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 RATIONAL USE OF DRUGS

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THE RATIONAL USE OF DRUGS: ISSUES SUGGESTED FOR CONSIDERATION<sup>1</sup>

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<sup>1</sup> This paper has been arrived at following consultation with the Peer Review Group. It is stressed that these issues are being suggested solely for the consideration of the Conference; no preconceived conclusions have been reached. This paper is therefore for the internal use of the Conference and no public statement should be made about it or its contents, nor should any suggestions contained in it be attributed to WHO, before the Conference.

THE RATIONAL USE OF DRUGS: ISSUES SUGGESTED FOR CONSIDERATION

1. The world drug situation could be improved by properly applying the existing array of measures available (see Working Paper WHO/CONRAD/WP/RI). Nevertheless, a number of issues that follow are suggested for particular consideration in view of their potential capacity to increase rationality in the use of drugs.

National drug policies

2. Governments that have not already done so could formulate and implement a national drug policy, for example as outlined in document WHO/CONRAD/WP/RI paragraph 7.

Drug information and education and training for rational drug use

3. The following are some possible ways of rendering drug information more objective, less biased and more accessible to prescribers and consumers.

4. Governments might consider setting up national consensus groups to monitor the objectivity and completeness of drug information disseminated by governments, industry, or consumer organizations. Such groups might be composed of members from governments, industry, the academic community, drug prescribers, professional nongovernmental organizations, and consumer organizations, and would conform with the information in approved product monographs issued by the regulatory authority. WHO should support Member States on request in setting up such mechanisms.

5. Governments that have not already done so may find it useful to prepare national drug formularies or at least national drug data sheets.

6. WHO should intensify its preparation and dissemination of drug data sheets for essential drugs for medical practitioners, pharmacists, nurses and nonprofessional health workers. Agreement on the information in such data sheets could be reached by, for example, using the Delphi method among panels of experts for different therapeutic categories. WHO should also actively support governments in preparing drug formularies or data sheets based on the model list of essential drugs.

7. Better use should be made of professional journals for the dissemination of complete and unbiased information on drugs. Editors should assume responsibility for ensuring that the information conforms with approved product monographs. Professional journals could also use information from national or WHO drug bulletins, the latter being translated into local languages; governments should be ready to assist journals in covering the costs involved.

8. In developed countries computerized drug information systems could be made easily accessible to prescribers and dispensers, the information content being controlled in the manner described in paragraph 4 above to ensure that it is complete and unbiased.

9. Pharmacists could assume a greater role in ensuring the provision of complete and unbiased information. Financial and other incentives could be given to them in some countries to encourage them to assume such a role.

10. Governments, nongovernmental organizations, and consumer groups should take measures to improve the quality of the information provided to the public. Thus they could supply information that conforms with approved product monographs in an attractive form. They could do this using modern communication techniques through the mass media, government-sponsored programmes, publications of consumer groups, and inclusion of the subject in general education in schools and universities.

11. Existing national and international measures should be reviewed for ensuring information on the long-term effects of drugs, particularly for chronic conditions, as well as the dissemination to health care providers and the public of information on adverse reactions and on withdrawals for whatever reason.

12. National drug regulatory authorities could consider what additional measures they need to take to make their decisions more widely known both domestically and internationally through WHO. For example, they might:

12.1 publish the reasons for regulatory decisions in extenso, including restrictive and negative reasons, making sure that any information that has to be kept confidential for any reason is reduced to the legal minimum;

12.2 formally designate a WHO liaison (or information) officer with a defined responsibility to ensure effective transfer and utilization of information in accordance with relevant World Health Assembly resolutions;

12.3 ensure that WHO is notified of the voluntary withdrawal of products by manufacturers when such action is taken for reasons of safety;

12.4 provide information to WHO, in compliance with United Nations General Assembly resolution 37/137, on drugs manufactured domestically that are available for export but have not been approved for use on the domestic market;

12.5 ensure that developing countries have ready access to independently validated information both through the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and through the distribution of national compendia containing approved information on drugs to other regulatory authorities.

13. WHO could take the following additional measures to ensure the international availability of complete and unbiased information.

13.1 It might publish the Drug information bulletin more frequently and extend its scope by including more information on the determinants of national regulatory decisions, on teaching and learning materials, and on economic and financial aspects, and by incorporating a questions and answers section and book reviews.

13.2 It could give more active support to countries wishing to draw up national formularies by publishing monographs on selected therapeutic categories based on broad consultation with those interested, including governments, industry, the academic world, drug prescribers, and consumer organizations.

13.3 WHO could organize meetings of the parties concerned to seek agreement on important issues, in addition to presenting the different viewpoints as it now does in the Drug information bulletin.

