used in the treatment of acne are classified in this group. Other dermatological corticosteroid preparations are classified in D07 - Corticosteroids, dermatological preparations.

D10A B *Preparations containing sulphur*

Preparations which contain sulphur in addition to a sulphur derivative, should be classified at the 5th level of the derivative.

The products may contain other active ingredients such as resorcinol.

D10A D *Retinoids for topical use in acne*

D10A E *Peroxides*

D10A F *Antiinfectives for treatment of acne*

This group comprises antibiotics for topical use with acne as the main indication.

Other topical antiinfectives are classified in D06.

D10A X *Other anti-acne preparations for topical use*

D10B ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

This group comprises drugs for systemic use in the treatment of acne. Antibiotics, such as tetracyclines and erythromycin, which are also used for the treatment of acne, are classified in group J.

Combinations of e.g. estrogen and antiandrogen, used for the treatment of acne, are classified in group G03.

D10B A *Retinoids for treatment of acne*

E.g. Isotretinoin is classified here.

Retinoids used in severe psoriasis and other diseases affecting epidermis are classified in D05B B.

D10B X *Other anti-acne preparations for systemic use*

Ichtammol preparations for systemic use in treatment of acne are classified in this group.

D11 OTHER DERMATOLOGICAL PREPARATIONS

D11A OTHER DERMATOLOGICAL PREPARATIONS

This group comprises various dermatological preparations which cannot be classified in the preceding groups.

Insect repellents are classified in P03B - Insecticides and repellents.

D11A A Antihidrotics

D11A C Medicated shampoos

Shampoos containing imidazoles are classified in D01A C.

D11A E Androgens for topical use

D11A F Wart and anti-corn preparations

Preparations such as keratolytics for the treatment of common warts and cornified lesions are classified in this group.

Podophyllotoxin/podophyllin e.g. for the treatment of genital warts, is classified in D06B B.

D11A X Other dermatologicals

This group comprises products which cannot be classified in the preceding groups. E.g. minoxidil for the treatment of male pattern baldness is classified here.
Lithium succinate in combination with other substances, e. g. zinc sulphate is classified in D11A X04 - Lithium succinate.

The DDD for gamolenic acid is based on treatment of atopic dermatitis.

G GENITO URINARY SYSTEM AND SEX HORMONES

G01 GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

- A Antiinfectives and antiseptics, excl. combinations with corticosteroids
- B Antiinfectives/antiseptics in combination with corticosteroids

G02 OTHER GYNECOLOGICALS

- A Oxytocics
- B Contraceptives for topical use
- C Other gynecologicals

G03 SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

- A Hormonal contraceptives for systemic use
- B Androgens
- C Estrogens
- D Progestogens
- E Androgens and female sex hormones in combination
- F Progestogens and estrogens in combination
- G Gonadotrophins and other ovulation stimulants
- H Antiandrogens
- X Other sex hormones and modulators of the genital system

G04 UROLOGICALS

- A Urinary antiseptics and antiinfectives
- B Other urologicals, incl. antispasmodics

G GENITO URINARY SYSTEM AND SEX HORMONES

G01 GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

This group comprises gynecological antiinfectives and antiseptics mainly for local use. See also:

J - General antiinfectives for systemic use
D06 - Antibiotics and chemotherapeutics for dermatological use
G04A - Urinary antiseptics and antiinfectives
P01A B - Nitroimidazole derivatives

The DDDs are based on the treatment of vaginal infections.

G01A ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

This group comprises preparations, mainly for local use.

Combinations with corticosteroids, see G01B.

Antivirals for topical use, including gynecological use, such as podophyllotoxin, are classified in D06 - Antibiotics and chemotherapeutics for dermatological use.

G01A A *Antibiotics*

G01A B *Arsenic compounds*

G01A C *Quinoline derivatives*

G01A D *Organic acids*

E.g. lactic acid and acetic acid are classified here.

G01A E *Sulfonamides*

Combinations of different sulfonamides are given the code G01A E10.

G01A F *Imidazole derivatives*

Imidazole derivatives (e.g. metronidazole and ornidazole) in formulations for vaginal administration are classified in this group. Parenteral formulations are classified in J01X D, as they are mainly used in connection with anaerobic infections, while imidazole derivatives in oral (including also tablets only used for treatment of gynecological infections) and rectal dosage forms are classified in P01A B. Metronidazole for topical use in skin disorders is classified in D06B X - Other chemotherapeutics.

Combinations of imidazole derivatives in vaginal formulations are classified at a separate 5th level: G01A F20.

G01A G *Triazole derivatives*

Fluconazole tablets in single dose packages, only for gynecological infections, are classified together with other packages for systemic use in J02A - Antimycotics for systemic use.

G01A X *Other antiinfectives and antiseptics*

G01B ANTIINFECTIVES/ANTISEPTICS IN COMBINATION WITH CORTICOSTEROIDS

All antiinfectives/antiseptics for gynecological use which contain corticosteroids are classified in this group.

G01B A *Antibiotics and corticosteroids*

G01B C *Quinoline derivatives and corticosteroids*

G01B D *Antiseptics and corticosteroids*

G01B E *Sulfonamides and corticosteroids*

G01B F *Imidazole derivatives and corticosteroids*

G02 OTHER GYNECOLOGICALS

Analgesics used in dysmenorrhea, see N02B - Other analgesics and antipyretics and M01A - Antiinflammatory and antirheumatic products, non-steroids.

G02A OXYTOCICS

Plain preparations of oxytocin and derivatives are classified in H01B - Posterior pituitary lobe hormones.

G02A B *Ergot alkaloids*

This group comprises ergot alkaloids, e.g. methylergometrin, used for stimulation of uterine contractions. Other ergot alkaloids are classified in C04A - Peripheral vasodilators, and in N02C - Anti-migraine preparations.

The DDDs are based on the use in delivery.

G02A C *Ergot alkaloids and oxytocin incl. derivatives, in combination*

G02A D *Prostaglandins*

This group comprises prostaglandins used for e.g. termination of pregnancy.

The DDDs are based on the use for termination of pregnancy.

G02A X *Other oxytocics*

This group comprises oxytocics which cannot be classified in the preceding groups.

G02B CONTRACEPTIVES FOR TOPICAL USE

Contraceptives for systemic use, see G03A.

No DDDs have been assigned.

G02B A Intrauterine contraceptives

IUDs are classified in this group. IUDs containing progestogens are also classified in this group.

G02B B Intravaginal contraceptives

Pessaries, vaginal foams etc. are classified in this group.

G02C OTHER GYNECOLOGICALS

G02C A Sympathomimetics, labour repressants

This group includes sympathomimetics used to repress labour, e.g. ritodrine. Similar adrenergic drugs which are mainly used in the treatment of asthma, are classified in R03C.

Fenoterol infusion only intended for repressing preterm labour is classified in this group, while other systemic formulations of fenoterol are classified in R03CC04.

The DDDs are based on the use as labour repressant.

G02C B Prolactine inhibitors

Bromocriptine low dose tablets (2.5 mg) are classified in this group. Bromocriptine tablets in higher strength are classified in N04 - Anti-Parkinson drugs.

Lisuride tablets in high strength (0.2 mg) are classified in this group, while low dose tablets (25 mcg) are classified in N02C - Anti-migraine preparations.

The DDDs are based on the use as lactation inhibitors. The DDD for depot parenteral formulation of bromocriptine is equal to the DDD for oral administration, based on the assumption that the single dose parenteral treatment equals 14 days of oral treatment.

G02C C *Antiinflammatory products for vaginal administration*

This group comprises e.g. non-steroidal antiinflammatory drugs for vaginal administration.

G03 SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

Other hormones, see H - Systemic hormonal preparations, excl. sex hormones.

Sex hormones used only in the treatment of cancer (often selected strengths) are classified in L - Antineoplastic and immunomodulating agents.

The DDDs of many of the hormone preparations may vary considerably with the route of administration due to substantial differences in bioavailability. The DDDs of depot preparations are calculated as the dose divided by the dosing interval.

The DDDs of combined preparations of estrogen and progestogen are based on the use in menstrual cycles of 28 days. Thus, the DDD is for instance 0.75 and 1 ED for 21 and 28 tablets cyclus package, respectively.

G03A HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

This group comprises hormonal preparations which are used as contraceptives. Similar hormonal preparations which are used for the treatment of e.g. menopausal symptoms and menstrual irregularities, are classified in G03F.

Combinations of cyproterone and estrogen also used as contraceptives are, however, classified in G03H B.

The DDDs are based on the use as contraceptives.

G03A A *Progestogens and estrogens, fixed combinations*

This group comprises preparations which contain fixed combinations of progestogen and estrogens.

The preparations are classified at 5th levels according to the progestogen.

G03A B *Progestogens and estrogens, sequential preparations*

This group comprises preparations with varying contents of progestogens and estrogens adjusted to the normal hormonal cyclus. A package which is intended for one cyclus, may contain e.g. three types of tablets, each designed to cover a special part of the menstrual period. Cyclus packages may contain some tablets with progestogen only.

5th levels are built up as in G03A A.

G03A C *Progestogens*

This group contains hormonal contraceptives which contain progestogens only ("mini-pills").

IUDs with progestogens are classified in G02B A.

G03B ANDROGENS

Anabolic steroids, see A14A.

This group comprises male sex hormones. Combined preparations are included in this group, except combinations with female sex hormones which are classified in G03E - Androgens and female sex hormones in combination.

The group is subdivided according to chemical structure:

The DDDs are based on the use as substitution in male hypogonadism. The DDDs for patches (e.g. testosteron) are given in amount delivered.

G03B A *3-oxoandrosten (4) derivatives*

G03B B *5-androstanon (3) derivatives*

G03C ESTROGENS

This group comprises estrogens and combinations, except combinations with

- androgens, see G03E
- progestogens, see G03F
- antiandrogens, see G03H B

Hormonal contraceptives, see G03A.

Estrogens used only in neoplastic diseases, see L - Antineoplastic and immunomodulating agents.

The DDDs are based on the systemic use as postmenopausal estrogen substitution therapy and premenstrual ailments. However, for some preparations for vaginal administration the DDDs are based on local treatment.

G03C A *Natural and semisynthetic estrogens, plain*

This group comprises preparations which contain one or more natural or semisynthetic estrogen. Estradiol/polyestradiol are classified at the same 5th level. The same applies to estriol/polyestriol. Combinations of estradiol and estriol are classified in G03C A53.

Combinations with other drugs, see G03C C.

G03C B *Synthetic estrogens, plain*

This group comprises preparations which contain synthetic estro-

gens only.

Combinations with other drugs, see G03C C.

G03C C *Estrogens, combinations with other drugs*

This group includes combined preparations with natural, semisynthetic or synthetic estrogens and other drugs.

G03D PROGESTOGENS

This group comprises progestogens and combinations, except combinations with

- androgens, see G03E
- estrogens, see G03F

Hormonal contraceptives, see G03A

Progestogens only used in neoplastic diseases, see L - Antineoplastic and immunomodulating agents.

The group is subdivided according to chemical structure:

The DDDs are based on gynecological indications, for instance corpus luteum insufficiency and endometriosis.

G03D A *Pregnen (4) derivatives*

G03D B *Pregnadien derivatives*

G03D C *Estren derivatives*

G03E ANDROGENS AND FEMALE SEX HORMONES IN COMBINATION

This group comprises preparations with androgen and estrogen and/or progestogen. The preparations are classified at 5th levels according to the androgen.

The DDDs are based on the treatment of climacterical ailments.

G03E A *Androgens and estrogens*

G03E B *Androgen, progestogen and estrogen in combination*

G03E K *Androgens and female sex hormones in combination with other drugs*

This group comprises preparations which in addition to the hormones also contain other drugs.

G03F PROGESTOGENS AND ESTROGENS IN COMBINATION

This group comprises combined preparations used in the treatment of menopausal symptoms, menstrual irregularities etc.

Hormonal contraceptives, see G03A.

The DDDs are based on the treatment of menopausal symptoms and menstrual irregularities.

G03F A *Progestogens and estrogens, fixed combinations*

This group comprises preparations which contain fixed combinations of progestogens and estrogens. Combination packages with separate tablets containing progestogens and estrogens intended to be taken together are also classified in this group. The preparations are classified at 5th levels according to the progestogen. At each 5th level various estrogens may occur.

Fixed combinations of progestogen and estrogen used as contraceptives are classified in G03A A.

G03F B *Progestogens and estrogens, sequential preparations*

This group comprises preparations with varying contents of progestogens and estrogens adjusted to the normal hormonal cyclus. A package which is intended for one cyclus, may contain e.g. three types of tablets, each designed to cover a special part of the men-

strual period. Cyclus packages may contain some tablets with progestogen only. Combination packages with separate tablets containing progestogens and estrogens intended to be taken together and in sequence are also classified in this group.

5th levels are built up as in G03F A.

Hormonal contraceptives, sequential preparations, see G03A B.

G03G GONADOTROPHINS AND OTHER OVULATION STIMULANTS

The DDDs are based on the treatment of infertility.

G03G A Gonadotrophins

This group comprises naturally occurring gonad-stimulating hormones.

G03G B Ovulation stimulants, synthetic

E.g. clomifene is classified here.

G03H ANTIANDROGENS

G03H A Antiandrogens, plain preparations

Finasteride used for treatment of prostatic hypertrophy is classified in G04B X.

The DDDs are based on the treatment of hypersexualism.

G03H B Antiandrogens and estrogens

This group comprises all combinations of cyproterone and estrogen regardless of indication.

The DDDs are based on the treatment of hirsutism or prophylaxis of postmenopausal osteoporosis.

G03X OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

This group comprises drugs modifying the genital functions which cannot be classified in the preceding groups.
Tibolone is classified in G03D C.

G03X A *Antigonadotrophins and similar agents*

The DDDs of danazol and gestrinone are based on the treatment of endometriosis.

G03X B *Antiprogestogens*

G04 UROLOGICALS

G04A URINARY ANTISEPTICS AND ANTIINFECTIVES

This group comprises preparations specifically used in urinary tract infections.

All combinations with sulfonamides are classified in G04A H. All other combined preparations are classified in G04A K. Preparations which in addition contain an urine acidifier, such as vitamin C, calcium- or ammonium chloride, are regarded as plain preparations.

General antiinfectives for systemic use, see group J.

Gynecological antiinfectives and antiseptics, see G01.

The DDDs are generally based on the treatment of acute urinary tract infections.

G04A A *Methenamine preparations*

The DDD for methenamine is based on prophylaxis of urinary tract infections.

G04A B *Quinolone derivatives (excl. J01M)*

G04A C *Nitrofuran derivatives*

G04A D *Salicylates*

G04A G *Other urinary antiseptics and antiinfectives*

G04A H *Sulfonamides in combination with other drugs*

G04A K *Urinary antiseptics and antiinfectives, combinations excl. sulfonamides*

G04B OTHER UROLOGICALS, INCL. ANTISPASMODICS

This group comprises urological preparations other than antiseptics and antiinfectives.

G04B A *Acidifiers*

This group comprises urine acidifiers, e.g. ammonium chloride.

G04B C *Urinary concrement solvents*

This group comprises agents which dissolve urinary concrements, e.g. citrates.

G04B D *Urinary antispasmodics*

This group comprises antispasmodics specifically used in the urogenital tractus, e.g. emepronium.

Gastrointestinal antispasmodics, see A03.

The DDD for oral administered emeperonium is higher than the DDD for parenteral administered formulations, due to low oral bioavailability.

