’.Pf
1
ox; "kn. a
, ,1 . , ,9 ,_
L gmlfgs (31 :se i :5! 0 CH / ?- / le
World Health Organization
Organisation mondiale de la Sante
FORTY-SEVENTH WORLD HEALTH ASSEMBLY
A47/A/SR/6
COMMITTEE A 9 May 1994
PROVISIONAL SUMMARY RECORD OF THE SIXTH MEETING
Palais des Nations, Geneva
Monday, 9 May 1994, at 9h00
Chairman: Dr N.K. RAI (Indonesia)
CONTENTS
Page

Note
This summary record is provisional only. The summaries of statements have not yet been approved by the speakers, and the text should not be quoted.
Corrections for inclusion in the final version should be handed in to the Conference Officer or sent to the Records Service (Room 4113, WHO headquarters), in writing, before the end of the session. Alternatively, they may be forwarded to Chief, Office of Publications, World Health Organization, 1211 Geneva 27, Switzerland, before 1 July 1994.
The final text will appear subsequently in Forty-seventh World Health Assembly: Summary records of committees (document WHA47/1994/REC/3).

A47/A/SR/6
SIXTH MEETING
Monday, 9 May 1994, at 9h00
Chairman: Dr N.K RAI (Indonesia)

1. IMPLEMENTATION OF RESOLUTIONS (PROGRESS REPORTS BY THE DIRECTOR-GENERAL): Item 19 of the Agenda (continued)

WHO ethical criteria for medicinal drug promotion (Resolution WHA45 .30; Document A47 / 7 )

Professor CALDEIRA DA SILVA (representative of the Executive Board), introducing the item , said that, in resolution WHA45.30, the Health Assembly had called upon Member States to intensify efforts to involve government agencies (including drug regulatory authorities), pharmaceutical manufacturers, distributors, the promotion industry, health personnel involved in the prescription, dispensing, supply and distribution of drugs, universities and other teaching institutions, professional associations, patient and consumer groups, and the professional and general media (including publishers and editors of medical journals and related publications) in the implementation of the principles embodied in the WHO ethical criteria for medicinal drug promotion. Pursuant to that resolution, the Council for International Organizations of Medical Sciences (CIOMS) and WHO had convened a consultation between interested parties to discuss possible approaches to further advance the principles embodied in the criteria, which had taken place in April 1993. The report and recommendations of the CIOMS/WHO Consultation were contained in the Director-General’s report (document A47/7).

In its consideration of the report, the Executive Board had noted that the participants had sought to avoid confrontation and encourage dialogue. That spirit of consensus would be very valuable for future work on such a controversial subject, where so many different interests were represented. Although the WHO ethical criteria had not been applied as widely as had originally been hoped, the participants in the meeting had clearly accepted their validity and were prepared to work together to improve their implementation. The Executive Board had endorsed the Consultatiorfs recommendations to governments, the pharmaceutical industry, the media and other parties.

The CHAIRMAN invited the Committee to consider the following draft resolution on the WHO ethical criteria for medicinal drug promotion, proposed by the delegations of Australia, Belgium, Botswana, Brazil, Cameroon, Canada, Chile, Denmark, Finland, Ghana, Guatemala, Iceland, J apan, Kenya, Kyrgyzstan, Lesotho, Lithuania, Mexico, Mozambique, Netherlands, New Zealand, Namibia, Niger, Norway, Spain, Sweden, Switzerland, Thailand, Togo, United Kingdom of Great Britain and Northern Ireland , United Republic of Tanzania and United States of America:

The Forty-seventh World Health Assembly,

Recalling resolutions WHA41.17, WHA43.20 and WHA45.30;

Noting the continued need to improve the quality of drug promotion through the use of the concepts embodied in the WHO Ethical Criteria for Medicinal Drug Promotion;

Having considered the report of the Director-General1 on the outcome of the CIOMS/WHO Consultation on the WHO Ethical Criteria,

1. THANKS the Council for International Organizations of Medical Sciences (CIOMS) for having convened the consultation in collaboration with WHO, and for the valuable report adopted by consensus and which covers a wide range of issues and the action to be taken;