14. National regulatory authorities with limited resources might consider to what extent existing international collaborative mechanisms provide a basis for drug assessment, thereby releasing national resources for the screening and adaptation of information that will determine the subsequent use of the drugs registered.

15. Since efficient international communication on drugs is dependent on a globally accepted system for designating international nonproprietary names (INNs), and is compromised unless all countries are legally entitled to refuse applications for trademarks that are similar to INNs, countries that have not already done so

might consider instituting this safeguard and creating effective liaison between the national drug regulatory authority and the office responsible for the registration of trademarks.

16. Governments, universities, and nongovernmental organizations - both national and international - could reconsider their responsibility for improving the training of different categories of health workers in the rational use of drugs. In developing countries, further measures should be taken to ensure that non-professional primary health care workers are properly trained in the use of drugs. For example, each country might work out its own training programme; learning material already prepared in other countries could be a useful starting point; and support could be provided by first referral level personnel; WHO should actively support the above endeavours by making available appropriate learning material and helping countries to use it.

17. Improvements in training in the use of drugs might include making the information more assimilable and using modern educational technology. Emphasis might be placed on the main principles of drug action and drug use, the study of important representative drugs in each therapeutic category, methods of selecting from among similar preparations, taking account of social and economic factors, methods of evaluating published claims of efficacy and safety, and the concept of essential drugs.

#### Drug marketing

18. The following are some possible ways of improving drug marketing.

19. Governments that have not already done so should assume responsibility for ensuring that the drugs available in the country are of acceptable quality, safety, and efficacy, using for that purpose such means as: registration or licensing, the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and information provided by major national drug control authorities concerning the approval or non-approval of drugs.

20. Developing countries unable to establish comprehensive drug registration systems could at least create simple administrative procedures for the identification and listing of marketed drugs so as to be able to monitor and control their marketing. A basic multipurpose model system for smaller developing countries might be developed, complementary to the WHO Certification Scheme for the Quality of Pharmaceutical Products Moving in International Commerce and providing for the identification of priority needs, the rationalization of procurement, the assurance of quality, and the establishment of information standards with which all promotional activities must comply.

21. WHO should provide Member States on request with the information they need to decide on the regulatory option most suitable for them, depending for example on whether they have research-based pharmaceutical companies or not, rely entirely on imports, or produce certain drugs but rely mainly on imports. It should utilize its lead role in the International Conference of Drug Regulatory Authorities to ensure the maximum exchange of information on drug regulation and encourage Member States that do not already do so to participate in the meetings.

22. The feasibility should be studied of establishing international norms for labelling drugs, including a study of appropriate ways of combining clarity with comprehensiveness. WHO should assume responsibility for such a study.

23. Governments could consider the most appropriate measures to ensure that drugs cost as little as possible consistent with acceptable quality and ensured availability. This could be achieved for example through free market forces,

government intervention, a Keynesian combination of free market forces and government intervention, the fixation of a reasonable margin of profit for the public and private domestic sectors with respect to "drug research and development countries" and "non drug research and development countries", fixation of a reasonable margin of profit from import through wholesale to retail, fixation of norms for the costs of distribution in the public and private domestic sector, bulk purchase and related packaging within individual countries or for a number of countries taking account of overhead costs, and the control of transfer pricing of raw materials and finished products.

24. To procure drugs internationally at the lowest possible cost for the public sector, governments could make more extensive use of open competitive tenders for generic drugs with accompanying quality control, as part of a national essential drugs programme. WHO and UNICEF should give active support.

25. Governments could consider measures to recover in whole or in part the costs of drugs in the public sector as part of their overall arrangements for financing health care. Consonant with the country's budgeting and financing practices and people's capacity to pay, this might include for example recovery of costs as part of health insurance schemes, drug insurance schemes, community drug cooperatives or taxation.

26. Governments that have not already done so should decide who should have the right to prescribe, distribute, and sell drugs. For example, in addition to the right of medical practitioners to prescribe, dentists could be authorized to prescribe specified drugs used in dentistry; in some countries pharmacists and nurses in the public sector could be authorized to prescribe specified drugs in the absence of a qualified medical practitioner, and non-professional primary health care workers to prescribe from a short list of drugs made available in the community. Governments could ensure that drug distribution is directed and supervised by a responsible person possessing the necessary managerial capacity. Some governments may find it necessary to authorize the sale of drugs not only by licensed pharmacists but also by other vendors in rural areas, for example village shops or community cooperatives, possibly under the guidance and supervision of the first referral level. National and international nongovernmental organizations could be more active in ensuring that their members abide by the regulations in force concerning the right to prescribe, distribute, and sell drugs.