G04B X *Other urologicals*

This group comprises urologicals which cannot be classified in the preceding groups, e.g. magnesium hydroxide and finasteride.

Alprostadil intracavernosal injection for treatment of impotence is classified here, while formulations used to maintain the patency of the ductus arteriosis in neonates are classified in C01E A01.

Alfuzosin used in the management of urinary obstruction caused by benign prostatic hypertrophy, is classified here, while other alpha-adrenoceptor blocking agents also used in hypertension (e.g. terazosin) are classified in C02C A.

Phenazopyridine, plain products, are classified here, while phenazopyridine in combination with sulfonamides is classified in G04A H.

The DDD of alprostadil is based on single treatment of impotence. The DDDs of alfuzosin and finasteride are based on treatment of benign prostata hypertrophy. The DDD of phenazopyridine is based on analgesic treatment of conditions such as cystitis, prostatitis and urethritis. The other DDDs are based on the prophylaxis of urinary concrements.

H SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES

H01 PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

A Anterior pituitary lobe hormones and analogues
B Posterior pituitary lobe hormones
C Hypothalamic hormones

H02 CORTICOSTEROIDS FOR SYSTEMIC USE

A Corticosteroids for systemic use, plain
B Corticosteroids for systemic use, combinations
C Antiadrenal preparations

H03 THYROID THERAPY

A Thyroid preparations
B Antithyroid preparations
C Iodine therapy

H04 PANCREATIC HORMONES

A Glycogenolytic hormones

H05 CALCIUM HOMEOSTASIS

A Parathyroid hormones
B Anti-parathyroid hormones

H SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES

This group comprises all hormonal preparations for systemic use, except:

- Insulins, see A10.
- Anabolic steroids, see A14.
- Catecholamines, see C01C and R03C.
- Sex hormones, see G03.

The DDDs are generally based on the treatment or diagnosis of endocrine disorders.

H01 PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

H01A ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

This group comprises anterior pituitary lobe hormones; extracts, purified natural hormones and synthetic analogues.

H01A A ACTH

This group comprises ACTH and synthetic analogues.

The DDD of corticotrophin is based on therapy, whereas that of tetracosactide is based on the use as a diagnostic agent.

H01A B Thyrotrophin

H01A C Somatropin and analogues

Mecasermin (insulin like growth factor) is classified in this group since it is used on the same indications as somatropin and somatrem.

The DDDs are based on the treatment of growth retardation in children.

H01B POSTERIOR PITUITARY LOBE HORMONES

This group comprises posterior pituitary lobe hormones; extracts, purified natural hormones and synthetic analogues.

H01B A Vasopressin and analogues

The DDDs are based on the treatment of diabetes insipidus.

H01B B Oxytocin and derivatives

Oxytocin and derivatives in combination with ergot alkaloids are classified in G02A - Oxytocics

The DDDs are based on the use in delivery.

H01C HYPOTHALAMIC HORMONES

This group comprises hypothalamic hormones; extracts, purified natural hormones and synthetic analogues.

Hypothalamic hormones used as diagnostic agents for pituitary function are classified in V04C D.

H01C A Gonadotrophin-releasing hormones

Gonadotrophin-releasing hormones used for neoplastic diseases are classified in L02A - Hormones and related agents.

Gonadorelin used as diagnostic agent is classified in V04C M.

The DDD of nafarelin is based on the treatment of endometriosis. No other DDDs have been assigned, due to the highly variable dosages used.

H01C B Antigrowth hormone

Somatostatin and octreotide, which are also used in cancer, are classified in this group.

H02 CORTICOSTEROIDS FOR SYSTEMIC USE

As a main rule, systemic corticosteroids should be classified in this group. There are, however, one exception: M01B A - Antiinflammatory and antirheumatic agents in combination with corticosteroids.

Corticosteroids for local oral treatment, see A01A C.

Enemas and rectal foams for local treatment of e.g. ulcerative colitis, see A07E.

Corticosteroids for topical use, see D07.

Combined corticosteroid preparations for local treatment of acne, see D10A A.

Corticosteroids in combination with antiinfectives/antiseptics for local treatment of gynecological infections, see G01B.

Corticosteroids for nasal use, see R01A D.

Corticosteroids for inhalation, see R03B A.

Corticosteroids, eye/ear preparations, see S.

H02A CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

Only plain preparations are classified in this group. The group also includes corticosteroid preparations for local injection.

H02A A Mineralocorticoids

The DDDs are based on substitution therapy in Addison's disease

H02A B *Glucocorticoids*

Depot preparations may have different DDDs, compared with other formulations, due to different indications.

The DDD of budesonide is based on treatment of Crohn's disease.

H02B CORTICOSTEROIDS FOR SYSTEMIC USE, COMBINATIONS

This group comprises all combined preparations, e.g. combinations with local anesthetics.

No DDDs have been assigned.

H02B X *Corticosteroids for systemic use, combinations*

H02C ANTIADRENAL PREPARATIONS

H02C A *Anticorticosteroids*

Trilostane used in Cushing's syndrome is classified in this group.

The DDD of trilostan is based on treatment of Cushing's syndrome.

H03 THYROID THERAPY

H03A THYROID PREPARATIONS

This group comprises thyroid extracts and synthetic analogues used in the treatment of hypothyreodism.

The DDDs are based on the treatment of hypothyreosis.

H03A A *Thyroid hormones*

This group comprises natural and synthetic thyroid hormones. Combinations of levothyroxine and liothyronine are classified at a sepa-

rate 5th level: H03A A03.

H03B ANTITHYROID PREPARATIONS

This group comprises preparations used in the treatment of hyperthyreoidism.

The DDDs are based on the treatment of hyperthyreoidism.

H03B A *Thiouracils*

H03B B *Sulphur-containing imidazole derivatives*

H03B C *Perchlorates*

H03B X *Other antithyroid preparations*

E.g. diiodotyrosine is classified in this group.

H03C IODINE THERAPY

This group comprises iodine preparations for systemic use.

H03C A *Iodine therapy*

The DDDs are based on systemic therapy in thyroid disease. The DDD is given in amount of iodide.

H04 PANCREATIC HORMONES

H04A GLYCOGENOLYTIC HORMONES

H04A A *Glycogenolytic hormones*

The pancreas glycogenolytic hormone glucagon is classified in this group.

Diazoxide, which is also used for treatment of hypoglycemia, is

classified in C02DA01 and V03AH01.

Insulins are classified in A10A A.

The DDD of glucagon is based on single dose treatment of hypoglycemia.

H05 CALCIUM HOMEOSTASIS

Drugs acting on calcium homeostasis are classified in this group.

Vitamin-D preparations, see A11C C.

H05A PARATHYROID HORMONES

H05A A Parathyroid hormones

Extracts from the parathyroid glands are classified in this group.

No DDDs have been assigned.

H05B ANTI-PARATHYROID HORMONES

H05B A Calcitonin preparations

Calcitonin, natural and synthetic, is classified in this group. Other drugs for treatment of hypercalcemia, see M05B.

The DDD of calcitonin is based on the treatment of Paget's disease.

J GENERAL ANTIINFECTIVES FOR SYSTEMIC USE

J01 ANTIBACTERIALS FOR SYSTEMIC USE

- A Tetracyclines
- B Amphenicols
- C Beta-lactam antibacterials, penicillins
- D Other beta-lactam antibacterials
- E Sulfonamides and trimethoprim
- F Macrolides and lincosamides
- G Aminoglycoside antibacterials
- M Quinolone antibacterials
- R Combinations of antibacterials
- X Other antibacterials

J02 ANTIMYCOTICS FOR SYSTEMIC USE

- A Antimycotics for systemic use

J04 ANTIMYCOBACTERIALS

- A Drugs for treatment of tuberculosis
- B Drugs for treatment of lepra

J05 ANTIVIRALS FOR SYSTEMIC USE

- A Agents affecting the virus directly

J06 IMMUNE SERA AND IMMUNOGLOBULINS

- A Immune sera
- B Immunoglobulins

J07 VACCINES

- A Bacterial vaccines
- B Viral vaccines
- C Bacterial and viral vaccines, combined

J GENERAL ANTIINFECTIVES FOR SYSTEMIC USE

Antiinfectives are also classified in the following groups:

A01A B	Antiinfectives for local oral treatment
A07A	Intestinal antiinfectives
D01	Antifungals for dermatological use
D06	Antibiotics and chemotherapeutics for dermatological use
D07C	Corticosteroids, combinations with antibiotics
D09A A	Ointment dressings with antiinfectives
D10A F	Antiinfectives for treatment of acne
G01	Gynecological antiinfectives and antiseptics
G04A	Urinary antiseptics and antiinfectives
P	Antiparasitic products, insecticides and repellents
R02A B	Antibiotics
R05X	Other cold combination preparations
S01/	
S02/	
S03	Eye and ear preparations with antiinfectives

Even systemically administered antibacterials and antimycotics may be classified in other groups if their target is exclusively local, e.g. the skin - D01 and the urinary tract - G04A.

The DDDs for the antiinfectives are as a main rule generally based on the use in infections of moderate severity. However, some antiinfectives are only used in severe infections and their DDDs are assigned accordingly. The DDDs assigned are based on **daily treatment**. The duration of the treatment periods is not taken into consideration. For antiinfectives given in a high initially starting dose followed by a lower daily "maintenance" dose, the DDDs are based on the "maintenance" dose if the total duration of the treatment course is more than one week. If, however, the treatment course is shorter than 1 week, the DDDs are assigned according to the average daily dose i.e. the total course dose divided by the number of treatment days (e.g azithromycin).

J01 ANTIBACTERIALS FOR SYSTEMIC USE

This group comprises antibacterials for systemic use, except antimycobacterials, which are classified in J04. The antibacterials are classified according to their mode of action and chemistry.

Combinations of two or more systemic antibacterials from different third levels are classified in J01R, except combinations of sulfonamides and trimethoprim, which are classified at a separate 4th level, J01E E.

Combinations of antibacterials with other drugs, including local anesthetics or vitamins, are classified at separate 5th levels in the respective antibacterial group by using the 50-series. Common cold preparations containing minimal amounts of antibacterials are classified in R05X.

J01A TETRACYCLINES

J01A A Tetracyclines

This group comprises tetracycline antibacterials inhibiting the bacterial protein synthesis through binding to the 30-S part of ribosomes.

The tetracylines have different DDDs due to kinetic differences. The use of tetracyclines in long-term, low dose treatment of acne is not taken into account in the assignment of DDDs.

J01B AMPHENICOLS

J01B A Amphenicols

This group comprises amphenicol antibacterials inhibiting the bacterial protein synthesis.

J01C BETA-LACTAM ANTIBACTERIALS, PENICILLINS

This group comprises penicillin beta-lactam antibacterials, inhibiting the bacterial cell wall synthesis. Combinations of penicillins from different 4th levels, including beta-lactamase inhibitors, are classified in J01C R.

J01C A Penicillins with extended spectrum

This group comprises penicillins with enhanced activity against gram negative rods, e.g. ampicillin and similar antibiotics.

The esters, for instance pivampicillin and pivmecillinam, have a higher bioavailability and thus a lower DDD than the corresponding non-ester compounds.

The DDDs for some of the compounds, for instance carbenicillin, piperacillin, ticarcillin and sulbenicillin, are based on the dosages used for narrow indications, i.e. life threatening infections.

J01C E Beta-lactamase sensitive penicillins

Benzylpenicillin and phenoxymethylpenicillin have different DDDs due to differences in indications, route of administration and bioavailability.

J01C F Beta-lactamase resistant penicillins

J01C G *Beta-lactamase inhibitors*

The DDD for sulbactam is based on its use together with ampicillin, usually in a dose ratio of 1:2 respectively.

J01C R *Combinations of penicillins, incl. beta-lactamase inhibitors*

This group comprises combinations of penicillins and/or beta-lactamase inhibitors. Combinations containing one penicillin and enzyme inhibitor are classified at different 5th levels according to the penicillin. Combinations of two or more penicillins with or without enzyme inhibitor are classified at a separate 5th level, J01C R50. Sultamicillin, a prodrug for sulbactam and ampicillin, is given a separate 5th level code: J01C R04.

The DDDs for preparations in this group correspond to the DDDs of the plain antibiotic.

The DDD for sultamicillin, a prodrug for sulbactam and ampicillin, is lower than the corresponding DDD for the ordinary combination due to higher bioavailability.

J01D OTHER BETA-LACTAM ANTIBACTERIALS

This group comprises beta-lactam antibacterials, other than penicillins.

J01D A *Cephalosporins and related substances*

All cephalosporins are classified at this 4th level. No further subdivision is made.

The cephalosporins are used in highly variable dosages for different indications, which should be reflected in the assigned DDDs. The indications for use of the cephalosporins (i.e. the severity of the infections) vary rather extensively from one country to another. The assigned DDDs are therefore not based on strict criteria for indications, and do not necessarily reflect equipotency.

J01D F *Monobactams*

J01D H *Carbapenems*

Combinations with enzyme inhibitors are classified at separate 5th levels, using the 50-series.

The DDD for the combination with enzyme inhibitor is given in terms of the antibiotic component (i.e. imipenem).

J01E SULFONAMIDES AND TRIMETHOPRIM

This group comprises systemic sulfonamide and trimethoprim preparations. Combinations of sulfonamide and trimethoprim are classified in J01E E. Preparations containing two or more sulfonamides are classified within the different 4th levels, using the 5th level code 20. In such combinations, the half-life of the most long-acting sulfonamide determines the classification. Sulfonamides in combinations with other antibacterials (excl. trimethoprim) are classified in J01R. Dapsone is classified in J04 - Antimycobacterials. Urinary antiseptics and antiinfectives, combinations with sulfonamides, see G04A H. See also A07A - Intestinal antiinfectives.

The DDDs for the sulfonamides are related to the duration of effect, i.e. usually the long-acting sulfonamides will have lower DDDs than the short-acting.

J01E A *Trimethoprim and derivatives*

The DDDs are based on the treatment of acute urinary-tract infections.

J01E B *Short-acting sulfonamides*

This group comprises sulfonamides with a biological half-life not exceeding approx. 7 hours.

J01E C *Intermediate-acting sulfonamides*

This group comprises sulfonamides with a biological half-life of approx. 11-12 hours.

J01E D *Long-acting sulfonamides*

This group comprises sulfonamides with a biological half-life of approx. 35 hours or more.

J01E E *Combinations of sulfonamides and trimethoprim, incl. derivatives*

The preparations are classified at different 5th levels according to the sulfonamide.

When establishing DDDs for combination products, both components are taken into consideration.

J01F MACROLIDES AND LINCOSAMIDES

This group comprises macrolide and lincosamide antibacterials inhibiting bacterial protein synthesis through binding to the 50-S part of the ribosomes.

J01F A *Macrolides*

Erythromycin ethylsuccinate tablets have been assigned a higher DDD than other preparations of erythromycin due to an assumed lower bioavailability. This DDD is mainly based on the dosages recommended.

J01F F *Lincosamides*

Orally and parenterally administered clindamycin have different DDDs due to different indications, i.e. the intestinal and systemic infections, respectively.

J01G AMINOGLYCOSIDE ANTIBACTERIALS

This group comprises aminoglycoside antibacterials disturbing the bacterial protein synthesis through binding to the 30-S part of the ribosomes.

J01G A *Streptomycins*

Streptomycins in combination with antimycobacterials are classified in J04A M.

J01G B *Other aminoglycosides*

The DDDs for the aminoglycosides are based on the continued use in severe infections.

