



# WORLD HEALTH ORGANIZATION

**EXECUTIVE BOARD**  
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## **Report on meetings of expert committees and study groups<sup>1</sup>**

**Report by the Secretariat**

### **FUTURE TRENDS IN VETERINARY PUBLIC HEALTH**

**Report of a WHO Study Group**  
**Teramo, Italy, 1-5 March 1999<sup>2</sup>**

#### **Main recommendations**

1. A national surveillance programme closely associating veterinary and medical surveillance systems should be established to enable assessment of the burden of zoonoses and animal-related hazards. This programme will entail collection, analysis, interpretation and exchange of appropriate information on animal and human populations at risk of disease, on animal husbandry practices and the environment, as well as on the impact of these diseases on human and animal health and national economy, which will assist in determining the cost-effectiveness of surveillance and control programmes. WHO should collaborate with Member States in harmonizing national surveillance systems for zoonoses, foodborne zoonotic diseases, human health surveillance and related issues.
2. A structure at the national level should be established to coordinate veterinary public health activities. This structure should have both the political authority and funding to design, implement and supervise programmes.
3. An integrated approach should be adopted to address the problems of hazards from farm to table, particularly in the case of foodborne diseases, to enable cost-effective risk-reduction interventions to be made.
4. Ownership and accountability of local communities in implementing sustainable local veterinary public health programmes should be increased. Communities should be trained to take

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<sup>1</sup> The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report on meetings of expert committees containing observations on the implications of the expert committee reports and recommendations on the follow-up action to be taken. The Executive Board is to consider the report submitted by the Director-General and address its comments to it.

<sup>2</sup> WHO Technical Report Series, No. 907, 2002.

decisions and manage their activities in collaboration with all stakeholders, including nongovernmental organizations.

5. Future veterinarians should be prepared more effectively for public health activities and careers. The concept of veterinary public health should be included throughout their undergraduate professional education and training in a consistent, harmonized format so that qualifications in veterinary public health are recognized internationally.

6. Policies and plans for implementation of the global and regional exchange of information and surveillance of diseases of common interest should be developed by WHO with FAO and the *Office international des Epizooties*. In collaboration with FAO and the *Office international des Epizooties*, WHO should update and review existing lists of reportable diseases common to humans and animals. Together, these organizations should continue to play a major role in promoting cost-effective, problem-oriented, risk-based research and in coordinating international research efforts and communicating research results to various users.

### **Significance for public health policies**

7. Since the adoption in 1975 of the report of the Joint FAO/WHO Expert Committee on Veterinary Public Health, new, emerging and re-emerging zoonotic diseases (such as Rift Valley fever, Nipah virus encephalitis) including foodborne diseases (such as those caused by *Salmonella enteritidis*, multidrug-resistant *Salmonella typhimurium* DT 104 and *Escherichia coli* O157:H7, as well as bovine spongiform encephalopathy) have acquired global significance for human health. These events have required rapid responses from physicians, veterinarians and biologists and teamwork between them.

8. Other zoonotic diseases such as rabies, brucellosis and bovine tuberculosis (caused by *Mycobacterium bovis*) have been controlled or eliminated in several industrialized countries, but remain endemic in developing regions. In addition, animal-associated infections (caused by, for example, *Toxoplasma gondii*, *Listeria monocytogenes*) have been reported in people at increased risk because of deficiencies in the normal immune response as a result of immunosuppressive drugs, cancer or HIV infection.

9. Factors that have contributed to these increasing trends are, *inter alia*, changing patterns of wildlife populations, intensive animal production practices, and globalization of the food industry with its changing patterns of food production, storage and distribution. These developments call for increased levels of epidemiological surveillance and preparedness and for novel approaches to control and prevention. Central to the mission of most veterinary public health organizations and services are the needs to assess and manage animal-related public health risks and to communicate these risks to the parties concerned.

### **Implications for the Organization's programmes**

10. In order to respond to these challenges and requests for action, WHO needs to maintain a core group of veterinary public health specialists in WHO headquarters and to create or strengthen synergies through increased coordination among all sectors of the Organization dealing with relevant issues.