1 Document A47/7.

2. APPRECIATES the commitment of the participants - drug regulatory authorities, pharmaceutical manufacturers and distributors, the promotion industry, health professionals, universities and teaching institutions, professional associations, patient and consumer groups, and the professional and general media - to a common responsibility, based on fundamental ethical principles, for the well-being of patients individually and the public collectively;
3. ENDORSES the report of the consultation and reaffirms:
(1) that the regulation of drugs must ensure not only the safety, efficacy and quality of drugs but also the accuracy of the information provided pursuant to their regulation;
(2) that patients, pharmacists and prescribers should have access to appropriate information about drugs;
(3) that the promotion of drugs must be accurate, fair and objective, and presented in such a way as to conform to legal requirements and also to high ethical standards;
(4) that promotional claims should not be stronger than valid, up-to-date scientiiic evidence warrants, every effort being made to avoid ambiguity;
4. CALLS UPON all concerned parties to continue to collaborate 1n order to promote further and implement the principles embodied 1n WHOls Ethical Criteria for Medicinal Drug Promotion, by rapidly adopting, as appropriate, measures based on the CIOMS/WHO recommendations;
5. URGES Member States to develop and implement national mechanisms, where relevant, to control drug promotion in accordance with the principles embodied in the WHO Ethical Criteria;
6. REQUESTS the Director-General:
(1) to implement the recommendations of the CIOMS/WHO consultation applicable to WHO, giving special attention to:
(a) wide dissemination of the WHO Ethical Criteria to all Member States and all other concerned parties;
(b) measures to develop and disseminate educational materials on the WHO Ethical Criteria, and methods to monitor their implementation;
(0) monitoring the implementation of the WHO Ethical Criteria and collecting information on voluntary, self-regulatory national and international codes and guidelines that relate to the promotion of medicinal drugs, in consultation with all concerned parties;
(d) carrying out studies or surveys of current promotional practices as necessary, and analysis of the effectiveness of the Ethical Criteria;
(e) periodical review of the WHO Ethical Criteria in consultation with interested parties;
(1) support to Member States, as appropriate, in strengthening drug regulatory capacity and mechanisms regarding the labelling and promotion of medicinal drugs; ’
(g) dissemination of national experience in the promotion of medicinal drugs;
(2) to report regularly, through the Executive Board, on progress made and problems encountered by WHO and Member States, as part of the reporting on the implementation of the revised drug strategy.
Ms ANDREW (Norway), introducing the draft resolution on behalf of the Nordic countries and the other sponsors, said that the CIOMS/WHO Consultation on the WHO Ethical Criteria had been held because of concern that the criteria were not being widely implemented. The meeting had led to consensus agreement on 19 recommendations, covering education, communication, information on the progress of implementation of the ethical criteria, and recommendations for national policies and action and international collaboration.
The sponsors of the draft resolution considered that the ethical marketing of medicinal drugs was so important for WHOls revised drug strategy that the achievements of the CIOMS/WHO Consultation should be reflected in a Health Assembly resolution, even though that might have certain financial implications for WHO.

Referring to traditional medicines and non-prescription drugs, she said that in many countries, including her own, products were used whose therapeutic efficacy had not been scientifically proven. The draft resolution was not intended to prevent the promotion of such products, provided that it was carried out in a responsible manner and in the spirit of the draft resolution. The issue could perhaps be addressed in more detail in a future review of the ethical criteria. She hoped that the draft resolution would be adopted by consensus. ’

Dr ANTEZANA (Assistant Director-General) said that the draft resolution did not have any immediate financial or administrative implications for the Organization, but implications might well arise in future budget cycles. For example, ftmding would be needed for the activities listed in operative paragraphs 6(1), subparagraphs (c) and (d), relating to monitoring of the implementation of the WHO ethical criteria and studies of current promotional practices, and the activities outlined in subparagraphs (e) and (f) would require extrabudgetary funding for extra meetings with interested parties and Member States.

Mr TESHIMA (Japan) welcomed the support of the other interested parties, particularly CIOMS. He hoped that, in its work to implement the WHO ethical criteria, the Organization would give due consideration to the different situations in the various Member States.

Professor NABI (Bangladesh) said that his Government had introduced a number of measures to promote the rational use of drugs, including a code of pharmaceutical marketing practices, drawn up with the collaboration of physicians, pharmacists and pharmaceutical manufacturers. The code reflected the objectives of the WHO ethical criteria. The Ministry of Health had formed a committee to monitor and implement the code.