J01M QUINOLONE ANTIBACTERIALS

This group comprises quinolone antibacterials, inhibiting the bacterial DNA-gyrase. Quinolone antibacterials exclusively used in urinary tract infections are classified in G04A B.

J01M A *Fluoroquinolones*

The DDDs for the fluoroquinolones are mainly based on treatment of complicated urinary tract infections.

J01M B *Other quinolones excl. G04A B*

J01R COMBINATIONS OF ANTIBACTERIALS

This group comprises combinations of two or more antibacterials for systemic use from different ATC 3rd levels.

J01R A *Combinations of antibacterials*

J01X OTHER ANTIBACTERIALS

This group comprises antibacterials with various modes of action not classified in the previous groups.

J01X A *Glycopeptide antibacterials*

This group comprises glycopeptide antibacterials, inhibiting the cell

wall synthesis of gram positive bacteria. Teicoplanin and intravenous preparations of vancomycin are classified in this group. Tablets containing vancomycin are classified in A07A.

J01X B *Polymyxins*

This group comprises polymyxin antibacterials acting on the bacterial cytoplasm membrane. Tablets containing colistin are classified in A07A.

J01X C *Steroid antibacterials*

This group comprises steroid antibacterials, inhibiting the binding of bacterial transfer-RNA and the 50-S part of the ribosomes. Fusidic acid is classified in this group.

J01X D *Imidazole derivatives*

This group comprises imidazole antibacterials acting through active metabolites in anaerobic bacteria. Only formulations for parenteral use of e.g. metronidazole are classified in this group. Oral formulations and suppositories of imidazole derivatives are classified in P01 - Antiprotozoals, and pessaries are classified in G01 - Gynecological antiinfectives and antiseptics.

The DDDs for the parenteral imidazole formulations are based on the use against anaerobic bacteria infections and are different from the DDDs for the other dosage forms classified in ATC group G and P.

J01X X *Other antibacterials*

E.g. fosfomycin and spectinomycin are classified in this group.

The DDD for fosfomycin is based on the use of a single prophylactic dose in connection with surgery.

The DDD for spectinomycin is based on the use of a single dose for treatment of uncomplicated gonorrhea.

J02 ANTIMYCOTICS FOR SYSTEMIC USE

J02A ANTIMYCOTICS FOR SYSTEMIC USE

This group does not include antimycotics specifically for dermatological use even if they are administered systemically (see D01B).

Antimycotics - see also:

A01A B	Antiinfectives for local oral treatment
A07A	Intestinal antiinfectives
D01	Antifungals for dermatological use
G01	Gynecological antiinfectives and antiseptics

The DDDs are based on the treatment of systemic mycosis.

J02A A Antibiotics

No separate DDD have been assigned for liposomal amphotericin.

J02A B Imidazole derivatives

J02A C Triazole derivatives

All oral and parenteral formulations of fluconazole are classified here. Vaginal formulations of triazole derivatives, see G01A G.

J02A X Other antimycotics for systemic use

E.g. flucytosine is classified in this group.

J04 ANTIMYCOBACTERIALS

This group comprises drugs mainly used for the treatment of tuberculosis or lepra. However, streptomycins are classified in J01G - Aminoglycoside antibacterials. Streptomycin in combination with antimycobacterials are classified in J04A M.

J04A DRUGS FOR TREATMENT OF TUBERCULOSIS

The DDDs are based on the use in combination therapy of tuberculosis.

J04A A *Aminosalicylic acid and derivatives*

J04A B *Antibiotics*

This group comprises antibiotics specifically used in tuberculosis, except streptomycin - see comment under J04A. Other antibiotics, see J01 - Systemic antibiotics.

J04A C *Hydrazides*

E.g. isoniazid is classified in this group.

Combinations of isoniazid and rifampicin or other tuberculostatics are classified in J04A M.

J04A D *Thiocarbamide derivatives*

E.g. ethionamide is classified in this group.

J04A K *Other drugs for treatment of tuberculosis*

E.g. pyrazinamide and ethambutol are classified in this group.

J04A M *Combinations of drugs for treatment of tuberculosis*

Combinations of drugs classified in J04A A - J04A K are classified in this group (e. g. isoniazid + rifampicin). Combinations of antimycobacterials and streptomycin are classified in this group while plain streptomycin is classified in J01G - Streptomycins.

J04B DRUGS FOR TREATMENT OF LEPRA

J04B A *Drugs for treatment of lepra*

E.g. dapsone is classified in this group.

Thalidomide which is also used for treatment of lepra is classified in L04A X.

J05 ANTIVIRALS FOR SYSTEMIC USE

This group comprises specific antiviral agents, excl. vaccines.

Antivirals for dermatological use, see D06B B.

Antivirals for ophthalmological use, see S01A - Antiinfectives.

Amantadine which is also used as an antiviral agent is classified in N04B B.

J05A AGENTS AFFECTING THE VIRUS DIRECTLY

This group comprises agents acting directly on the virus.

J05A A *Thiosemicarbazones*

J05A B *Nucleosides*

This group comprises e.g. aciclovir, idoxuridine, vidarabine, ribavirin and zidovudine.

Valaciclovir, a prodrug of aciclovir is classified at a separate 5th level.

The DDDs for aciclovir, valaciclovir and famciclovir are based on treatment of herpes zoster infections.

The DDD for ribavirin is based on treatment of respiratory syncytial viral (RSV) infections in neonates and infants.

The DDD for zidovudine and didanosine is based on treatment of serious manifestations of HIV infections. The oral DDD for zidovudine is higher than the parenteral DDD due to lower bio-availability.

The DDD for ganciclovir is based on treatment of cytomegalovirus infections in immunosuppressed patients.

J05A C *Cyclic amines*

This group comprises e.g. rimantadine. Amantadine is classified in N04B B - Anti-Parkinson drugs.

J05A D *Phosphonic acid derivatives*

This group comprises e.g. foscarnet and fosfonet.

J05A X *Other antivirals*

E.g. moroxydine is classified in this group.

J06 IMMUNE SERA AND IMMUNOGLOBULINS

No DDDs have been assigned.

J06A IMMUNE SERA

J06A A *Immune sera*

This group comprises specific antisera.

J06B IMMUNOGLOBULINS

This group comprises normal human immunoglobulin and specific immunoglobulins.

J06B A *Immunoglobulins, normal human*

J06B B *Specific immunoglobulins*

Combinations with vaccines are classified in J07.

J06B C *Other immunoglobulins*

J07 VACCINES

The vaccines are divided in bacterial, virus and combinations of bacterial and virus at separate ATC 3rd levels. Subdivision at the 4th level is made according to indication, while subdivision at the 5th level is mainly related to the process of manufacturing. Combinations of vaccines within the same 3rd level are classified at separate 5th levels using the 50-series.

No DDDs have been assigned.

J07A BACTERIAL VACCINES

J07A C *Anthrax vaccines*

J07A D *Brucellosis vaccines*

J07A E *Cholera vaccines*

Combinations with typhoid vaccine are classified in this group.

J07A F *Diphtheria vaccines*

Different strengths of the diphtheria vaccines are classified at the same 5th level. Combinations with tetanus vaccine are classified in J07A M. Combinations with both tetanus and pertussis are classified in J07A J.

Combinations with hemophilus influenza and tetanus vaccines are classified in J07A G.

J07A G *Hemophilus influenza B vaccines*

Combinations with diphtheria and tetanus vaccines are classified here.

Combinations with poliomyelitis are classified in J07C A.

J07A H *Meningococcal vaccines*

Meningococcal vaccines are classified at separate 5th levels according to the number of serotypes of neisseria meningitis contained in the vaccine. Monovalent vaccines obtained from group A are classified at a separate 5th level, while other monovalent vaccines are classified together.

J07A J *Pertussis vaccines*

Combinations with tetanus and/or diphtheria vaccine are classified in this group.

J07A K *Plague vaccines*

J07A L *Pneumococcal vaccines*

J07A M *Tetanus vaccines*

Combinations with tetanus immunoglobulin are classified in this group. Combinations with diphtheria and/or typhoid vaccines are classified here.

Combinations with diphtheria and pertussis vaccines are classified in J07A J.

Combinations with hemophilus influenza and diphteria vaccines are classified in J07A G.

J07A N *Tuberculosis vaccines*

J07A P *Typhoid vaccines*

Combinations with tetanus vaccine, also when including diphtheria vaccine, are classified in J07A M.

J07A R *Typhus (exanthematicus) vaccines*

J07A X *Other bacterial vaccines*

This group comprises bacterial vaccines which cannot be classified in the preceding groups, e.g. Q fever vaccine.

J07B VIRAL VACCINES

J07B A *Encephalitis vaccines*

J07B B *Influenza vaccines*

Split vaccine is classified as whole virus vaccine.

J07B C *Hepatitis vaccines*

Recombinant and plasma derived hepatitis vaccines are classified at the same 5th level.

J07B D *Morbilli vaccines*

Combinations with parotitis and/or rubella are classified in this group.

J07B E *Parotitis vaccines*

Combinations with morbilli vaccine, with or without rubella, are classified in J07B D. Combinations with rubella vaccine are classified in J07B J.

J07B F *Poliomyelitis vaccines*

Poliomyelitis vaccines are classified according to the number of virus types included and according to administration form, i.e. oral or parenteral.

J07B G *Rabies vaccines*

J07B H *Rota virus diarrhea vaccines*

J07B J *Rubella vaccines*

Combinations with parotitis vaccine are classified in this group. Combinations with morbilli vaccine, with or without parotitis vaccine, are classified in J07B D.

J07B K *Varicella vaccines*

J07B L *Yellow fever vaccines*

J07B X *Other viral vaccines*

J07C BACTERIAL AND VIRAL VACCINES, COMBINED

J07C A *Bacterial and viral vaccines, combined*

Combinations including bacterial and viral vaccines are classified at separate 5th levels. No specific system for subdivision is established.

L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

L01 ANTINEOPLASTIC AGENTS

- *A Alkylating agents*
- *B Antimetabolites*
- *C Plant alkaloids and other natural products*
- *D Cytotoxic antibiotics and related substances*
- *X Other antineoplastic agents*

L02 ENDOCRINE THERAPY

- *A Hormones and related agents*
- *B Hormone antagonists and related agents*

L03 IMMUNOMODULATING AGENTS

- *A Immunostimulating agents*

L04 IMMUNOSUPPRESSIVE AGENTS

- *A Immunosuppressive agents*

L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

This group comprises preparations used in the treatment of malignant neoplastic diseases, and immunomodulating agents.

Corticosteroids for systemic use, see H02.

No DDDs have been established yet because of highly individualized use and wide dosage ranges. The doses used vary substantially because of various types and severity of neoplastic diseases, and also because of the extensive use of combination therapy.

L01 ANTINEOPLASTIC AGENTS

Combination products are classified in L01X Y - Combinations of antineoplastic agents.

Detoxifying agents used in connection with high dose treatment of antineoplastic agents are classified in V03A (e.g. calcium folinate)

L01A ALKYLATING AGENTS

L01A A *Nitrogen mustard analogues*

L01A B *Alkyl sulphonates*

L01A C *Ethylene imines*

L01A D *Nitrosoureas*

L01A G *Epoxides*

L01A X *Other alkylating agents*

L01B ANTIMETABOLITES

L01B A *Folic acid analogues*

Trimetrexate is classified in P01A X - Other agents against amoebiasis and other protozoal agents.

L01B B *Purine analogues*

L01B C *Pyrimidine analogues*

Fluorouracil for systemic and local treatment is classified here.

L01C PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

L01C A *Vinca alkaloids and analogues*

Synthetic analogues are also classified in this group.

L01C B *Podophyllotoxin derivatives*

Antivirals for topical use, e.g. aciclovir and podophyllotoxin, see D06B B - Antivirals.

L01C C *Colchicine derivatives*

See also M04A C01 - Colchicine.

L01C D *Taxanes*

L01D CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

L01D A *Actinomycines*

L01D B *Anthracyclines and related substances*

L01D C *Other cytotoxic antibiotics*

L01X OTHER ANTINEOPLASTIC AGENTS

This group comprises antineoplastic preparations which cannot be classified in the preceding groups.

L01X A *Platinum compounds*

L01X B *Methylhydrazines*

L01X X *Other antineoplastic agents*

L01X Y *Combinations of antineoplastic agents*

All combinations of antineoplastic agents in L01 are classified in this group.

L02 ENDOCRINE THERAPY

Only preparations used specifically in the treatment of neoplastic diseases are classified in this group. This means that some strengths may be classified in this group, while remaining strengths are classified in G03.

See G03 - Sex hormones and modulators of the genital system.

See H01C A - Gonadotrophin-releasing hormones.

L02A HORMONES AND RELATED AGENTS

Antigrowth hormones as somatostatin and octreotide, which are also used in the treatment of neoplastic diseases, are classified in H01C B.

L02A A *Estrogens*

Polyestradiol and combined products which contain estradiol and local anestethics are classified at the plain level L02A A02 - Estradiol.

L02A B *Progestogens*

L02A E *Gonadotrophin releasing hormone analogues*

L02A X *Other hormones*

L02B HORMONE ANTAGONISTS AND RELATED AGENTS

L02B A *Anti-estrogens*

L02B B *Anti-androgens*

L02B G *Enzyme inhibitors*

L03 IMMUNOMODULATING AGENTS

Immunosuppressive agents, see L04A.

L03A IMMUNOSTIMULATING AGENTS

Levamisole which also affects the immune response is classified in P02C E.

L03A A *Cytokines*

L03A X *Other immunostimulating agents*

L04 IMMUNOSUPPRESSIVE AGENTS

L04A IMMUNOSUPPRESSIVE AGENTS

This group comprises immunosuppressive agents excl. corticosteroids, see H02.

L04A A *Selective immunosuppressive agents*

L04A X *Other immunosuppressive agents*

Thalidomide also used in treatment of lepra is classified in this group.

M MUSCULO-SKELETAL SYSTEM

M01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

A Antiinflammatory and antirheumatic products, non-steroids
B Antiinflammatory and antirheumatic agents in combination
C Specific antirheumatic agents

M02 TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

A Topical products for joint and muscular pain

M03 MUSCLE RELAXANTS

A Muscle relaxants, peripherally acting agents
B Muscle relaxants, centrally acting agents
C Muscle relaxants, directly acting agents

M04 ANTIGOUT PREPARATIONS

A Antigout preparations

M05 DRUGS FOR TREATMENT OF BONE DISEASES

B Drugs affecting mineralization

M09 OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

A Other drugs for disorders of the musculo-skeletal system

M MUSCULO-SKELETAL SYSTEM

M01 ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

M01A ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

This group comprises antiinflammatory and antirheumatic preparations for systemic use.

Azathioprine, see L04A X.
Corticosteroids, see H02 - Corticosteroids for systemic use.
Methotrexate, see L01B A.

All preparations containing salicylic acid and derivatives are classified in N02B A - Salicylic acid and derivatives, as it is difficult to differentiate between use of salicylates in rheumatic conditions and other therapeutic uses.

Exception: Salicylates in combination with corticosteroids are classified in M01B.

Combinations of antiinflammatory and antirheumatic agents (e.g. corticosteroids) are classified in M01B.

Antiinflammatory or antirheumatic products in combination with other drugs (incl. codeine less than 20 mg per unit) are classified at separate 5th levels using the corresponding 50-series. Combinations with codeine (20 mg or more per unit dose) are classified in N02A A.