27. Governments that have not already done so could establish lists of drugs authorized for sale over the counter without prescription and define who, if anyone, in addition to pharmacists should be permitted to sell them:

28. Any legal measures that governments take concerning the right to prescribe, distribute, and sell drugs should be based on a balance between the need on the one hand for people throughout the country to have access to drugs, and on the other for responsible prescribing, distribution, and selling.

29. WHO should provide Member States with information on experience in other countries in the above domains and cooperate with them on request in deciding on and introducing the necessary measures.

30. Governments could review the role of sales representatives with a view to deciding to what extent they have a rightful place in drug marketing. If they are considered acceptable, ethical standards could be defined for their conduct and they should be properly trained.

31. Up-to-date ethical norms for drug advertising could be established by governments, starting with those defined by the Twenty-first World Health Assembly in resolution WHA21.41 (see working paper 2.1, paragraph 26). National consensus groups of the kind mentioned in paragraph 4 above, could monitor adherence to these

norms. The norms could for example include: the obligation to use for both prescription and OTC drugs only such information as has been approved by the national regulatory authority; the restriction of advertising of prescription drugs to professional journals; legislative sanction to facilitate compliance with the norms; and the use of the mass media for public education and to give publicity both to those complying with the norms and to those infringing them. Advertisements to the public should not be permitted for prescription drugs, for the treatment of conditions which can be treated only by a doctor, or in a form that could provoke fear or distress or that claims infallibility or suggests that the drug is recommended by members of the medical profession.

32. Ethical norms for promotion could also include those for the control of drug samples, permitting them, for example, only at the request of a prescriber and establishing limitations on the quantity supplied. Norms applied to symposia sponsored by industry should ensure that they are genuinely educational and not used for unethical drug promotion. Among possible requirements are prior approval by the postgraduate education committee or similar body, screening of the lecture material, obligatory attendance of competent staff from the pharmaceutical company concerned, participation of one or more independent medical specialists, separation of promotional material from the educational content, and limitation of sponsoring to the provision of light refreshments and printing of the programme.

33. The pharmaceutical industry, both national and multinational, should assume the major responsibility for complying with established drug promotional norms and avoiding double standards in different countries. However, governments could assume responsibility for supervising compliance; the health professions could insist on being provided only with information that has been properly screened; and the public could, as individuals, and through consumer groups and its elected representatives, demand compliance with the agreed norms and draw the attention of the health authorities to suspected infringements. The governments concerned could be more active in denouncing infringements of drug promotional ethics.

34. Governments that have not already done so might review their legislation on drug marketing practices. They might also consider how far such legislation can be enforced, particularly if supervision of a highly technical nature is required. Legislation has to be made known to those who need to know it, for example regulatory agencies, industry, importers, prescribers, professional organizations, patients and the general public. Governments might consider both formal ways of making the legislation known, as through official publications, and informal ways, as through consumer organizations and the mass media.

35. WHO should support governments that wish to adopt or update their legislation on drug marketing. This it could do through the dissemination of information on national legislation and the WHO Certification Scheme, monographs on specific issues, the preparation of guiding principles for formulating legislation, and cooperation with countries on request in formulating legislation.

#### Prescription practices

36. The following are some possible ways of rendering prescription practices more rational and improving distribution systems.

37. With a view to improving prescribing practices, governments, nongovernmental organizations, and industry could collaborate to ensure that prescribers, particularly those outside hospitals, have trustworthy information on the therapeutic indications and the criteria for the selection of drugs from among a variety in the same therapeutic category. One means of ensuring this is the incorporation of relevant drug information in the continuing education of health care providers.

38. As better information alone does not necessarily ensure better prescribing practices, additional measures could be taken. Governments and professional organizations could be responsible for ensuring that health care providers meet acceptable prescribing standards.

39. The education of consumers could be undertaken through the mass media, including popular journals, to help people understand the need to follow the instructions for the use of drugs so that they take the right dose at the right intervals and for the right length of time. Governments, nongovernmental organizations, and consumer groups could share the responsibility for such measures.

40. In order to obtain a better understanding of drug use, governments might promote relevant behavioural and field research on prescribing practices in different settings in both developed and developing countries. WHO could collate and analyse the results of such research on an international basis with a view to improving the impact of drug information.

#### Distribution systems

41. The following are some possible ways of improving distribution systems:

42. To ensure acceptable drug distribution governments have to identify needs and estimate quantities required for all social groups. They may have to adopt political measures to ensure equity in the distribution of drugs, for example to overcome preferential distribution to the urban elite. They may also consider providing incentives to ensure equitable distribution.

43. The governments of developing countries could take measures to improve the physical conditions of importation, storage, inventory control and distribution, for example by diminishing spoilage through reducing the length of customs clearance and through proper storage in warehouses, by the control of distribution through authorized sources, by the control of pilfering, by ensuring proper conditions of transport, and by ensuring proper storage conditions in pharmacies and particularly in other drug outlets.