Mr KIM Won Ho (Democratic Peoples Republic of Korea) said that substandard and spurious drugs could lead to serious health problems. Proper surveillance and certification schemes for pharmaceuticals on the international market were essential in order to regulate marketing practices, and he hoped that WHO would take further action in that field in the future. He supported the report and draft resolution before the Committee.

Dr MEREDITH (United Kingdom of Great Britain and Northern Ireland) supported the WHO ethical criteria and the draft resolution, particularly the point that both patients and prescribers should have access to factual and, where possible, impartial information. He noted that the information requirements of patient and prescriber groups might differ.

Dr VIOLAKI-PARASKEVA (Greece) welcomed the progress made at the CIOMS/WHO Consultation and endorsed its recommendations. It was a difficult but nevertheless vital task to ensure that patients received the information they needed for informed consent to treatment. Universities had an important role to play in promoting greater understanding of the WHO ethical criteria by health personnel, and appropriate training should be included in undergraduate curricula and continuing education courses. She accordingly wished to propose the inclusion of a new subparagraph in operative paragraph 6(1) of the draft resolution, to read:

alert Member States to the importance of the role of universities and other educational institutions and assist them in educational programme development.

Further, subparagraph (e) of operative paragraph 6(1), concerning the periodical review of the ethical criteria, should become the final subparagraph.

Dr ADAMS (Australia) supported the amendment suggested by Greece and hoped that the draft

resolution would be adopted, even though it might have some administrative and financial implications for
the Organization in the future.
Dr MILLER (Barbados) said that the recent Seventh International Conference of Drug Regulatory
Authorities had discussed the provision of information on drugs to health care professionals. One of the

main concerns expressed there had been the promotion of information in a factual manner, without any attempt to influence the prescribing of drugs from purely commercial motives. Her delegation supported the draft resolution.

Dr PHILIPPON (Canada) supported the draft resolution which reflected the principle that patients, prescribers and pharmacists had a right to accurate, complete and up-to-date information about drugs they might wish to use. The recommendations of the CIOMS/WHO Consultation had indicated the action needed to promote the use of the WHO ethical criteria and the responsibilities of all parties concerned. That meeting had established a spirit of consensus, dialogue and trust, which would be a useful basis for future progress.

The ethical criteria had originally been drafted in response to concern about prescription drugs. He hoped that the proposed periodic reviews would take into account the rather different situation relating to over-the-counter drugs.

Dr MOURA FE (Brazil) said that effective implementation of the WHO ethical criteria was essential to prevent abuses, such as false claims concerning drug action and benefits, the omission of information about contraindications, side-effects and adverse reactions, and the marketing of medicinal drugs as purely commercial products rather than products related to peoplels health. Inappropriate marketing practices led to unnecessary consumption and price rises which, in turn, meant that millions of people all over the world were deprived of essential drugs they really needed. WHO should encourage all Member States to facilitate access to essential drugs for their peoples, implement measures to control drug quality, take action to counter inappropriate promotion practices and protect the right of prescribers and the public in general to receive more precise drug information. His delegation supported the draft resolution.

Mrs HERZOG (Israel) said that regulations relevant in the country in which drugs were manufactured should also apply to those drugs when they were exported to other countries. She therefore proposed that the words "and should be unified in all countries where the drugs are marketed", be added at the end of operative paragraph 3(3) or 3(4). Her delegation supported the draft resolution, and wished to be included as a sponsor.

Dr SAWADOGO (Burkina Faso) said that drugs were a very important link in the whole health system. In the African Region in general, and in Burkina Faso in particular, medicinal drugs had always been a source of concern for the health authorities because the purchasing power of the population was very low, local manufacture of drugs was in an embryonic state, most imported drugs were expensive and unadapted to local needs, and a large number of medical prescriptions were inadequate. The issue was complicated by promotion practices; it was not uncommon to find drugs accompanied by information which had little medical content and nothing in common with that published in the country of origin, and some of the approaches made to prescribing physicians were by no means therapeutic in purpose. Nevertheless, in Burkina Faso action had been initiated to bring about a rational use of drugs. His delegation hoped that WHOls concern for ethical criteria would be understood by all people of goodwill, leading to fairer and more reliable objective information on drugs. WHO support was needed at all levels to secure the dissemination and implementation of the criteria. The implementation of the draft resolution would lead to a rational use of drugs, which was an important stage along the road to health for all