Combined cold preparations with therapeutic levels of antiinflammatory agents are classified in this group at separate 5th levels by using the 50-series.

The ATC 4th level is subdivided according to chemical structure.

The DDDs are based on the treatment of rheumatoid arthritis.

M01A A Butylpyrazolidines

M01A B *Acetic acid derivatives and related substances*

M01A C *Oxicams*

Piroxicam and piroxicam-beta-cyclodextrin are given the same ATC 5th level code M01A C01.

M01A E *Propionic acid derivatives*

All ibuprofen preparations are classified in this group, even if they are only intended for use as pain relief.

M01A G *Fenamates*

M01A X *Other antiinflammatory and antirheumatic agents, non-steroids*

This group comprises antiinflammatory and antirheumatic drugs which cannot be classified in the preceding groups.

E. g. tenidap is classified here.

M01B ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS IN COMBINATION

M01B A *Antiinflammatory and antirheumatic agents in combination with corticosteroids*

This group comprises antiinflammatory and antirheumatic drugs in combination with corticosteroids.

Combinations with salicylic acid derivatives are classified in this group.

The preparations are classified at 5th levels according to the anti-inflammatory/analgesic component. At each 5th level, different corticosteroids may occur.

M01B X *Other antiinflammatory and antirheumatic agents in combination with other drugs*

All combinations of different antiinflammatory agents (excl. corti-

costeroids) are classified in this group.

M01C SPECIFIC ANTIRHEUMATIC AGENTS

This group comprises specific antirheumatic preparations.

Penicillamine, which is also used in conditions associated with impaired copper metabolism and as an antidot in copper poisoning, is classified in this group regardless of indication.

Sulfasalazine which is also used in rheumatoid arthritis is classified in group A07E C.

Tenidap, which has both antiinflammatory action and disease modifying effect is classified in M01A X.

Azathioprine, see L04A X.
Methotrexate, see L01B A.

The DDDs are based on treatment of rheumatoid arthritis.

M01C A Quinolines

Chloroquine and hydroxychloroquine are classified as antimalaria agents in P01B A.

M01C B Gold preparations

M01C C Penicillamine and similar agents

M02 TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

M02A TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

This group comprises ointments, liniments, plasters, etc. which may produce symptomatic relief in joint and muscular pain.

No DDDs have been assigned in this group

M02A A *Antiinflammatory preparations, non-steroids for topical use*

Combinations of non-steroidal antiinflammatory derivatives and other products for topical use are classified together with plain preparations at the different 5th levels.

M02A B *Capsicum preparations and similar agents*

No separate 5th levels are established in this group.

Capsaicin is classified in this group.

Combined preparations containing nonivamide used as a rubefacient are classified in this group.

M02A C *Preparations with salicylic acid derivatives*

No separate 5th levels are established in this group.

Combinations of salicylic acid derivatives and other products are classified in this group.

M02A X *Other topical products for joint and muscular pain*

This group comprises topical products which cannot be classified in the preceding groups, e.g. tolazoline is classified here.

Preparations with menthol are generally classified in D04 - Antipruritics etc.

M03 MUSCLE RELAXANTS

This group comprises peripherally, centrally and directly acting muscle relaxants.

See also G04B D - Urinary antispasmodics.

M03A MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS

This group comprises peripherally acting muscle relaxants such as

curare alkaloids and suxamethonium.

The drugs in this group are mainly used together with anesthetics.

Like for other drugs used in general anesthesia (see N01A), no DDDs have been established in this group because the doses used vary substantially.

M03A A *Curare alkaloids*

M03A B *Choline derivatives*

M03A C *Other quaternary ammonium compounds*

M03A X *Other muscle relaxants, peripherally acting agents*

Botulinum toxin which is used for treatment of blepharospasm and hemifacial spasm is classified in this group.

M03B MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

This group comprises centrally acting muscle relaxants. Combined preparations are classified at separate 5th levels using the corresponding 50-series (comb. excl. psycholeptics), or the 70-series (comb. incl. psycholeptics):

The group is subdivided according to chemical structure.

These drugs are used in different conditions associated with pain and rigidity in the muscles, joints etc.

For combined preparations, the DDDs are based on the average of recommended dosages in drug catalogues. These preparations often contain many substances, and the DDD cannot be based on a single ingredient. Thus all ingredients are taken into account.

M03B A *Carbamic acid esters*

M03B B *Oxazol-, thiazine-, triazine derivatives*

M03B C *Ethers, chemically close to antihistamines*

Orphenadrine citrate is classified here. Preparations containing orphenadrine chloride are classified in N04A B. Combinations with e.g. paracetamol are classified in this group at separate 5th levels by using the 50-series.

M03B X *Other centrally acting agents*

M03C MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

This group comprises directly acting agents such as dantrolene.

M03C A *Dantrolene and derivatives*

The DDD of dantrolene is based on treatment of spasticity after spinal injury.

M04 **ANTIGOUT PREPARATIONS**

M04A ANTIGOUT PREPARATIONS

This group comprises preparations used in the treatment of gout.

The group is subdivided according to mode of action.

The DDDs are based on prophylactic use.

M04A A *Preparations inhibiting uric acid production*

M04A B *Preparations increasing uric acid excretion*

M04A C *Preparations with no effect on uric acid metabolism*

E.g. colchicine is classified in this group.

M04A X *Other antigout preparations*

This group comprises preparations which cannot be classified in the

preceding groups.

M05 DRUGS FOR TREATMENT OF BONE DISEASES

This group comprises mainly agents used in hypercalcemia.

Drugs used for the treatment of bone disease, see also:

A11CC -	Vitamin D and analogues
A12A -	Calcium
A12C D -	Fluoride
G03C/G03F -	Estrogens
H05BA -	Calcitonins

M05B DRUGS AFFECTING MINERALIZATION

M05B A Bisphosphonates

This group includes plain preparation. Combination packages with calcium for sequential use are classified in M05B B.

The DDDs for the bisphosphonates are based on treatment of tumour induced hypercalcemia. Since the duration of the intravenous treatment courses with the bisphosphonates are varying, from 1-5 days, the DDDs for these parenteral formulations are assigned according to the total *course* dose. The DDDs for the oral formulations, which are mainly used for maintenance therapy, are assigned according to *daily* dosages.

The DDD for alendronic acid is based on treatment of osteoporosis.

M05B B Bisphosphonates and calcium, sequential preparations

M05B X Other drugs affecting mineralization

E.g. ipriflavone is classified in this group.

M09 OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

M09A OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

This group comprises preparations used in disorders of the musculo-skeletal system, which cannot be classified in the preceding groups.

M09A A Quinine and derivatives

Hydroquinine, which is used in the treatment of nocturnal leg cramps is classified in this group.

Quinine is classified as an antimalaria agent in P01B C. Quinine in combination with psycholeptics is classified in M09A A72, since these combinations are used for treatment of nocturnal leg cramps.

Combinations used for cold conditions, containing quinine as an antipyretic, are classified in R05X.

M09A B Enzymes

All enzyme preparations which are used to treat inflammatory conditions in the musculo-skeletal system are classified in this group, e.g. chymopapain.

M09A X Other drugs for disorders of the musculo-skeletal system

Hyaluronic acid injection for intraarticular administration (e.g. 2.5 mg/ampoule) used in the treatment of arthritis is classified in this group. Hyaluronic acid injection used during surgical procedures on the eye (e.g. 4-20 mg/ampoule) is classified in S01K.

The DDD of hyaluronic acid is based on intraarticular treatment of arthritis. The DDD is assigned according to daily dose even if the product is given as weekly injections.

N NERVOUS SYSTEM

N01 ANESTHETICS
- *A Anesthetics, general*
- *B Anesthetics, local*

N02 ANALGESICS
- *A Opioids*
- *B Other analgesics and antipyretics*
- *C Antimigraine preparations*

N03 ANTIEPILEPTICS
- *A Antiepileptics*

N04 ANTI-PARKINSON DRUGS
- *A Anticholinergic agents*
- *B Dopaminergic agents*

N05 PSYCHOLEPTICS
- *A Antipsychotics*
- *B Anxiolytics*
- *C Hypnotics and sedatives*

N06 PSYCHOANALEPTICS
- *A Antidepressants*
- *B Psychostimulants and nootropics*
- *C Psycholeptics and psychoanaleptics in combination*

N07 OTHER NERVOUS SYSTEM DRUGS
- *A Parasympathomimetics*
- *B Antismoking agents*
- *C Antivertigo preparations*
- *X Other nervous system drugs*

N NERVOUS SYSTEM

N01 ANESTHETICS

No DDDs have been established in this group because the doses used vary substantially.

N01A ANESTHETICS, GENERAL

This group comprises agents which produce general anesthesia, surgical analgesia or neuroleptanalgesia. See also M03A - Peripherally acting muscle relaxants.

Benzodiazepine derivatives are classified in N05B A or N05C D.

N01A A Ethers

N01A B Halogenated hydrocarbons

N01A F Barbiturates, plain

This group comprises barbiturates used as anesthetics.

Barbiturates used as hypnotics/sedatives and as premedication, see N05C A - Barbiturates, plain.

N01A G Barbiturates in combination with other drugs

Only preparations used as anesthetics are classified in this group. See also N05C B - Barbiturates, combinations.

N01A H Opioid anesthetics

Opioid anesthetics in combination with other anesthetics are classified in this group at separate 5th levels using the corresponding 50-series.

Transdermal formulations of fentanyl are classified in N02A B.

N01A X *Other general anesthetics*

This group comprises various plain and combined drugs used to produce anesthesia/analgesia, which cannot be classified in the preceeding groups, e.g. droperidol, ketamin and propofol.

Oral formulations of droperidol are classified in N05A D.

N01B ANESTHETICS, LOCAL

Local anesthetics in this context means anesthetics which only affect a local area as opposed to general anesthetics affecting the entire body.

Creams containing e.g. lidocaine and prilocaine used as anesthetics in the skin are classified in this group, see N01B B.

Local anesthetics for dermatological use such as treatment of pruritus, minor burns, insect stings are classified in D04A B - Anesthetics for topical use.

Antihemorrhoidals containing anesthetics, see C05A D - Products containing local anesthetics.

Stomatologicals with anesthetics, see A01A D.

Throat preparations with anesthetics, see R02A D - Anesthetics, local.

Ophthalmological anesthetics, see S01H A.

Combinations with e.g. epinephrine are classified at separate 5th levels by using the 50-series.

N01B A *Esters of amino benzoic acid*

N01B B *Amides*

Lidocaine injections used as antiarrhythmics are classified in C01B B.

Different amides in combination are given the ATC-code N01B B20 (e.g. creams containing lidocaine and prilocaine).

N01B C *Esters of benzoic acid*

N01B X *Other local anesthetics*

E.g. ethyl chloride is classified in this group.

N02 ANALGESICS

This group comprises general analgesics and antipyretics.

All salicylic acid derivatives except combinations with corticosteroids are classified in N02B A - Salicylic acid and derivatives, as it is difficult to differentiate between the use of salicylates in rheumatic conditions and other therapeutic uses of salicylates.

All ibuprofen preparations are classified in M01A, even if they are only intended for use as pain relief.

Salicylic acid derivatives in combination with corticosteroids are classified in M01B.

There are a number of combined preparations which contain analgesics and psycholeptics. These are classified in N02, as pain relief must be regarded as the main indication. Analgesics used on specific indications are classified in the respective ATC groups. E.g.:

A03D/
A03E A - Antispasmodic/analgesic combinations
M01 - Antiinflammatory and antirheumatic products
M02A - Topical products for joint and muscular pain
M03 - Muscle relaxants

See comments to these groups.

N02A OPIOIDS

This group comprises strong analgesics of the opiate type and

analgesics with similar structure or action.

Sufentanil which is also used as an epidural analgesic is classified in N01A H.

Combinations are classified at separate 5th levels, using the corresponding 50-series (combinations excl. psycholeptics) or the 70-series (combinations with psycholeptics).

Combinations with antispasmodics are classified in N02A G.

The parenteral DDD for morphine is based on treatment of pain, and other substances in this group have as far as possible been given equipotent DDDs. For pentazocine, the potency is lower and the duration is shorter than for morphine.

The DDD for oral morphine is higher than the parenteral DDD because of lower bioavailability. For other drugs in this group, the oral and rectal formulations have the same DDDs as the parenteral preparations.

N02A A *Natural opium alkaloids*

Opium, see also A07D A - Antipropulsives.

Plain codeine preparations are classified in R05D - Antitussives. Codeine or dihydrocodeine in combination with other analgesics are classified in this group at separate 5th levels by using the 50-series, if the codeine or dihydrocodeine content are 20 mg or more per unit dose. Combinations with a lower content of codeine or dihydrocodeine are classified at the respective 4th levels in N02B or M01A of the other analgesic components (e.g. paracetamol or acetylsalicylic acid).

When establishing DDDs for combination products in the 50-series, all analgesic components are taken into account if the amount of each component is on a therapeutic level.

When codeine is used as a plain analgesic it has been given a DDD of 0.2 g.

N02A B *Phenylpiperidine derivatives*

Fentanyl atches are classified in this group whereas parenteral formulations are classified in N01A H.

N02A C *Diphenylpropylamine derivatives*

This group comprises e.g. methadone and dextropropoxyphene.

Dextropropoxyphene in combination with a muscle relaxant is classified in M03B.

Different DDDs are assigned for different dextropropoxyphene salts based on their different solubility.

N02A D *Benzomorphan derivatives*

N02A E *Oripavine derivatives*

N02A F *Morphinan derivatives*

N02A G *Opioids in combination with antispasmodics*

Preparations are classified at 5th levels according to the analgesic. At each level different antispasmodics may occur.

The DDDs in this group are as far as possible equipotent to the DDD for parenteral morphine.

N02A X *Other opioids*

The group comprises opioids which cannot be classified in the preceding groups.

N02B OTHER ANALGESICS AND ANTIPYRETICS

See general considerations under N02.

Combined preparations within each 4th level are classified by using the corresponding 50-series (combinations excl. psycholeptics) or

the 70-series (combinations with psycholeptics).

Combinations with opioid analgesics should be classified in N02A at separate 5th levels, using the corresponding 50-series (combinations excl. psycholeptics) or the 70-series (combinations with psycholeptics) or in N02A G - Opioids in combination with antispasmodics. Combinations with codeine or dihydrocodeine are, however, classified in this group if the codeine or dihydrocodeine content per unit dose is less than 20 mg. Otherwise these combinations are classified in N02A A.

Combined preparations which contain more than one analgesic, should be classified by using the following ranking:

1. Phenacetin
2. Bucetin
3. Dipyrocetyl
4. Paracetamol
5. Acetylsalicylic acid
6. Phenazone
7. Salicylamide
8. Propyphenazone
9. Codeine

This means, in practice, that a product containing paracetamol and phenazone should be classified in N02B E51 - Paracetamol, combinations excl. psycholeptics and not in N02B B51 - Phenazone, combinations excl. psycholeptics.

Dextropropoxyphene plain, and in combination with other analgesics, is classified in N02A C.

Cold preparations with therapeutic levels of analgesics are classified in this group at separate 5th levels by using the 50-series.

Preparations are subdivided on 4th levels according to chemical structure.

Combinations with ascorbic acid (i.e. 50 mg or more per unit dose) are classified at separate 5th levels using the corresponding 50-

series. Products containing less than 50 mg per unit dose are classified at the plain level of the analgesic component.