11. WHO should support national veterinary public health structures and activities, by establishing and maintaining a focal point at each of its regional offices and by providing support for these focal points.
12. WHO should collaborate further with other relevant international organizations (e.g. the World Bank and WTO) to help to promote and build the required capacity in Member States, especially in developing regions.

## EVALUATION OF CERTAIN FOOD ADDITIVES AND CONTAMINANTS

### Fifty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives Rome, 5-14 June 2001<sup>1</sup>

#### Main recommendations

13. The Committee evaluated the following food additives using normal toxicological procedures: diacetyltartaric and fatty acid esters of glycerol, and quillaia extracts that are used as emulsifiers;  $\beta$ -carotene from *Blakeslea trispora* and curcumin that are used as food colours; phosphates, diphosphates and polyphosphates that are used as food salts; the glazing agent hydrogenated poly-1-decene; the preservative natamycin; the sweetening agent D-tagatose; the thickening agents carrageenan, processed *Eucheuma* seaweed and curdlan; and the miscellaneous substances acetylated oxidized starch,  $\alpha$ -cyclodextrin and sodium sulfate. Acceptable daily intakes (ADIs), some of them temporary, or maximum tolerable daily intakes (MTDIs) were allocated to all of these substances. Use of the enzyme preparation invertase from *Saccharomyces cerevisiae* was considered to be acceptable. The Committee prepared new or revised specifications for the identity and purity of the food additives that were evaluated toxicologically and considered specifications for seven other food additives.
14. The Committee evaluated 203 flavouring agents in six chemical groups using the Procedure for the Safety Evaluation of Flavouring Agents. On the basis of the toxicological, metabolic and intake data on these flavouring agents and their structural characteristics, the Committee concluded that all but 19 of them were of “no safety concern”. Additional data were required on one of them, while the evaluations of 18 of them could not be finalized because it was unclear whether they were in current use as flavouring agents.
15. The contaminants 3-chloro-1,2-propanediol and 1,3-dichloro-2-propanol (chloropropanols), and the polychlorinated dibenzodioxins, polychlorinated dibenzofurans and dioxin-like polychlorinated biphenyls (the latter three taken together are referred to as dioxins) were evaluated. A provisional maximum tolerable daily intake (PMTDI) of 2  $\mu\text{g}/\text{kg}$  of body weight was established for 3-chloro-1,2-propanediol. The establishment of a tolerable intake was considered to be inappropriate for 1,3-dichloro-2-propanol because of the nature of the toxicity (tumorigenic in various organs in rats and the contaminant can interact with chromosomes and/or DNA); the Committee noted that the dose that caused tumours in rats was about 20 000 times the highest estimated intake of 1,3-dichloro-2-propanol by consumers of soya sauce. The Committee established a provisional tolerable monthly intake (PTMI) of 70  $\text{pg}/\text{kg}$  of body weight for the dioxins.

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<sup>1</sup> WHO Technical Report Series, No. 909, 2002.

16. Summaries of the toxicological and related information which served as the basis for the Committee's evaluations of the safety of these food additives and contaminants have been published separately by WHO.<sup>1</sup> Specifications have been published by FAO.<sup>2</sup>

### **Significance for public health policies**

17. The Committee's work emphasizes the public health significance of the risk assessment of chemicals used in food. It highlights the complexity of the process, which includes assembling and analysing all relevant data; interpreting the results of studies of carcinogenicity, genotoxicity, reproductive toxicity, teratogenicity, etc.; extrapolating to humans the effects observed in experimental animals; and characterizing hazards to humans based on available toxicological and epidemiological data.

18. Although all Member States face the problem of assessing potential risks of chemicals in food, only a few scientific institutions can assess the relevant toxicological and related data at this stage. Therefore it is important that Member States are provided with valid information on both the general aspects of risk assessment and specific food additives and contaminants so that risks can be assessed at the national level.

19. The Committee's recommendations are used by the Codex Alimentarius Commission for setting international food standards. Such standards are established only for substances that have been evaluated by the Committee and have been allocated an ADI (food additives) or for which a tolerable intake level has been established or potencies have been estimated (contaminants). This approach ensures that food commodities in international trade meet strict safety standards.

