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Revised procedures for updating the WHO Model List of Essential Drugs: a summary of proposals and process

1. Essential drugs are those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.¹
2. The WHO Model List of Essential Drugs serves as a model for the selection of drugs on the basis of comparative efficacy and safety, quality and consideration of cost. Every two years since 1977 it has been updated by the WHO Expert Committee on the Use of Essential Drugs, consisting of experienced scientists and clinicians from all regions of the world. The last revision took place in November 1999. The current (eleventh) model list contains 306 active ingredients and is divided into a main list and a complementary list. There is a separate category of “reserve antimicrobials”, which are useful for a wide range of infections but which cannot be recommended for unrestricted use.
3. The list is a model for national and institutional essential drugs lists. By the end of 1999, 156 Member States had an official national list of essential drugs, of which 127 had been updated in the past five years. None is the same as the WHO model list. Many national lists are linked to national standard treatment guidelines used for training and supervision, and serve as a guide for drug supply in the public sector, drug benefits within reimbursement schemes, drug donations and local production.
4. About 250 of the 306 active substances on the eleventh model list are included in WHO standard treatment guidelines, and 55 are in the interagency New Emergency Health Kit, which provides drugs and medical supplies for 10 000 people for about three months. All drugs on the model list are included in the WHO Model Formulary, and are a priority for inclusion in *The International Pharmacopoeia* and the *Basic Tests* series of publications.
5. The following **selection criteria** have been used for inclusion of drugs on the model list: sound and adequate data of efficacy and safety from clinical studies; evidence of performance in different health care settings; availability in a form in which adequate quality, including bioavailability, can be assured; stability in the anticipated conditions of storage and use; and total cost of the treatment; a preference for single compounds. Where drugs appear to be similar in the above respects, comparative pharmacokinetic properties and the availability of facilities for manufacture and/or storage are used as secondary criteria.

¹ The Use of Essential Drugs, Ninth Report of the WHO Expert Committee, Technical Report Series, No. 895, 2000.

6. For nearly 25 years the model list has been one of WHO's most powerful public health tools. However, in recent years it has become the subject of discussion:

- the range of disease for which essential drugs are selected is not clear;
- the selection criteria are insufficiently clear; the choice of essential drugs has been based more on experience than evidence; the influence of cost considerations is not clear;
- there are discrepancies between the model list and WHO treatment guidelines;
- drugs are included for which there is no pharmacopoeial standard or no supplier;
- the reasons underlying the recommendations of the Expert Committee are insufficiently recorded; and
- the reports of the Expert Committee have not been published on a timely basis.

PROPOSED REVISIONS IN THE PROCEDURES FOR UPDATING AND DISSEMINATING THE MODEL LIST

7. At its meeting in 1999, the Expert Committee reviewed these issues and recommended that the methods of updating and disseminating the model list be revised. The model list should be not only a model *product*, indicating the most cost-effective drugs for priority diseases, but also a model *process*, as an example for national and institutional committees.

8. An informal consultation, which included an open session with delegations from Member States, was held in March 2001 to pursue the recommendations of the 1999 meeting of the Expert Committee and to formulate a discussion paper. A draft of this paper, entitled "Updating and disseminating the WHO Model List of Essential Drugs: the way forward", makes the following major recommendations:

- (a) the definition of essential drugs (see paragraph 1 above) does not need to be changed;
- (b) the model list should continue to contain a **core list**, which should indicate the minimum drug needs for a basic health care system – and a **complementary list**, which should list drugs for priority diseases that are cost-effective but not necessarily affordable, or that may need special diagnostic or therapeutic skills and/or facilities;
- (c) the process of updating the model list should become more systematic and transparent, with a standardized format for applications, a systematic review of comparative efficacy, safety and cost-effectiveness, and an external review of the applications. The systematic reviews and the draft recommendations should be made available before the meetings of the Expert Committee;
- (d) the report of the Expert Committee should specify the reasons for its recommendations, link them to WHO clinical guidelines, and summarize the underlying evidence. The report and the model list should be published both electronically and in hard copy;

(e) several sections of the existing model list should be reviewed systematically and in close collaboration with the relevant WHO programmes, drawing on the expertise of relevant WHO Expert Advisory Panels. This process will require additional Expert Committee meetings;

(f) an essential drugs library should be created on the WHO web site, which should include at least: summaries of WHO clinical guidelines for priority diseases; the model list, with reasons for inclusion of drugs, with linked references to systematic reviews, WHO clinical guidelines and cost information; the WHO Model Formulary; and quality assurance information such as **Basic Tests**, the International Pharmacopoeia and reference standards.

(g) as the health care industry and patient advocacy groups could contribute to the work of the Expert Committee with relevant technical and other information as needed, consideration should be given to the question of whether their representatives could attend the meetings of the Committee as observers.

OUTLINE OF THE GLOBAL REVIEW PROCESS

9. The timetable of the review process so far and planned next steps are set out below:

- November 1999 – the Expert Committee on the Use of Essential Drugs recommended revising the process of updating the model list, linking it as much as possible to WHO clinical guidelines;
- January 2000 – WHO Cabinet discussed procedures for developing evidence-based WHO treatment guidelines;
- May-December 2000 – a database of WHO treatment guidelines was developed and summaries of drug treatment guidelines were prepared;
- August 2000 – a document on recommended processes for the Development of WHO practice guidelines was drafted;
- March 2001 – an informal expert consultation, with an open session for Member States was held in order to formulate the discussion paper on updating and disseminating the model list;
- May 2001 – an information document was prepared for the Executive Board summarizing the proposals and review process;
- June-July 2001 – a discussion paper “Updating and disseminating the WHO Model List of Essential Drugs: the way forward” will be made available for review by all stakeholders, including Member States, United Nations bodies, World Bank, members of relevant WHO Expert Advisory Panels, nongovernmental organizations and pharmaceutical industries; comments will be expected by 30 July 2001;
- June 2001 – discussion at the WHO Meeting of Interested Parties;
- September 2001 – WHO Cabinet discussion of recommendations for new procedures of updating the model list;

- October 2001 – discussion at the Expert Committee on the Use of Essential Drugs;
- January 2002 - discussion at the 109th session of the Executive Board.

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