When establishing DDDs for combination products in the 50-series, all analgesic components are taken into account if the amount of each component is on a therapeutic level. For combination products with codeine (i.e. less than 20 mg per unit dose), the amount of codeine is not taken into account when assigning a DDD.

Preparations in the 70-series are combinations with psycholeptics. The amounts of the psycholeptic substances are sometimes on such a high level, and the DDD can therefore not be based only on the analgesic compounds since this would give too high doses of the psycholeptic substances. The DDDs for these preparations are based on the doses recommended by the national drug authorities.

N02B A *Salicylic acid and derivatives*

All salicylic acid derivatives including some commonly regarded as non-steroid antiinflammatory drugs, e.g. diflunisal, are classified in this group. See comment under N02.

Salicylic acid derivatives in combination with corticosteroids are classified in M01B. Acetylsalicylic acid preparations specifically intended for use as antithrombotic agents are classified in B01A C.

The DDD for acetylsalicylic acid is based on treatment of moderately severe pain and not on use in rheumatic diseases. Other drugs are as far as possible given equipotent DDDs.

DDD for combined preparations, see N02B.

N02B B *Pyrazolones*

N02B E *Anilides*

Propacetamol, a prodrug of paracetamol is classified in the same ATC 5th level as paracetamol.

Benorilate which is an acetylsalicylic paracetamol ester is classified

in N02B A.

Paracetamol in combination with orphenadrine (citrate) is classified in M03B C.

N02B G *Other analgesics and antipyretics*

This group comprises analgesics which cannot be classified in the preceding groups.

N02C ANTIMIGRAINE PREPARATIONS

This group comprises preparations specifically used in the prophylaxis and treatment of migraine. Analgesics, see N02A and N02B.

Beta blocking agents, see C07.

Antivertigo preparations, see N07.

Cyproheptadine, see R06A - Antihistamines for systemic use.

N02C A *Ergot alkaloids*

Ergot alkaloids for gynecological use, see G02A and G02C B.

See also C04A E - Ergot alkaloids.

Dihydroergotamine which is also used in the treatment of hypotension, is classified in this group.

Combined preparations are classified at separate 5th levels using the corresponding 50-series (combinations excl. psycholeptics) or the 70-series (combinations with psycholeptics).

The DDD for ergotamine is based on treatment of acute attacks of migraine, whereas the DDDs for dihydroergotamine and methysergide are based on prophylactic treatment.

N02C B *Corticosteroid derivatives*

The DDDs for corticosteroid derivatives are based on prophylactic treatment of migraine.

N02C X *Other antimigraine preparations*

This group comprises antimigraine preparations which cannot be classified in the preceding groups, e.g. sumatriptan.

Clonidine low strength tablets (e.g. 25 μg) are classified here, even if the indication also may be "opioid withdrawal symptoms".

The DDD of sumatriptan is based on treatment of acute attacks of migraine. The oral DDD of sumatriptan is much higher than the parenteral due to lower bioavailability.

The DDDs for the other substances in this group are based on prophylactic treatment.

N03 **ANTIEPILEPTICS**

N03A ANTIEPILEPTICS

This group comprises preparations used in the treatment of epilepsy.

Combined preparations are classified at separate 5th levels using the corresponding 50-series.

The group is subdivided according to chemical structure.

The DDDs are based on monotherapy treatment. The DDD for vigabatrin is, however, based on combined therapy with other antiepileptics.

N03A A *Barbiturates and derivatives*

Barbiturates used mainly as hypnotics/sedatives are classified in N05C - Hypnotics and sedatives.

Phenobarbital which is used both as an antiepileptic and as a sedative, is classified in this group.

Combinations with phenytoin are classified in N03A B.

N03A B *Hydantoin derivatives*

Combinations of phenytoin and barbiturates are classified in this group.

N03A C *Oxazolidine derivatives*

N03A D *Succinimide derivatives*

N03A E *Benzodiazepine derivatives*

Benzodiazepines with epilepsy as the main indication (anticonvulsive effect more pronounced than the sedative effect) are classified in this group, e.g. clonazepam.

Benzodiazepines mainly used as anxiolytics or hypnotics/sedatives, see N05B and N05C.

N03A F *Carboxamide derivatives*

E.g. carbamazepine is classified in this group.

N03A G *Fatty acid derivatives*

E.g. valproic acid is classified in this group.

N03A X *Other antiepileptics*

This group comprises antiepileptics which cannot be classified in the preceding groups.

N04 ANTI-PARKINSON DRUGS

This group comprises preparations used in the treatment of Parkinson's disease and related conditions, including drug-induced parkinsonism.

The DDDs are based on recommended doses for long-term treatment of the symptoms of Parkinson's disease.

No separate DDDs are established for oral depot formulations.

N04A ANTICHOLINERGIC AGENTS

N04A A *Tertiary amines*

N04A B *Ethers chemically close to antihistamines*

Orphenadrine chloride is classified in this group, while orphenadrine citrate is classified in M03B C.

N04A C *Ethers of tropine or tropine derivatives*

N04B DOPAMINERGIC AGENTS

N04B A *Dopa and dopa derivatives*

Preparations containing levodopa and decarboxylase inhibitor are given the ATC code N04B A02.

N04B B *Adamantane derivatives*

N04B C *Dopamine agonists*

Bromocriptine used in parkinsonism is classified in this group (e.g. tablets of 5 mg and 10 mg). Low strength bromocriptine tablets (e.g. 2.5 mg) used as prolactine inhibitor are classified in G02C B - Prolactine inhibitors.

Lisuride in high strength formulations which is also used in the treatment of Parkinsonism are classified in G02C B while lisuride in low strength formulations are classified in N02C A.

N04B D *Monoamine oxidase type B inhibitors*

E.g. selegiline is classified in this group.

N04B X *Other dopaminergic agents*

This group comprises dopaminergic agents which cannot be classified in the preceding groups.

N05 PSYCHOLEPTICS

The group is divided into therapeutic subgroups:

N05A - Antipsychotics
N05B - Anxiolytics
N05C - Hypnotics and sedatives

N05A ANTIPSYCHOTICS

This group comprises drugs with antipsychotic actions (i.e. neuroleptics).

Reserpine is classified in C02 - Antihypertensives.

Antipsychotics in combination with antidepressants are classified in N06C - Psycholeptic/psychoanaleptic combinations.

The group is subdivided mainly according to chemical structure.

The DDDs are based on treatment of psychosis. The substances in this group are sometimes used on other indications in much lower doses.

For depot injections, the DDDs are based on the average recommended doses divided by the dosing interval.

N05A A *Phenothiazine with dimethylaminopropyl group*

N05A B *Phenothiazine with piperazine structure*

N05A C *Phenothiazine with piperidine structure*

N05A D *Butyrophenone derivatives*

Parenteral formulations of droperidol are classified in N01A X, while oral formulations are classified in this group.

N05A E *Indole derivatives*

N05A F *Thioxanthene derivatives*

N05A G *Diphenylbutylpiperidine derivatives*

N05A H *Dibenzodiazepine and dibenzoxazepine derivatives*

N05A K *Neuroleptics, in tardive dyskinesia*

E.g. tetrabenazine is classified in this group.

N05A L *Benzamides*

N05A N *Lithium*

The DDD is based on prophylactic treatment of mania or depression.

Antidepressants, see N06A.

N05A X *Other antipsychotics*

This group comprises antipsychotics which cannot be classified in the preceding groups.

N05B ANXIOLYTICS

This group comprises preparations used in the treatment of neuroses and psychosomatic disorders associated with anxiety and tension, e.g. benzodiazepines.

See also:
N05A - Antipsychotics
N05C - Hypnotics and sedatives

Usually the presence of an anxiolytic (or other psycholeptics) in combined preparations must be regarded as being of secondary importance and the preparations should be classified in the respective therapeutic groups (e.g. A03C - Antispasmodics in combination with psycholeptics, N02 - Analgesics etc.).

Combined preparations used mainly for the treatment of anxiety are classified at separate 5th levels using the corresponding 50-series.

The group is subdivided according to chemical structure.

The DDDs are based on treatment of anxiety.

N05B A *Benzodiazepine derivatives*

Benzodiazepines used mainly in the treatment of sleep disturbances are classified in N05C - Hypnotics and sedatives.

Benzodiazepines used mainly in the treatment of epilepsy are classified in N03 - Antiepileptics.

The parenteral DDD for chlordiazepoxide is higher than the oral DDD due to lower bioavailability for intramuscular injections.

N05B B *Diphenylmethane derivatives*

N05B C *Carbamates*

N05B D *Dibenzo-bicyclo-octadiene derivatives*

E.g. benzoctamine is classified in this group.

N05B E *Azaspirodecanedione derivatives*

E.g. buspirone is classified in this group.

N05B X *Other anxiolytics*

This group comprises anxiolytics which cannot be classified in the preceding groups.

N05C HYPNOTICS AND SEDATIVES

This group comprises preparations with mainly sedative or hypnotic actions.

See also:
N05A - Antipsychotics
N05B - Anxiolytics
R06A - Antihistamines for systemic use

Combined preparations are classified at separate 4th levels, N05C B and N05C X.

Regarding classification of combined preparations, see comments under N05B - Anxiolytics.

Combined preparations with barbiturates are mainly classified in A03 (mainly antispasmodic effect) or in N02 (mainly analgesic effect).

Combined preparations with barbiturates which remain in N05C are mainly "neurostabilizers".

The group is subdivided according to chemical structure.

The DDDs are based on use of the drugs as hypnotics.

N05C A Barbiturates, plain

This group comprises barbiturates used for insomnia.

Preparations used as premedication are also classified in this group.

Barbiturates used in general anesthesia are classified in N01 - General anesthetics.

Barbiturates used mainly in the treatment of epilepsy, e.g. phenobarbital, are classified in N03 - Antiepileptics.

Combined preparations are classified in N05C B, see comment under N05C.

N05C B *Barbiturates, combinations*

This group comprises combined preparations with mainly sedative action. Combinations with analgesics etc., see comments under N05C - Hypnotics and sedatives.

All hypnotic and sedative components are considered when DDDs are assigned for combined preparations.

N05C C *Aldehydes and derivatives*

N05C D *Benzodiazepine derivatives*

Benzodiazepine derivatives used mainly in sleeping disorders are classified in this group.

See also N05B A.

N05C E *Piperidinedione derivatives*

N05C F *Cyclopyrrolones*

N05C G *Imidazopyridines*

N05C M *Other hypnotics and sedatives*

This group includes drugs which cannot be classified in the preceding groups, e.g. methaqualone, clomethiazole, bromides, valerian.

N05C X *Hypnotics and sedatives in combination, excl. barbiturates*

All combination products mainly used in sleeping disorders are classified in this group, except combinations with barbiturates, see N05C B.

All hypnotic and sedative components are considered when DDDs are assigned for combined preparations.

N06 PSYCHOANALEPTICS

This group comprises antidepressants, psychostimulants, nootropics and combinations with psycholeptics.

Antiobesity preparations are classified in A08 - Antiobesity preparations, excl. diet products.

N06A ANTIDEPRESSANTS

This group comprises preparations used in the treatment of endogenous and exogenous depressions.

The group is subdivided mainly according to mode of action. The various antidepressants have different mode of actions and the classification will not reflect the exact mode of actions of the various antidepressants.

Lithium, see N05A N - Lithium.

Combination with psycholeptics, see N06C.

The DDDs are based on treatment of moderately severe depressions.

N06A A *Non-selective monoamine reuptake inhibitors*

N06A B *Selective serotonin reuptake inhibitors*

N06A F *Monoamine oxidase inhibitors, non-selective*

N06A G *Monoamine oxidase type A inhibitors*

N06A X *Other antidepressants*

This group includes antidepressants which cannot be classified in the preceding groups.

E.g. bifemelane, mirtazapine and nefazodone are classified in this group.

N06B PSYCHOSTIMULANTS AND NOOTROPICS

Nootropics are classified in N06B X.

N06B A *Centrally acting sympathomimetics*

Amfetamine is classified in this group, see comment under A08A A - Centrally acting antiobesity products.

N06B C *Xanthine derivatives*

Caffeine is classified in this group, while combinations with respiratory stimulants are classified in R07A B.

N06B X *Other psychostimulants and nootropics*

This group comprises substances regarded as nootropics. Psychostimulants which cannot be classified in the preceding groups are also classified here.

Tacrine is classified in N07A A.

N06C PSYCHOLEPTICS AND PSYCHOANALEPTICS IN COMBINATION

Combinations of e.g. antidepressants and anxiolytics are classified in this group.

N06C A *Antidepressants in combination with psycholeptics*

Preparations are classified at 5th levels according to the antidepressant. At each level various psycholeptics may occur.

N06C B *Psychostimulants in combination with psycholeptics*

N07 OTHER NERVOUS SYSTEM DRUGS

This group comprises parasympathomimetics, antivertigo preparations and other nervous system drugs which cannot be classified in the preceding 2nd levels in ATC group N.

N07A PARASYMPATHOMIMETICS

See also cholinergics used in glaucoma therapy, S01E B.

This group includes various drugs used on different indications. The DDDs are therefore established individually for each ATC 5th level.

N07A A Anticholinesterases

N07A B Choline esters

N07A X Other parasympathomimetics

N07B ANTISMOKING AGENTS

N07B A Antismoking agents

N07C ANTIVERTIGO PREPARATIONS

This group comprises agents mainly used in the treatment of vertigo.

See also:

A04A - Antiemetics and antinauseants
C04A X - Other peripheral vasodilators
N02C - Antimigraine preparations
N05A - Antipsychotics
R06A - Antihistamines for systemic use

The DDDs are based on treatment of vestibular symptoms.

N07C A Antivertigo preparations

N07X OTHER NERVOUS SYSTEM DRUGS

N07X A Gangliosides and ganglioside derivatives

N07X X Other nervous system drugs

This group contains substances which cannot be classified in the preceding groups. E.g. tirilazad is classified here.

P ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

P01 ANTIPROTOZOALS

A Agents against amoebiasis and other protozoal diseases
B Antimalarials
C Agents against leishmaniasis and trypanosomiasis

P02 ANTHELMINTICS

B Antitrematodals
C Antinematodal agents
D Anticestodals

P03 ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

A Ectoparasiticides, incl. scabicides
B Insecticides and repellents

P ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

The group is subdivided according to types of parasites.

P01 ANTIPROTOZOALS

P01A AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

This group comprises drugs mainly used for amoeba infections and other protozoal diseases such as giardiasis and trichomoniasis.

P01A A Hydroxyquinoline derivatives

This group comprises e.g. broxyquinoline and clioquinol. All combined preparations containing clioquinol are classified in this group.

No DDDs are established in this group.

P01A B Nitroimidazole derivatives

Nitroimidazole derivatives used for amoebiasis, trichomoniasis and giardiasis are classified in this group. Formulations for vaginal administration are classified in G01A F. Parenteral formulations mainly used for treatment of anaerobic bacterial infections are classified in J01X D.

The DDDs are based on the treatment of amoebiasis, giardiasis and trichomoniasis. The duration of the treatment periods is not taken into consideration.

P01A C Dichloroacetamide derivatives

This group comprises luminal amoebicides such as e.g. diloxanide.

The DDDs in this group are based on treatment of luminal amoebiasis.

P01A R *Arsenic compounds*

This group comprises e.g. glycobiarsol. Combinations containing clioquinol are classified in P01A A.

P01A X *Other agents against amoebiasis and other protozoal diseases*

This group comprises agents which cannot be classified in the preceding groups. E.g. trimetrexate is classified here. Combinations with clioquinol are classified in P01A A.