### **Implications for the Organization's programmes**

20. The evaluation of chemicals in food by the Committee is an ongoing activity. Four meetings of the Joint FAO/WHO Expert Committee on Food Additives, two on food additives and contaminants, one on contaminants, and one on residues of veterinary drugs in food, were held during 2000-2001. Four meetings are scheduled during the biennium 2002-2003.

21. WHO is a partner in the Joint FAO/WHO Food Standards Programme, which administers the Codex Alimentarius Commission. The Committee's work is crucial for that of the Commission.

22. Regional offices and WHO representatives also make use of the Committee's evaluations when advising Member States on food safety regulatory programmes.

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<sup>1</sup> *Safety evaluation of certain food additives and contaminants*. WHO Food Additives Series, No. 48, 2002.

<sup>2</sup> *Compendium of food additive specifications, Addendum 9*. FAO Food and Nutrition Paper, No. 52, Add. 9, 2001.

## PREVENTION AND CONTROL OF SCHISTOSOMIASIS AND SOIL-TRANSMITTED HELMINTHIASIS

### Report of the WHO Expert Committee on the Prevention and Control of Schistosomiasis and Soil-transmitted Helminthiasis Geneva, 8-14 October 2001<sup>1</sup>

#### Main recommendations

23. The Committee provided guidance on implementation of the strategy to reduce morbidity from schistosomiasis and soil-transmitted helminthiasis, which had been endorsed by the Health Assembly in 2001 (see resolution WHA54.19). The strategy focuses on early treatment of symptomatic cases and regular treatment of high-risk groups. A minimum of 75% of all school-age children in areas of high endemicity should receive periodic drug treatment, and other groups at high risk of morbidity should also be offered regular drug treatment.

24. On policy issues, the Committee recommended that Member States should ensure access to essential medicines for the treatment of schistosomiasis and soil-transmitted helminthiasis in all health systems in endemic areas. Member States should integrate operational control programmes for schistosomiasis and/or soil-transmitted helminthiasis into existing primary health care systems and continue active surveillance and treatment in all endemic areas. Health education, safe water supplies, sanitation, and snail control (for schistosomiasis) remain important elements in prevention and control. Work should continue to reduce the risks of schistosomiasis and other public health problems associated with the development and management of water resources (dams, irrigation, reclamation projects).

25. On technical issues, the Committee recommended that WHO should convene an informal consultation to evaluate the risks and benefits of treating pregnant and lactating women with praziquantel for schistosomiasis and of treating children under the age of two years with albendazole or mebendazole for soil-transmitted helminthiasis, and should make recommendations regarding such treatment.<sup>2</sup> A mechanism should be established for monitoring the quality of anthelmintic drugs, and methods should be developed for the detection, monitoring and prevention of drug resistance in schistosomes and soil-transmitted helminths. WHO should urge the pharmaceutical industry to develop and market new drugs for the treatment of schistosomiasis and soil-transmitted helminthiasis.

26. In response to concerns about an apparent underestimation, WHO should recalculate disability-adjusted life years (DALYs) lost due to schistosomiasis, taking into account mortality, severe morbidity specific to schistosomiasis (hepatic fibrosis, urinary obstruction) and “subtle” morbidity (anaemia, growth stunting) in which schistosomiasis is a significant contributory factor.

#### Significance for public health policies

27. The Committee noted that the high-risk groups for the infections largely overlap: for soil-transmitted helminthiasis they include preschool and school-age children, women of childbearing age,

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<sup>1</sup> WHO Technical Report Series, No. 912, 2002.

<sup>2</sup> Since the meeting of the Expert Committee, WHO has convened the recommended consultation. See Report of the WHO informal consultation on the use of praziquantel during pregnancy/lactation and albendazole/mebendazole in children under 24 months (document WHO/CDS/CPE/PVC/2002.4).

and people in certain occupations (e.g. tea-pickers and miners); for schistosomiasis the groups are school-age children and adolescents, but also those whose occupations involve contact with infested water (e.g. fishermen, irrigation workers, and women in their domestic tasks).

28. Since praziquantel and other anthelmintics are now available at low cost, targeted treatment for schistosomiasis and soil-transmitted helminthiasis should be given in all endemic areas; the treatment interval should be determined by the pre-control prevalence rate, the indicator of intensity of transmission.