44. Governments of developing countries could introduce additional measures to improve distribution, for example direct distribution from central warehouses to community health centres, short-circuiting intermediate hospitals; the proper use of middlemen, both public and private; and the setting up of adequate logistic and information systems, with an information feedback on the quantities required and the stocks remaining.

45. Governments, particularly those of developing countries, might note that limitation of the number of drugs through an essential drugs list, quite apart from its other advantages, would simplify the drug distribution situation.

#### National essential drugs programmes

46. The following are some possible ways of accelerating the development and implementation of national essential drugs programmes.

47. Governments might review their existing drug policies and programmes, institute effective registration procedures, and consider establishing or reinforcing essential drugs programmes along the lines adopted by the Thirty-fifth World Health Assembly.

48. Governments might take steps to convince health workers and the general public that the rational use of essential drugs is good medical practice. Nongovernmental

organizations and associations of doctors, nurses and pharmacists might be encouraged to participate in essential drugs programmes. Teaching institutions might introduce the concept and principles of essential drugs in the training of health personnel. Consumer groups could add their influence.

49. WHO should accelerate the promotion of national essential drugs programmes, at the policy level through its governing bodies, in particular providing them with periodic reports on progress and effectiveness, and at the technical level through direct support to countries and guiding principles on such aspects of the programme as methods of selecting appropriate drugs and quantifying requirements.

50. Bilateral agencies could increase their support to the essential drugs programmes of developing countries as part of their strategies for health for all through primary health care.

51. To ensure the availability of good-quality low-priced drugs for the vast numbers of people in the public sector of developing countries ("medicines for the masses"), pharmaceutical manufacturers might agree to mass produce essential drugs and market them at prices that people in those countries can afford. This applies to national and multinational companies, and the research-based industry as well as generic manufacturers. Since industry cannot be expected to sell at a loss, governments might consider fiscal measures favouring low prices for the consumer, for example exemption from import taxes, relief on company turnover taxes, and price discrimination in favour of essential drugs.

52. Governments might control expenditure on drugs by applying essential drugs policies appropriate to the country. They might better align budgeting and financial systems for procurement. Bilateral and multilateral agencies and development banks could investigate ways of alleviating foreign currency problems related to drug imports by developing countries. Some developed countries might be able to help in that respect as part of broader economic relationships with developing countries.

53. In addition to the funding of drug research from profits on patented drugs, other ways should be sought to generate funds for research to develop badly needed new or improved drugs in neglected fields. WHO has been a pioneer in this field by funding research through voluntary contributions for the development of new drugs, for example to control human reproduction and to treat tropical diseases. Some governments have introduced schemes to foster the development of "orphan drugs". Such funding, not necessarily through WHO, could be expanded to cover research in other priority health fields.

54. Developing countries wishing to attain the long-term goal of national self-reliance in drug production should consider carefully technical and economic feasibility and desirability, as advocated by the Thirty-fifth World Health Assembly. Developing countries accordingly might become more actively involved in technical and economic cooperation among themselves, taking into account the need to ensure that they produce drugs they really require rather than more easily manufactured products of less relevance. WHO could support them in establishing lists of drugs suitable for local manufacture and in calculating the quantities that could be sold in the light of present and future trends.

#### WHO Certification Scheme

55. The following improvements in the use of the WHO Certification Scheme could be considered.

56. The following recommendations of the Third International Conference of Drug Regulatory Authorities might be considered:

- the WHO Certification Scheme should be extended, by formal agreement if necessary, to include provision of product information approved in the country of origin;
- the Scheme should be complemented both by more systematic exchange of information on the results of formal reviews of marketed drugs undertaken by national regulatory authorities and by periodic status reports on the categories of drugs that have been reviewed by each national authority and on those that are pending for assessment.

57. To ensure quality control developing countries might consider:

- the utilization of a portion of their country programme budget allocations from WHO for this purpose;
- the merits and feasibility of establishing a small national quality control laboratory where it does not at present exist as recommended by the WHO Expert Committee on Specification for Pharmaceutical Preparations (Technical Report Series No. 704);
- the possibility of increased technical cooperation among developing countries, those with a larger national laboratory assuming service and training responsibilities on a regional or subregional level.

58. WHO should continue to collaborate closely with the Secretary General of the United Nations in implementation of United Nations General Assembly resolution 37/137 on the dissemination of information to countries on drugs that have been banned, withdrawn, severely restricted or not approved by governments.

59. Governments should take necessary action to prevent drug counterfeiting. WHO should investigate with other international agencies and nongovernmental organizations the feasibility of creating a clearing-house to collect data and inform governments on the nature and extent of counterfeiting.