P01B ANTIMALARIALS

This group comprises drugs mainly used for treatment and prophylaxis of malaria.

Most antimalarials are used both therapeutically and prophylactically. The duration of treatment differs for the various antimalarials. The DDDs are based on the treatment of malaria, except for those substances which are used prophylactically only (e.g. proguanil). For most of the substances the DDDs are expressed as amount of base.

P01B A *Aminoquinolines*

Combinations with clioquinol are classified in P01A A.
Combinations with glycobiarsol are classified in P01A R.

The DDDs are based on the average daily dose for the treatment period.

P01B B *Biguanides*

E.g. proguanil and cycloguanil are classified in this group.

The DDD for proguanil is based on the weekly dose given for prophylaxis of malaria.

P01B C *Quinine alkaloids*

Combined preparations with quinine and psycholeptics used for treatment of nocturnal cramps are classified in M09A A.

Combined preparations with quinine for symptomatic relief in cold conditions are classified in R05X.

Hydroquinine is classified in M09A A.

P01B D *Diaminopyrimidines*

E.g. pyrimethamine and combinations of pyrimethamine and sulfadoxime are classified in this group.

The DDD for pyrimethamine is based on the combination therapy with a sulphonamide for the treatment of malaria.

P01B X *Other antimalarials*

This group comprises agents which cannot be classified in the preceding groups.

P01C AGENTS AGAINST LEISHMANIASIS AND TRYPANOSOMIASIS

P01C A *Nitroimidazole derivatives*

Nitroimidazole derivatives used for trypanosomiasis are classified in this group, e.g. benznidazole. Other nitroimidazole derivatives see P01A B.

The DDD for benznidazole is based on the treatment of trypanosomiasis.

P01C B *Antimony compounds*

E.g. meglumine antimonate and sodium stibogluconate are classified in this group.

The DDDs are expressed as pentavalent antimony (Sb^{5+}) used in the treatment of visceral leishmaniasis.

P01C C *Nitrofurane derivatives*

E.g. nifurtimox and nitrofural are classified in this group.

The DDDs are based on the treatment of trypanosomiasis.

P01C D *Arsenic compounds*

The DDDs are based on the treatment of trypanosomiasis.

P01C X *Other agents against leishmaniasis and trypanosomiasis*

This group comprises agents which cannot be classified in the preceding groups. E.g. pentamidine isethionate is classified in this group.

The DDD for pentamidine isethionate is based on amount given per injection.

P02 **ANTHELMINTICS**

The anthelmintics are subdivided according to the main type of worms (i.e. trematodes, nematodes and cestodes) causing the infections.

P02B ANTITREMATODALS

This group comprises drugs mainly used for trematode infections such as e.g. schistosomiasis. Niclosamide which is also used in trematode infections, is classified in P02D A.

The DDDs are based on the treatment of schistosomiasis.

P02B A *Quinoline derivatives and related substances*

E.g. praziquantel and oxamniquine are classified in this group.

P02B B *Organophosphorous compounds*

E.g. metrifonate is classified in this group.

Metrifonate is administered every second week. The DDD is the dose dived by the dosing interval.

P02B X *Other antitrematodal agents*

This group comprises agents which cannot be classified in the preceding groups. E.g. bithionol, niridazole and stibophen are classified in this group.

P02C ANTINEMATODAL AGENTS

This group comprises drugs mainly used for nematode infections.

The DDDs are based on the treatment of different nematode infections e.g. ascariasis (roundworm) and hookworm infections.

P02C A *Benzimidazole derivatives*

P02C B *Piperazine and derivatives*

E.g. diethylcarbamazine is classified in this group.

The DDD for diethylcarbamazine is based on the treatment of lymphatic filiariasis.

P02C C *Tetrahydropyrimidine derivatives*

E.g. pyrantel and oxantel are classified in this group.

P02C E *Imidazothiazole derivatives*

E.g. levamizole is classified in this group.

P02C F *Avermectines*

E.g. ivermectin is classified in this group.

P02C X *Other antinematodals*

This group comprises agents which cannot be classified in the preceding groups.

P02D ANTICESTODALS

This group comprises drugs mainly used for cestode infections. Praziquantel and mebendazole which are also used in cestode infections, are classified in P02B A and P02C A respectively.

The DDDs are based on the treatment of cestode (tapeworm) infections.

P02D A *Salicylic acid derivatives*

E.g. niclosamide is classified in this group.

P02D X *Other anticestodals*

This group comprises agents which cannot be classified in the preceding groups.

P03 ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

P03A ECTOPARASITICIDES, INCL. SCABICIDES

This group comprises preparations used against scabies, lice and other ectoparasites.

No DDDs are assigned in this group. Substances classified in this group are for topical use and the consumption figures for these preparations could be expressed in e.g. grams of preparations regardless of strength.

P03A A *Sulphur containing products*

This group comprises various sulphur compounds, e.g. dixanthogen, mesulfen and disulfiram.

Combinations with e.g. benzyl benzoate are classified in this group.

Combinations with chlorine compounds, see P03A B.

P03A B *Chlorine containing products*

This group comprises e.g. clofenotane and lindane. Combinations with sulphur compounds are classified in this group.

P03A C *Pyrethrines, incl. synthetic compounds*

This group comprises various pyrethrum products, including synthetic pyrethrinoids and combinations with e.g. piperonyl butoxide.

P03A X *Other ectoparasiticides, incl. scabicides*

This group comprises e.g. benzyl benzoate and malathion. Crotamiton preparations are classified in D04A X - Other antipruritics.

P03B INSECTICIDES AND REPELLENTS

P03B A *Pyrethrines*

P03B X *Other insecticides and repellents*

R RESPIRATORY SYSTEM

R01 NASAL PREPARATIONS

A Decongestants and other nasal preparations for topical use
B Nasal decongestants for systemic use

R02 THROAT PREPARATIONS

A Throat preparations

R03 ANTI-ASTHMATICS

A Adrenergics, inhalants
B Other anti-asthmatics, inhalants
C Adrenergics for systemic use
D Other anti-asthmatics for systemic use

R05 COUGH AND COLD PREPARATIONS

C Expectorants, excl. combinations with cough suppressants
D Cough suppressants, excl. combinations with expectorants
F Cough suppressants and expectorants, combinations
X Other cold combination preparations

R06 ANTIHISTAMINES FOR SYSTEMIC USE

A Antihistamines for systemic use

R07 OTHER RESPIRATORY SYSTEM PRODUCTS

A Other respiratory system products

R RESPIRATORY SYSTEM

R01 NASAL PREPARATIONS

R01A DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

This group comprises preparations for local treatment in nasal congestion (e.g. sympathomimetics) or for prophylaxis and treatment of allergic rhinitis (e.g. corticosteroids, cromoglicate preparations). Most of the products are nasal drops, nasal sprays or nasal inhalants.

See also R01B - Nasal decongestants for systemic use, and R06 - Antihistamines for systemic use.

The DDDs are based on treatment of both nostrils.

R01A A Sympathomimetics, plain

Small amounts of antiseptics etc. are allowed at each 5th level.

Combinations with antibiotics, antihistamines etc. are classified in R01A B, while combinations with corticosteroids are classified in R01A D.

The DDDs are based on therapeutic treatment of acute rhinitis.

R01A B Sympathomimetics, combinations excl. corticosteroids

Combinations with e.g. antibiotics and antihistamines are classified in this group.

This group also includes preparations with two or more sympathomimetics. These combinations are classified in a ranking according to the ATC codes, e.g. substances classified in R01A B01 take precedence over substances classified in R01A B02 etc.

The DDDs are based on therapeutic treatment of rhinitis. DDDs are given in volume (i.e. ml). Most of the products classified in this group are combinations with antihistamines. So far, all these products are given a fixed DDD of 0.8 ml.

R01A C *Antiallergic agents, excl. corticosteroids*

Antihistamines, cromoglicate disodium and analogues are classified here.

The DDD of cromoglicic acid is based on prophylactic treatment of rhinitis. The DDDs of the antihistamines are based on therapeutic treatment of rhinitis.

R01A D *Corticosteroids*

Combinations of corticosteroids and antiinfectives, sympathomimetics etc. should be classified in this group at separate 5th levels by using the 50-series.

The DDDs are based on treatment of rhinitis.

R01A X *Other nasal decongestants*

This group comprises antiinfectives, antiseptics, mucolytics etc. which cannot be classified in the preceding groups. E.g. ipratropium bromide and mupirocin are classified here.

ATC level R01A X10 is an old level where rather obsolete nasal preparations are classified. The combination level R01A X30 is for combination products of nasal decongestants which can not be classified in the preceding groups.

The DDDs are based on therapeutic treatment of rhinitis.

R01B NASAL DECONGESTANTS FOR SYSTEMIC USE

This group comprises preparations for systemic use in vasomotoric or allergic rhinitis etc., excl. plain antihistamines (see R06).

Combinations with antihistamines are classified in this group.

Combined preparations are classified at separate 5th levels using the corresponding 50-series.

The DDDs are based on treatment of rhinitis.

DDDs for most of the combination products are equal to the DDDs of the different active ingredients (e.g. phenylpropanolamine and an antihistamine).

R01B A *Sympathomimetics*

R02 **THROAT PREPARATIONS**

R02A THROAT PREPARATIONS

Throat preparations and mouth preparations are classified in the groups R02 and A01 according to assumed main therapeutic use. Preparations used in common minor infections of mouth and throat are classified in R02, while preparations used in gingivitis, stomatitis etc. are classified in A01 - Stomatological preparations.

Expectorants administered as tablets are classified in R05 - Cough and cold preparations.

The DDDs are based on treatment of common minor infections of mouth and throat. For combination products, DDDs are given as fixed doses of 6 UD (6 tablets).

R02A A *Antiseptics*

See also A01A B - Antiinfectives for local oral treatment. At each 5th level combinations with anesthetics are allowed.

R02A B *Antibiotics*

See also A01A B - Antiinfectives for local oral treatment. At each 5th level combinations with anesthetics are allowed. Antibiotics for

systemic use, see J01.

R02A D *Anesthetics, local*

This group comprises e.g. throat lozenges containing local anesthetics. Dental anesthetics for local application are classified in N01B - Anesthetics, local.

Combinations of anesthetics and antiseptics/antibiotics are classified in R02A A/R02A B respectively.

R03 ANTI-ASTHMATICS

R03A ADRENERGICS, INHALANTS

It is complicated to decide DDDs for the different dosage forms and even the different inhalation *devices* of the same dosage form. It has been shown that certain inhalation devices give a better deposition in the lungs and a better clinical effect than other devices, and therefore can be used in lower dosages. It has been decided not to take this aspect into consideration when assigning DDDs in this group, since the picture is very complex and satisfactory comparative documentation is lacking for many substances and devices. Accordingly, only one DDD is assigned for a substance administered by e.g. powder inhalation.

The DDDs for inhalation aerosol and inhalation powder of the same substance are in most cases given the same DDD value. The DDDs for inhalation solutions are, however, different from these and much higher, partly because less amount of the active ingredient will reach the target organ, and partly because this dosage form often is used in more severe and unresponsive asthma.

R03A A *Alpha- and beta-adrenoceptor agonists*

The DDDs are based on therapeutic treatment of asthma.

R03A B *Non-selective beta-adrenoceptor agonists*

The DDDs are based on therapeutic treatment of asthma.

R03A C *Selective beta-2-adrenoceptor agonists*

The DDDs are mainly based on therapeutic treatment of asthma.

R03A H *Combinations of adrenergics*

See comments to R03A K.

R03A K *Adrenergics and other anti-asthmatics*

All adrenergics for inhalation in combination with other anti-asthmatics are classified in this group.

The preparations are classified at 5th levels according to the adrenergic component. At each 5th level different other anti-asthmatics may occur.

The DDDs for combination products are based on treatment of severe asthma. The DDDs for all active ingredients in a combination are taken into consideration.

R03B OTHER ANTI-ASTHMATICS, INHALANTS

This group comprises all anti-asthmatics for inhalation excl. adrenergics (R03 A).

See comment under R03A.

R03B A *Glucocorticoids*

The DDDs are based on prophylactic treatment of asthma.

R03B B *Anticholinergics*

Combinations with adrenergics are classified in R03A K.

The DDDs are based on therapeutic treatment of asthma.

R03B C *Antiallergic agents, excl. corticosteroids*

The DDDs are based on prophylactic treatment of asthma.

DDD for inhalation aerosol and inhalation powder differ in this group, due to differences in dosage recommendations for these dosage forms.

R03B X *Other anti-asthmatics, inhalants*

No DDDs are assigned in this group.

R03C ADRENERGICS FOR SYSTEMIC USE

This group comprises adrenergics for systemic use indicated for bronchial asthma. Sympathomimetics used in the treatment of hypotension, see C01C A. Fenoterol infusion only intended for repression of labour is classified in G02C A. Combinations with xanthines are classified in R03D B. Combinations with other anti-asthmatics are classified in R03C K.

The DDDs are based on treatment of asthma.

R03C A *Alpha- and beta-adrenoceptor agonists*

R03C B *Non-selective beta-adrenoceptor agonists*

Isoprenaline for systemic use is classified in this group only if bronchial asthma is the only indication for the preparation, otherwise in C01C - Cardiac stimulants excl. cardiac glycosides.

R03C C *Selective beta-2-adrenoceptor agonists*

Tretoquinol has a much higher oral DDD than parenteral DDD, because of differences in bioavailability.

R03C K *Adrenergics and other anti-asthmatics*

Combinations of adrenergics and other anti-asthmatics (excl. xanthines, see R03D B) are classified here.

R03D OTHER ANTI-ASTHMATICS FOR SYSTEMIC USE

Theophyllines are classified in this group. Other respiratory stimulants are classified in R07A B - Respiratory stimulants.

Corticosteroids for systemic use, see H02.

Sympathomimetics for systemic treatment of rhinitis, see R01B A.

This group comprises mainly the xanthines. The DDDs for these substances are based on treatment of obstructive lung diseases. The various xanthines have as far as possible been given equipotent DDDs to theophylline.

The DDDs for the combination products classified in this group are mainly based on the DDDs of the xanthine components.

R03D A *Xanthines*

A number of preparations containing e.g. theophylline are classified in this group even if they do not have asthma as an indication.

Combined products of xanthines are given the ATC code R03D A20. Combinations of xanthines and other agents (except adrenergics, see R03D B - Xanthines and adrenergics) are classified at separate 5th levels using the corresponding 50-series (e.g. mucolytics). Combinations with psycholeptics are classified at separate 5th levels using the corresponding 70-series.

R03D B *Xanthines and adrenergics*

All combinations of xanthines and adrenergics are classified in this group.

R03D X Other anti-asthmatics for systemic use

This group comprises preparations which cannot be classified in the preceding groups. E.g. amlexanox is classified here.

R05 COUGH AND COLD PREPARATIONS

This group comprises a large number of preparations, most of which are combined preparations. Cold preparations with therapeutic levels of antiinfectives should be classified in ATC group J - Antiinfectives for systemic use.

Cold preparations with therapeutic levels of analgesics/anti-inflammatory agents should be classified in the respective N02/M01 groups, at separate 5th levels by using the 50-series.

Cold preparations with both antiinfectives and analgesics should be classified in ATC group J - Antiinfectives for systemic use.

Cold preparations with minimal amounts of antiinfectives or analgesics are classified in R05X - Other cold combination preparations.