29. Treatment can safely be administered by non-medical personnel such as schoolteachers, assisted and supervised by health personnel. Practical field tools exist, such as rapid epidemiological assessment methods, a dose pole for the administration of praziquantel according to height, and WHO manuals<sup>1</sup> that will greatly facilitate implementation of control in areas with few resources.

### **Implications for the Organization's programmes**

30. The Committee recommended that WHO should continue to list the drugs albendazole, levamisole, mebendazole, and pyrantel against soil-transmitted helminthiasis and praziquantel (effective against all schistosome species) and oxamniquine (effective only against *Schistosoma mansoni*) against schistosomiasis.

31. The goal set by resolution WHA54.19 is to offer, by the year 2010, regular treatment at appropriate intervals to 75% to 100% of all school-age children, regardless of whether they are enrolled in school or not, who live in areas where schistosomiasis, ascariasis, hookworm disease, and trichuriasis have public health consequences. Today, approximately 800 million school-age children are infected with soil-transmitted helminths and/or schistosomes, and are physically and intellectually affected by anaemia, attention deficits, learning disabilities, school absenteeism and higher dropout rates. The Committee was of the opinion that the target is attainable, delivering significant reductions in morbidity and preventing irreversible sequelae in adulthood.

## **WHO EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS**

### **Thirty-seventh report Geneva, 22-26 October 2001<sup>2</sup>**

#### **Main recommendations**

32. The Committee was brought up to date on various cross-cluster activities relating to priority disease programmes and quality of drugs. The Committee endorsed the policy of developing quality specifications for priority drugs used to treat tuberculosis, malaria and HIV/AIDS.

33. The Committee endorsed the new WHO strategy for a global step-wise approach to the quality control of pharmaceuticals, including basic tests, screening tests and International Pharmacopoeia

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<sup>1</sup> Montresor A et al., *Helminth control in school-age children. A guide for managers of control programmes*. Geneva, World Health Organization, 2002.

<sup>2</sup> WHO Technical Report Series, No. 908, 2003 (in preparation).

monographs. The development of new monographs for *The international pharmacopoeia* would focus on the needs of specific disease programmes and the essential medicines nominated under these programmes. The Committee adopted the revised concepts and future perspectives of *The international pharmacopoeia*. The uniqueness of WHO's role in developing global quality control standards was reinforced.

34. The Committee considered that WHO had an important role in international standard setting and should intensify its efforts to develop international standards on the approval of generic products in consultation with the generic industry, related organizations and national authorities. This would improve access to quality essential medicines.

35. The Committee endorsed the continuation of the external quality assessment scheme for quality control laboratories.

36. The Committee recommended a text on the risk of transmitting animal spongiform encephalopathy agents via medicinal products.

37. The Guidelines on good manufacturing practices for radiopharmaceutical products (developed jointly with IAEA), the revised Good manufacturing practices for pharmaceutical products: main principles, Model certificates of good manufacturing practices, and Guidance for good manufacturing practices: inspection report were adopted. The Committee agreed that WHO should review its guide for good manufacturing practices for active pharmaceutical ingredients, taking into consideration a step-wise approach to its implementation.

38. The hazard analysis and critical control point system was newly recommended to be used as a methodology for pharmaceuticals.

39. Within the scope of a new project involving several organizations of the United Nations system and nongovernmental organizations, a procedure for assessing the acceptability, in principle, of pharmaceutical products for purchase by procurement agencies has been developed and was adopted by the Committee.

40. In line with international harmonization efforts the Committee adopted a revision of the WHO stability-testing requirements for hot and humid climatic zones. It also endorsed the joint International Pharmaceutical Federation/WHO guidance document on Good storage practices for pharmaceuticals.

41. The Committee reviewed progress made on drug terminology, in particular within the International Nonproprietary Names programme.

### **Significance for public health policies**

42. Access to safe drugs of good quality plays an important role in improving human health and promoting well-being. Vigorous implementation of good manufacturing practices and other international standards is prerequisite. With increasing international trade and commerce, new mechanisms and target groups need to be involved.

