



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



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**WHO PROPOSAL FOR REVISING  
THE WHO MODEL LIST OF ESSENTIAL DRUGS:  
DISCUSSION OF THE PROCESS FOR INVOLVING MEMBER STATES**

*(Proposed by the Government of the United States of America)*

**1. Revision of the World Health Organization (WHO) Model List of Essential Drugs.**

The World Health Organization (WHO) Model List of Essential Drugs has over the past 25 years served as an excellent tool for assisting Member States to develop their own national essential drug lists. It represents an excellent example of WHO's normative role. As with every good practice it is useful to review whether it can be improved. A major revision of the practice to be followed in revising the procedures for updating the Model list is being proposed. We believe that this process must have maximum input from Member States.

**2. Background**

The World Health Organization Model List of Essential Drugs (EDL) has contributed greatly to public health care in many countries in the Americas and elsewhere, and is widely acknowledged as one of WHO's most successful programs. The WHO/EDL has been critical in establishing and promoting the concept of essential drugs, now adopted and adapted globally. Both the methodology of the selection process and the contents of the list itself have served as very useful models. Although the List is not a global standard, it provides important guidance for developing national and institutional essential drugs lists. By the end of 1999, 156 Member States had an official national essential drugs list, of which 127 had been updated in the previous five years. Many national lists are linked to clinical guidelines, are used for training and supervision, and indicate the public health priorities for national pharmaceutical systems.

The WHO Expert Committee has updated the Model List every two years since 1977, and the latest revision took place in November 1999. The current 11<sup>th</sup> Model List contains 306 active ingredients and is divided into a main list and a complementary list.

A WHO Expert Committee in 1999 decided that the EDL was in need of revision, and recommended that, as a matter of urgency, an overall review of the methodology of decision-making by the Committee be carried out.

### **3. Recent Developments**

Subsequent to the Expert Committee's discussions, a private "brainstorming" session hosted by a nongovernmental organization took place in September 2000 and an ad hoc Committee meeting was organized by the WHO staff of Health Technology and Pharmaceuticals (HTP), in March 2001 in Geneva, Switzerland. A several page Information Document was prepared for the May 2001 Executive Board (EB)<sup>1</sup> A very brief discussion was held and the EB members asked that they be involved more directly in the substance of this issue. HTP staff then completed a document entitled "Updating and Disseminating the WHO Model List of Essential Drugs: The Way Forward."<sup>2</sup> The document was first circulated to Member States in June 2001, with comments requested by July 30, 2001. While a small number of Member States has submitted written comments, there has been no opportunity to discuss this major proposal within WHO governing bodies or at the Regional levels, and the active involvement of Member States has so far been missing in the revision process.

### **4. A Further Role for Member States**

Given the EDL's critical importance especially to primary health care, any proposed plan to make fundamental changes to the criteria, guidelines and procedures for selecting drugs and maintaining the EDL must be undertaken deliberately and with caution. Some of the proposals for changing the current EDL are major departures from past practice and can have wide-ranging implications for Member States. The EDL revision process not only requires, but could greatly benefit from, the active participation and input from Member States, including advice from national drug regulatory authorities. Member States must adopt and strongly support any resulting changes from the WHO/EDL revision process for them to be effective and embraced at national levels.

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<sup>1</sup> Document EB 108/Inf. Doc./2, May 2001.

<sup>2</sup> Updating and Disseminating the WHO Model List of Essential Drugs: The Way Forward, WHO, Geneva, May 2001.

## **5. Guidance and Involvement of the Regional Committees**

Given the importance of the issue, it would be appropriate for the Regional Committees to express their opinions as to the method of moving this process forward. The following are some of the issues that might be considered.

- (a) Should the procedures for selecting drugs for and maintaining the WHO Model List of Essential Drugs (EDL) be changed?
- (b) If change is envisaged that might lead to improvement, what is the best way for Member States to become involved in this process, both at national levels and in partnership with WHO?
- (c) What are possible recommendations for WHO regarding the management and coordination of a proposed EDL revision process?
- (d) Given the importance of the process, we submit that proposals for the management and coordination of the EDL revision process should be presented to and discussed by the Executive Board and approved by the World Health Assembly.

## **6. Action by the Directing Council**

The Directing Council is being asked to express its opinion on this issue and give its support.