See also R01 - Nasal preparations, R02 - Throat preparations, and R03D - Other anti-asthmatics for systemic use.

The DDDs for combination products are based on treatment three times daily, and the upper recommended dosages are chosen. The DDDs are given in UD (unit dose), and different strengths are not considered when the DDDs are established.

R05C EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

This group comprises preparations with expectorants and mucolytics.

Combined preparations are classified at separate 5th levels using the code number 10. These may also contain bronchodilating agents, antihistamines etc.

Preparations which contain small amounts of herbal extracts, menthol etc. are regarded as plain preparations.

R05C A *Expectorants*

All combined products of expectorants are classified in R05C A10.

R05C B *Mucolytics*

Mesna in i.v. formulations used for the prophylaxis of urothelial toxicity is classified in V03A F. Mesna used as a mucolytic agent (e.g. administered by a nebuliser) is classified here.

All combined products of mucolytics are classified in R05C B10.

Combinations with xanthines are classified in R03D A.

Combinations with antiinflammatory agents are classified in M01.

For acetylcysteine, the DDD for inhalation solution is higher than for the oral formulation, due to differences in the dosages recommended.

R05D COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

Combined preparations are classified at separate 5th levels using the code number 20. These may also contain bronchodilating agents, antihistamines etc.

Combinations with expectorants, see R05F.

Combinations with xanthines, see R03D A.

Preparations which contain small amounts of herbal extracts, menthol etc., are not regarded as combined preparations.

R05D A *Opium alkaloids and derivatives*

Plain codeine, which is classified in this group, is also used as an analgesic.

All combined products of opium alkaloids and derivatives, are classified in R05D A20.

R05D B *Other cough suppressants*

All combined products of other cough suppressants are classified in R05D B20.

R05F COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS

In addition to cough suppressants and expectorants, the preparations may contain bronchodilating agents, antihistamines etc. Combinations which contain respiratory stimulants, e.g. theophylline, should be classified in R03D A.

R05F A *Opium derivatives and expectorants*

The group is subdivided in:

R05F A01 - Opium derivatives and mucolytics
R05F A02 - Opium derivatives and expectorants

R05F B *Other cough suppressants and expectorants*

The group is subdivided in:

R05F B01 - Cough suppressants and mucolytics
R05F B02 - Cough suppressants and expectorants

R05X OTHER COLD COMBINATION PREPARATIONS

This group comprises cold preparations with various ingredients, which cannot be classified in the preceding groups. Combinations with therapeutic amounts of various ingredients (e.g. quinine as an antipyretic, antihistamines, ascorbic acid and caffeine) are classified in this group. Various remedies for symptomatic relief in cough and cold, e.g. inhalants with menthol, camphora, thymol etc. are also classified here.

No DDDs are established in this group.

R06 ANTIHISTAMINES FOR SYSTEMIC USE

R06A ANTIHISTAMINES FOR SYSTEMIC USE

This group comprises plain and combined antihistamine preparations for systemic use. Antihistamines used in motion sickness are classified in this group. Other preparations used in motion sickness, see A04 - Antiemetics and antinauseants.

See also N07C - Antvertigo preparations.

Combined preparations (incl. combinations with hydroxyzine) are classified at separate 5th levels using the corresponding 50-series. Combinations of antihistamines and psycholeptics are classified at separate 5th levels using the corresponding 70-series.

Combinations of antihistamines are classified at a separate 4th level, R06A K.

Antihistamines are also included in combined preparations classified in other groups:

Combinations with analgesics - N02

Combinations with xanthines - R03D A

Combinations with expectorants - R05C

Combinations with nasal decongestants for systemic use - R01B

Combinations with cough suppressants - R05D

Allergen extracts, see V01.

The group is subdivided according to chemical structure.

The DDDs are established on the basis of the use in allergic diseases. For some of the substances, different dosage forms are given different DDDs, due to differences in bioavailability.

The DDDs for the combination products refer to the DDD of the antihistamine component.

R06A A *Aminoalkyl ethers*

Different DDDs are established for the two salts of diphenhydramine: -chloride and -teoclate (dimenhydrinate).

R06A B *Substituted alkylamines*

R06A C *Substituted ethylene diamines*

R06A D *Phenothiazine derivatives*

R06A E *Piperazine derivatives*

Cinnarizine and flunarizine are classified in N07C - antivertigo preparations.

R06A K *Combinations of antihistamines*

R06A X *Other antihistamines for systemic use*

This group comprises e.g. terfenadine, astemizole, loratadine, thenalidine and cyproheptadine.

R07 **OTHER RESPIRATORY SYSTEM PRODUCTS**

R07A OTHER RESPIRATORY SYSTEM PRODUCTS

This group comprises lung surfactants and respiratory stimulants. Caffeine is classified in N06B - Psychostimulants. See also comments under R07A B - Respiratory stimulants.

R07A A *Lung surfactants*

This group comprises surface-tension lowering agents used in respiratory distress syndrome. Combinations of different lung surfactants are classified in R07A A30.

The DDD of colfosceril palmitate and natural phospholipids are based on treatment of respiratory distress syndrome in neonates, and corresponds to the treatment of children weighing 1.6 kg.

R07A B *Respiratory stimulants*

Centrally acting respiratory stimulants mainly used for asthma and similar respiratory diseases (e.g. theophylline) are classified in R03D. Other respiratory stimulants are classified here. This group includes plain and combined preparations.

Combinations with respiratory stimulants and caffeine are classified in this group. Plain caffeine preparations are classified in N06B Psychostimulants.

This group includes various drugs used on different indications. The DDDs are therefore established individually for each ATC 5th level.

R07A X *Other respiratory system products*

This group comprises preparations used for respiratory disorders which cannot be classified in the preceding groups.

No DDDs are assigned in this group.

S SENSORY ORGANS

S01 OPHTHALMOLOGICALS

A Antiinfectives
B Antiinflammatory agents
C Antiinflammatory agents and antiinfectives in combination
E Antiglaucoma preparations and miotics
F Mydriatics and cycloplegics
G Decongestants and antiallergics
H Local anesthetics
J Diagnostic agents
K Surgical aids
X Other ophthalmologicals

S02 OTOLOGICALS

A Antiinfectives
B Corticosteroids
C Corticosteroids and antiinfectives in combination
D Other otologicals

S03 OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

A Antiinfectives
B Corticosteroids
C Corticosteroids and antiinfectives in combination
D Other ophthalmological and otological preparations

S SENSORY ORGANS

S01 OPHTHALMOLOGICALS

Small amounts of antiseptics in eye preparations do not influence the classification.

See also S03 - Ophthalmological/otological preparations.

DDDs have been assigned for antiglaucoma preparations only.

S01A ANTIINFECTIVES

This group comprises plain and combined antiinfective preparations for ophthalmological use.

Combinations with corticosteroids are classified in S01C A - Corticosteroids and antiinfectives in combination.

S01A A Antibiotics

Combinations of different antibiotics (incl. sulfonamides) are classified at a separate 5th level: S01A A30.

Combinations with other drugs (e.g. sympathomimetics) are classified at a separate 5th level: S01A A20.

Combinations with antiinflammatory agents are classified in group S01C.

S01A B Sulfonamides

Combinations with antibiotics are classified in S01A A.

S01A D Antivirals

S01A X Other antiinfectives

This group comprises preparations for ophthalmological use which cannot be classified in the preceding groups. Products containing

boric acid, also in low strengths, are classified in this group.

S01B ANTIINFLAMMATORY AGENTS

This group comprises all eye preparations with non-steroidal anti-inflammatory agents and corticosteroids, plain and combinations. Combinations with antiinfectives are classified in S01C - Antiinflammatory agents and antiinfectives in combination.

S01B A Corticosteroids, plain

S01B B Corticosteroids and mydriatics in combination

Combinations which in addition contain anticholinergics are classified here.

Combinations which in addition contain antiinfectives are classified in S01C B - Corticosteroids, antiinfectives and mydriatics in combination.

S01B C Antiinflammatory agents, non-steroids

S01C ANTIINFLAMMATORY AGENTS AND ANTIINFECTIVES IN COMBINATION

This group comprises all eye preparations which contain corticosteroids, non-steroidal antiinflammatory agents and antiinfectives. Preparations may also contain additional drugs.

S01C A Corticosteroids and antiinfectives in combination

The preparations are classified according to the corticosteroid. Different antiinfectives may occur at each 5th level.

S01C B Corticosteroids/antiinfectives/mydriatics in combination

This group is built up as S01C A.

S01E ANTIGLAUCOMA PREPARATIONS AND MIOTICS

This group comprises preparations for local and systemic treatment of glaucoma.

Drugs used for producing miosis are classified in this group, even if the main indication is not glaucoma.

The DDDs are based on average recommended therapeutic doses and administration frequencies. A single dose is defined as one eye drop in each eye corresponding to 0.1 ml. In eye ointments one dose corresponds to about 10 mm (20 mg) per eye thus corresponding to 40 mg for both eyes. For single use packages one dose is the volume of one package.

S01E A Sympathomimetics in glaucoma therapy

Preparations containing parasympathomimetics in combination with epinephrine, are classified in S01E B.

The DDDs are established according to the dose of epinephrine.

S01E B Parasympathomimetics

The DDD for pilocarpine lamellas has been obtained by dividing two lamellas by seven days (the recommended dose is 1 lamella /eye/week).

S01E C Carbonic anhydrase inhibitors

The DDDs are based on the average recommended doses in the treatment of chronic glaucoma.

S01E D Beta blocking agents

Combinations of beta blocking agents and other drugs, e.g. pilocarpine, are classified in this group, at separate 5th levels using the corresponding 50-series.

S01E X *Other antiglaucoma preparations*

E.g. guanethidine is classified in this group.

S01F MYDRIATICS AND CYCLOPLEGICS

S01F A *Anticholinergics*

Combinations with sympathomimetics are classified in this group.

Combinations with corticosteroids are classified in S01B B.

S01F B *Sympathomimetics excl. antiglaucoma preparations*

Phenylephrine in high strength is classified in this group, see also S01G A.

Sympathomimetics used in glaucoma therapy, see S01E A.

S01G DECONGESTANTS AND ANTIALLERGICS

This group comprises drugs used to treat symptoms of e.g. allergy.

S01G A *Sympathomimetics used as decongestants*

This group comprises sympathomimetics used as decongestants, plain and in combination. E.g. low strength phenylephrine in combination with other drugs is classified in this group. See also S01F B.

S01G X *Other antiallergics*

E.g. cromoglicic acid is classified in this group.

Combinations of cromoglicic acid and antihistamines are classified by using the 50-series.

S01H LOCAL ANESTHETICS

This group comprises topical drugs used as local anesthetics in the eye.

Local anesthetics for other indications are classified in N01B - Anesthetics, local. Other exceptions, see comments to N01B.

Combinations of local anesthetics and diagnostic agents, e.g. fluorescein, are classified in S01J.

S01H A *Local anesthetics*

S01J DIAGNOSTIC AGENTS

This group comprises topical drugs used for diagnosing diseases in the eye. Mydriatics and cycloplegics used as diagnostic aids are classified in S01F.

Diagnostic agents for systemic use for ophthalmological diagnoses, e.g. fluorescein injection, are classified in V04C X - Other diagnostic agents.

S01J A *Colouring agents*

S01J X *Other ophthalmological diagnostic agents*

S01K SURGICAL AIDS

This group comprises drugs used in ophthalmological surgery.

Miotics are classified in S01E - Antiglaucoma preparations and miotics.

Mydriatics and cycloplegics are classified in S01F.

S01K A *Viscoelastic substances*

Hyaluronic acid injection used during surgical procedures on the eye (e.g. 4-20 mg/ampoule) is classified in this group. Hyaluronic acid

injection for intra-articular administration (e.g. 2.5 mg/ampoule) used in the treatment of arthritis is classified in M09A.

Hypromellose is classified in this group. Hypromellose used as artificial tears is, however, classified in S01X A20.

S01K X *Other surgical aids*

Preparations containing e.g. enzymes (chymotrypsin) for use in eye surgery, are classified in this group.

S01X OTHER OPHTHALMOLOGICALS

This group comprises topical products which cannot be classified in the preceding groups e.g. artificial tears, products for use with contact lenses, drugs against cataract etc.

All products containing boric acid are classified in S01A X - Other antiinfectives.

S01X A *Other ophthalmologicals*

Hypromellose is classified in this group if it is used as artificial tears. See S01K A.

S02 OTOLOGICALS

Small amounts of antiseptics in otological preparations do not influence the classification.

See also S03 - Ophthalmological and otological preparations.

No DDDs are assigned in this group.

S02A ANTIINFECTIVES

This group comprises plain and combined antiinfective preparations for otological use.

Combined preparations are classified at a separate 5th level - S02A A30 - Antiinfectives, combinations. This level includes combinations of different antiinfectives and combinations of antiinfectives/other substances.

Combinations with corticosteroids are classified in S02C - Corticosteroids and antiinfectives in combination.

S02A A *Antiinfectives*

S02B CORTICOSTEROIDS

This group comprises all otological preparations with corticosteroids, plain and combinations, except combinations with antiinfectives. These are classified in S02C - Corticosteroids and antiinfectives in combination.

S02B A *Corticosteroids*

S02C CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

This group comprises all otological preparations which contain corticosteroids and antiinfectives. Preparations may also contain additional drugs.

The preparations are classified at separate 5th levels according to the corticosteroid.

S02C A *Corticosteroids and antiinfectives in combination*

S02D OTHER OTOLOGICALS

This group comprises ear preparations which cannot be classified in the preceding groups.

S02D A *Analgesics and anesthetics*

This group comprises e.g. preparations with analgesics and local anesthetics.

S02D C *Indifferent preparations*

This group comprises e.g. oil-preparations used to remove ear wax.

S03 OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

This group comprises preparations which can be used in both eye and ear.

Small amounts of antiseptics in eye/ear preparations do not influence the classification.

No DDDs ar assigned in this group.

S03A ANTIINFECTIVES

S03A A *Antiinfectives*

This group comprises plain and combined antiinfective preparations for use in eye/ear.

Combined preparations are classified at a separate 5th level, S03A A30 - Antiinfectives, combinations. This level includes combinations of different antiinfectives and combinations of antiinfectives and other substances.

Combinations with corticosteroids are classified in S03C - Corticosteroids and antiinfectives in combination.

S03B CORTICOSTEROIDS

This group comprises all eye/ear preparations with corticosteroids, plain and combinations, except combinations with antiinfectives.

These are classified in S03C - Corticosteroids and antiinfectives in combination.

S03B A *Corticosteroids*

S03C CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

This group comprises all eye/ear preparations which contain corticosteroids and antiinfectives. Preparations may also contain additional drugs.

The preparations are classified according to the corticosteroid.

S03C A *Corticosteroids and antiinfectives in combination*

S03D OTHER OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

This group comprises eye/ear preparations which cannot be classified in the preceding groups.