43. The need for regulatory measures covering the safety of starting materials and trade in them – including active pharmaceutical ingredients and excipients – and implementation of good manufacturing practices has been identified. The participation and support of policy-makers and the entire public health community are required, involving both the public and private sectors.

44. Evidence shows that problems associated with the quality assurance of pharmaceuticals persist, especially in relation to the growing incidence worldwide of production, distribution and sale of counterfeit, spurious and substandard pharmaceutical products. A waste of money for the people who buy them, counterfeit and substandard drugs prolong treatment periods, exacerbate the conditions being treated, help create drug resistance and can even cause death. The statutory instruments, advice and recommendations provided in the Committee's report can help national authorities – in particular drug regulatory authorities – to combat these problems.

### **Implications for the Organization's programmes**

45. WHO should continue to promote a comprehensive approach to quality assurance of pharmaceutical products. It should also lead and coordinate international efforts to define and harmonize clear, practical standards and guidelines for pharmaceuticals, particularly in response to increased globalization of trade.

## **THE SELECTION AND USE OF ESSENTIAL MEDICINES**

### **Report of the WHO Expert Committee, 2002 (including the 12th Model List of Essential Medicines)**

**Geneva, 15-19 April 2002<sup>1</sup>**

46. After a global consultation process, the procedures for updating and disseminating the Model List of Essential Medicines were reviewed by the Executive Board at its 108th and 109th sessions.<sup>2</sup> This meeting of the Expert Committee on the Selection and Use of Essential Medicines (formerly the Expert Committee on the Use of Essential Drugs) was the first to follow the new procedures, under which applications for changes in the Model List were posted on the WHO web site for external review prior to the meeting, and an open session was held on the first day in which stakeholders made statements to the Committee regarding items on the agenda.

### **Main recommendations**

47. In line with the new WHO clinical guidelines on the use of these medicines in resource-poor settings, the Committee recommended to add 10 antiretroviral medicines to the Model List and to broaden the indications for the two antiretroviral medicines which were already listed. The applications for these medicines referred to a systematic review of evidence, a summary of which is annexed to the Committee's report. The Committee also recommended to include a first artemether-based combination for the treatment of malaria, again based on a systematic review. The report of the Committee, including the twelfth Model List of Essential Medicines, was approved by the Director-General and posted on the WHO web site 10 working hours after the meeting closed; by September 2002 it was available in all six official languages.

48. The Committee reviewed the new procedures as discussed at the Executive Board at its 109th session in January 2002 and made a few practical suggestions to facilitate their implementation. The Committee recommended a step-wise introduction of the use of information on cost and cost-

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<sup>1</sup> WHO Technical Report Series, No. 914, 2003 (in preparation).

<sup>2</sup> Documents EB108/INF.DOC./2 and EB109/8.



effectiveness in the selection of essential medicines, and recommended to review the use in practice of the Core and the Complementary List at its next meeting in 2003.

### **Significance for public health policies**

49. The inclusion of 12 antiretroviral medicines in the Model List has many practical implications. For WHO it implies that these medicines are now the focus of training materials and programmes, development of pharmacopoeal standards, provision of information on sources and prices, and inclusion in the WHO-initiated United Nations Pilot Procurement Quality and Sourcing Project. For Member States and international organizations, the joint publication of the new clinical guidelines and the information mentioned above help to focus limited resources on those essential medicines that have been identified as meeting criteria on public health relevance, efficacy, safety and comparative cost-effectiveness.

50. The expansion of the Model List into the WHO essential medicines library has increased its value as a source of independent information for all Member States. The new WHO Model Formulary is the first concrete outcome of this process; it presents independent drug information on all medicines on the Model List, linking this information with WHO clinical guidelines.

### **Implications for the Organization's programmes**

51. The new procedures, with a considerable shift from consensus-based to evidence-based selection, have greatly increased the public health value of the Model List for national lists of essential medicines. The stronger link between the Model List and WHO's clinical guidelines puts more emphasis on the systematic review of evidence; future updates of the Model List will create an opportunity for many WHO departments to review their clinical guidelines in this light. The publication of the first Model Formulary has also proved to be an excellent tool to strengthen the consistency of WHO's clinical recommendations.

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