V VARIOUS

V01 ALLERGENS

A Allergens

V03 ALL OTHER THERAPEUTIC PRODUCTS

A All other therapeutic products

V04 DIAGNOSTIC AGENTS

B Urine tests
C Other diagnostic agents

V06 GENERAL NUTRIENTS

A Diet formulations for treatment of obesity
B Protein supplements
C Infant formulas
D Other nutrients

V07 ALL OTHER NON-THERAPEUTIC PRODUCTS

A All other non-therapeutic products

V08 CONTRAST MEDIA

A X-ray contrast media, iodinated
B X-ray contrast media, non-iodinated
C Magnetic resonance imaging contrast media
D Ultrasound contrast media

V09 DIAGNOSTIC RADIOPHARMACEUTICALS

A Central nervous system
B Skeleton
C Renal system
D Hepatic and reticulo endothelial system
E Respiratory system
F Thyroid
G Cardiovascular system
H Inflammation and infection detection
I Tumour detection
X Other diagnostic radiopharmaceuticals

V10 ***THERAPEUTIC RADIOPHARMACEUTICALS***

A Antiinflammatory agents

B Pain palliation (bone seeking agents)

X Other therapeutic radiopharmaceuticals

V VARIOUS

This group comprises many different types of drugs, and the assigning of DDDs are difficult. Very few DDDs are assigned in this group.

V01 ALLERGENS

V01A ALLERGENS

V01A A Allergen extracts

This group comprises preparations mainly used in hyposensitization. Preparations for diagnostic use, e.g. prick and scratch tests, are classified in V04C L.

This group is divided according to type of allergen, e.g. grass pollen, tree pollen, fungi etc.

V03 ALL OTHER THERAPEUTIC PRODUCTS

V03A ALL OTHER THERAPEUTIC PRODUCTS

The only DDDs assigned in this group are for calcium folinate, levofolinate and yohimbine.

V03A A Drugs for treatment of chronic alcoholism

V03A B Antidotes

Hydroxocobalamine which is also used as a cyanide antidote is classified in B03B A.

Medicinal charcoal is classified in A07B A.

Atropine is classified in A03B A.

Penicillamine which is also used in copper poisoning, is classified in M01C C.

Silibinin which is also used in amanita poisoning, is classified in A05B A at the same 5th level as silymarin.

Anticholinesterases which are used as curare antidotes, are classified in N07A A.

Clonidine low strength tablets (e.g. 25 μg) are classified in N02C X, even if the indication also may be "opioid withdrawal symptoms".

V03A C *Iron chelating agents*

V03A E *Drugs for treatment of hyperkalemia*

V03A F *Detoxifying agents for cytostatic treatment*

Mesna in i.v. formulations used for the prophylaxis of urothelial toxicity is classified in this group. Mesna used as a mucolytic agent (e.g. administered by a nebuliser) is classified in R05C B.

The DDD for calcium folinate and calcium levofolinate is based on the combined treatment with high doses of methotrexate.

V03A G *Drugs for treatment of hypercalcemia*

Sodium cellulose phosphate is classified here.
See also M05 - Drugs for treatment of bone diseases.

V03A H *Drugs for treatment of hypoglycemia*

Oral preparations containing diazoxide for treatment of hypoglycemia, are classified in this group, while preparations used for treatment of hypertension, are classified in C02D A.

V03A K *Tissue adhesives*

V03A M *Drugs for embolisation*

V03A X *Other therapeutic products*

This group comprises agents which cannot be classified in the preceding groups, e.g. yohimbin.

The DDD for yohimbin is based on treatment of impotence.

V03A Z *Nerve depressants*

V04 **DIAGNOSTIC AGENTS**

V04B URINE TESTS

V04C OTHER DIAGNOSTIC AGENTS

V04C A *Tests for diabetes*

V04C B *Tests for fat absorption*

V04C C *Tests for bile duct patency*

Pancreocymin is classified in V04C K.

V04C D *Tests for pituitary function*

See also V04C M - Tests for fertility disturbances.

V04C E *Tests for liver functional capacity*

V04C F *Tuberculosis diagnostics*

V04C G *Tests for gastric secretion*

V04C H *Tests for renal function*

V04C J *Tests for thyreoidea function*

V04C K *Tests for pancreatic function*

V04C L *Tests for allergic diseases*

See also V01.

V04C M *Tests for fertility disturbances*

V04C X *Other diagnostic agents*

V06 **GENERAL NUTRIENTS**

This group comprises nutrients for oral use, incl. preparations used in feeding with stomach tube. Solutions for parenteral nutrition are classified in B05B A.

V06A DIET FORMULATIONS FOR TREATMENT OF OBESITY

See also A08 - Antiobesity preparations, excl. diet products.

V06A A *Low-energy diets*

V06B PROTEIN SUPPLEMENTS

V06C INFANT FORMULAS

This group comprises preparations used in metabolic disorders. Milk substitutes are classified V06D F.

V06C A *Nutrients without phenylalanine*

V06D OTHER NUTRIENTS

This group comprises a major part of the general nutrients.

V06D A *Carbohydrates/proteins/minerals/vitamins, combinations*

V06D B *Fat/carbohydrates/proteins/minerals/vitamins, combinations*

V06D C *Carbohydrates*

V06D D *Amino acids, incl. combinations with polypeptides*

V06D E *Amino acids/carbohydrates/minerals/vitamins, combinations*

V06D F *Milk substitutes*

This group comprises milk substitutes used in persons with milk allergy.

V06D X *Other combinations of nutrients*

V07 ALL OTHER NON-THERAPEUTIC PRODUCTS

V07A ALL OTHER NON-THERAPEUTIC PRODUCTS

This group comprises e.g. solvents, diluents and solutions for blood transfusion products. Auxiliary products for performing medical examinations, e.g. plain exploration creams and lubricants, are also classified in this group.

V07A A *Plasters*

Non-medicated adhesive plasters, surgical tapes etc. are classified in this group.

Medicated dressings are classified in D09.

V07A B *Solvents and diluting agents, incl. irrigating solutions*

This group comprises sterile water preparations and solvents for diluting or dissolving active substances, e.g. allergen extracts.

V07A C *Blood transfusion, auxiliary products*

Citric acid/citrate/dextrose (ACD) solutions and similar products are classified in this group.

V07A D *Blood tests, auxiliary products*

Solutions used as diluents or transport media for blood samples are classified in this group.

V07A N *Incontinence equipment*

V07A R *Sensitivity tests, discs and tablets*

E.g. antibiotic discs may be classified in this group.

V07A S *Stomi equipment*

V07A T *Cosmetics*

V07A V *Technical disinfectants*

V07A X *Washing agents etc.*

V07A Y *Other non-therapeutic auxiliary products*

Exploration creams and lubricants are classified in this group. Creams which contain antiseptics, are classified in D08 - Antiseptics and disinfectants.

Preparations only used as negative contrast media in double-contrast radiography, containing e.g. bicarbonates or hypromellose are classified in this group.

V07A Z *Chemicals and reagents for analysis*

V08 CONTRAST MEDIA

This group comprises X-ray, MRI and Ultrasound contrast media. The X-ray contrast media are subdivided into iodinated and non-iodinated compounds, and are further classified according to water solubility, osmolarity and nephrotropic/hepatotropic properties. High osmolar substances correspond mainly to ionic substances, except from ioxaglic acid which are classified together with the non-ionic substances. MRI contrast media are subdivided according to magnetic properties.

V08A X-RAY CONTRAST MEDIA, IODINATED

V08A A Watersoluble, nephrotropic, high osmolar X-ray contrast media

V08A B Watersoluble, nephrotropic, low osmolar X-ray contrast media

V08A C Watersoluble, hepatotropic X-ray contrast media

V08A D Non-watersoluble X-ray contrast media

V08B X-RAY CONTRAST MEDIA, NON-IODINATED

V08B A Barium sulphate containing X-ray contrast media

V08C MAGNETIC RESONANCE IMAGING CONTRAST MEDIA

V08C A Paramagnetic contrast media

V08C B Superparamagnetic contrast media

V08C X Other magnetic resonance imaging contrast media

V08D ULTRASOUND CONTRAST MEDIA

V08D A Ultrasound contrast media

V09 DIAGNOSTIC RADIOPHARMACEUTICALS

An expert group consisting of Dik Blok (the Netherlands), Per Oscar Bremer (Norway) and Trygve Bringhammar (Sweden) is responsible for the ATC classification of radiopharmaceuticals in V09 and V10. The group has also prepared the guidelines for classification of these products.

Radiopharmaceuticals for diagnostic use are classified in this group, while radiopharmaceuticals for therapeutic use are classified in V10. In general, the 3rd level are subdived according to site of action or organ system, the 4th level according to radionuclide and the 5th

level specifies the chemical substance. The ATC 5th level defines the actual form essential in nuclear medicine procedures, which includes radionuclide and carrier molecule. Therefore, products on the market, that can often be regarded as intermediate products rather than ready-to-use radiopharmaceuticals, can be given more than one (5th level) ATC-code, e.g. ^{99m}Tc-technetium-exametazime (V09A A01) and ^{99m}Tc-technetium-exametazime labelled cells (V09H A02).

No DDDs have been assigned for radiopharmaceuticals.

V09A CENTRAL NERVOUS SYSTEM

This group comprises preparations used in CNS investigations in diagnostic nuclear medicine.

V09A A *^{99m}Tc-technetium compounds*

V09A B *^{123}I-iodine compounds*

V09A X *Other central nervous system diagnostic radiopharmaceuticals*

V09B SKELETON

This group comprises preparations used in bone imaging. Radiopharmaceuticals used for the investigation of bone marrow are classified in V09D - Hepatic and Reticulo Endothelial System.

V09B A *^{99m}Tc-technetium compounds*

This group comprises various technetium bisphosphonates and pyrophosphate.

V09C RENAL SYSTEM

This group comprises preparations used for the visualisation of kidneys and urinary tract and preparations for functional studies of the renal system.

V09C A *^{99m}Tc-technetium compounds*

This group comprises technetium compounds given intravenously. Technetium compounds used in aerosols for inhalation are classified in V09E - Respiratory system.
Technetium-succimer prepared as 'pentavalent' is classified in V09I - Tumour detection.

V09C X *Other renal system diagnostic radiopharmaceuticals*

V09D HEPATIC AND RETICULO ENDOTHELIAL SYSTEM

This group comprises radiopharmaceuticals used for the imaging of liver, gall bladder, lymphatic system and bone marrow.

V09D A *^{99m}Tc-technetium compounds*

This group contains technetium iminodiacetic acid derivatives for cholescintigraphy.

V09D B *^{99m}Tc-technetium, particles and colloids*

This group contains technetium colloidal and particle containing preparations for the scintigraphy of liver, spleen, lymphatic system and bone marrow. Also orally administered preparations used for gastrointestinal tract imaging (gastric emptying, reflux etc.) are classified in this group.

Preparations containing larger particles that are used for lung perfusion studies are classified in V09E - Respiratory system.
Denatured labelled erythrocytes for spleen scintigraphy are classified in V09G - Cardiovascular system.

V09D X *Other hepatic and reticulo endothelial system diagnostic radiopharmaceuticals*

V09E RESPIRATORY SYSTEM

This group comprises radiopharmaceuticals for the lung ventilation and lung perfusion studies.

V09E A *^{99m}Tc-technetium, inhalants*

Technetium preparations for inhalation are classified in this group. Preparations with other indications when given intraveneously are classified according to such indications, e.g. technetium-pentetate is classified in V09C - Renal system.

V09E B *^{99m}Tc-technetium, particles for injection*

Preparations containing smaller particles or colloids that are used for RES function are classified in V09D - Hepatic and Reticulo Endothelial System.

V09E X *Other respiratory system diagnostic radiopharmaceuticals*

V09F THYROID

This group comprises radiopharmaceuticals used for thyroid imaging. Thalliumchloride and technetium-sestamibi used for parathyroid imaging are classified in V09G - Cardiovascular system.

V09F X *Various thyroid diagnostic radiopharmaceuticals*

Technetium-pertechnetate used for the scintigraphy of salivary glands and Meckels diverticulum is classified in this group. Technetium-pentavalent succimer used in medullary thyroid carcinoma is classified in V09I - Tumour detection. ^{131}I-iodine-sodiumiodide in low dose is classified here. ^{131}I-iodine-sodiumiodide in high dose for therapy is classified in V10X - Other therapeutic radiopharmaceuticals.

V09G CARDIOVASCULAR SYSTEM

This group comprises radiopharmaceuticals for myocardial scintigraphy, ejection fraction measurements, and vascular disorders.

V09G A *^{99m}Tc-technetium compounds*

Labelled cells (erythrocytes) for the investigation of cardiovascular function are classified in this group. No subdivision is made for in

vitro or in vivo labelling. Pertechnetate for thyroid imaging is classified in V09F - Thyroid.

V09G B *^{125}I-iodine compounds*

V09G X *Other cardiovascular system diagnostic radiopharmaceuticals*

V09H INFLAMMATION AND INFECTION DETECTION

This group comprises agents for the detection of inflammation and infection. Labelled blood cells are classified in this group. Agents that are used for the labelling of these cells can also be classified elsewhere, e.g. technetium-exametazime is classified in V09A - Central Nervous System. No subdivision is made for the type of labelled cells (erythrocytes, granulocytes or autologous etc.).

V09H A *^{99m}Tc-technetium compounds*

V09H B *^{111}In-indium compounds*

V09H X *Other diagnostic radiopharmaceuticals for inflammation and infection detection*

V09I TUMOUR DETECTION

This group comprises monoclonal antibodies and other compounds used for tumour detection.

V09I A *^{99m}Tc-technetium compounds*

V09I B *^{111}In-Indium compounds*

V09I X *Other diagnostic radiopharmaceuticals for tumour detection.*

Gallium-citrate used for non-specific tumour localisation is classified in V09H - Inflammation and infection detection. Thallium-chloride used for tumour detection is classified in V09G - Cardiovascular system. ^{131}I-iodine-iobenguane in low dose is classified here while high dose for therapy is classified in V10X - Other therapeutic radiopharmaceuticals.

V09X OTHER DIAGNOSTIC RADIOPHARMACEUTICALS

This group contains various diagnostic radiopharmaceuticals which cannot be classified in the preceding groups.

V09X A *^{131}I-iodine compounds*

V09X X *Various diagnostic radiopharmaceuticals*

V10 THERAPEUTIC RADIOPHARMACEUTICALS

Radiopharmaceuticals for therapeutic use are classified in this group, while radiopharmaceuticals for diagnostic use are classified in V09.

See comments to V09.

V10A ANTIINFLAMMATORY AGENTS

This group comprises radiopharmaceuticals for the therapy of inflammatory processes.

V10A A *^{90}Y-yttrium compounds*

In this group yttrium colloidal preparations used for radiation synovectomy are classified.

V10A X *Other antiinflammatory therapeutic radiopharmaceuticals*

This group comprises non-yttrium particulate radiopharmaceuticals for radiation synovectomy and intracavitary instillation.

V10B PAIN PALLIATION (BONE SEEKING AGENTS)

This group comprises therapeutic radiopharmaceuticals used for pain palliation in bone malignancies.

V10B X *Various pain palliation radiopharmaceuticals*

V10X OTHER THERAPEUTIC RADIOPHARMACEUTICALS

This group contains various therapeutic radiopharmaceuticals which cannot be classified in the preceding groups.

V10X A *^{131}I-iodine compounds*

^{131}I-iodine sodiumiodide in low dose for diagnostic nuclear medicine is classified in V09F - Thyroid.
^{131}I-iodine iobenguane in low dose for diagnostic nuclear medicine is classified in V09I - Tumour detection.

V10X X *Various therapeutic radiopharmaceuticals*

V20 SURGICAL DRESSINGS

A detailed classification of surgical dressings is prepared and maintained by the Ministry of Defence in the UK. Further information can be obtained from:

Ministry of Defence
Medical Supply Branch
First Avenue House
High Holborn
London WC1V 6HE
United Kingdom

Att.: Paul Clark