.
Dr VAN E'ITEN (Netherlands) said that the Netherlands had strongly supported the initiative for convening the CIOMS/WHO Consultation and welcomed its recommendations. There was a need to ensure that patients and prescribers had access to appropriate information on drugs, that the principles embodied in the WHO ethical criteria were widely disseminated, and that the criteria were subject to periodic review. His delegation therefore fully supported the draft resolution and wished to express its appreciation to the delegation of Norway for its efforts to bring about a consensus on it.

Dr NIGHTINGALE (United States of America), said that his delegation was pleased to be a sponsor of the draft resolution, which gave priority to the implementation of a number of the recommendations of the CIOMS/WHO Consultation in which he had participated. The goodwill so evident at the Consultation,

and the consensus approach to future action by all parties must continue to be fostered. The draft resolution provided a basis for WHOts contribution to the collective action required to implement the recommendations and helpfully identified those recommendations that should take priority. Member States and other concerned parties must assume responsibility for implementing the recommendations, most of which did not, of course, appear in the operative paragraphs of the draft resolution. The United States of America would continue to cooperate with WHO and all interested parties at both the national and international level in promoting the principles of the ethical criteria.

Dr AL-JABER (Qatar) supported the draft resolution with the amendments proposed and wished to be included as a sponsor, in particular because of its importance in regulating drug distribution, in calling for full information on individual drugs, and in controlling the quality of drugs distributed.

Dr ABU BAKAR SULEIMAN (Malaysia) fully supported the 19 recommendations of the CIOMS/WHO Consultation and the draft resolution before the Committee. It was imperative that certain recommendations be implemented without delay, in order to improve compliance with the WHO ethical criteria, in particular: action by WHO and interested parties on the further development of performance indicators, and the development of monitoring procedures and educational modules; and action by the International Federation of Pharmaceutical Manufacturers Associations, the World Federation of Proprietary Medicine Manufacturers and related organizations on the establishment and maintenance of common international codes for responsible drug promotion, to be adopted by the industry at large and consistent with the WHO ethical criteria, with self-regulation imposed in the form of remedial measures in cases of non-compljance.

Dr SAVELlEV (Russian Federation) supported WHOls activities in the field under consideration.

Regulation of the advertising of drugs and other forms of drug promotion was becoming increasingly important in the Russian Federation as a result of its transition to a market economy. Certain non-pharmaceutical publications were printing material that was not in conformity with the WHO ethical criteria. The best way to overcome the difficulty would be to introduce those criteria into the national system of drug advertising as quickly as possible. WHO, together with CIOMS, should consider the question from time to time to assess the degree of implementation of the criteria and the need for their review and improvement. In discussing the problem, all concerned parties should be involved, not only the state regulatory authorities and the pharmaceutical industry but also medical journals, universities, consumersl associations and so forth. A comprehensive review showed the superiority of WHOts criteria in comparison to other existing rules or requirements. It was clear, however, that the decisive role in establishing rules for the advertising of drugs should essentially be played by national bodies, primarily public health bodies.

His delegation supported the draft resolution, as amended by Greece and Israel.

Dr MOREAU (France) stressed the importance of WHOis role in controlling the promotion of essential drugs. The Organization should continue to develop the ethical criteria. The CIOMS/WHO consultation had provided appropriate guidance, now incorporated in the draft resolution under consideration, in regard to controlling the application of the criteria and intensifying that control through

the development of a framework for their implementation at the national level, periodic reviews of the criteria, and broad dissemination of educational material on them. The universities could make a valuable contribution in that regard. It was also important to develop WHO as a centre for the exchange of regulatory and legal information, to strengthen the role of national administrations in training, and to invite States to support the preparation and dissemination of objective and comprehensive information on drugs, in accordance with the policy of promoting their rational use.

Dr KHOJA (Saudi Arabia) said that in 1990 his country had adopted a quality control programme for drug promotion, especially in regard to safe motherhood, primary health care and essential drugs. Booklets on the subject had been published by the Regional Office for the Eastern Mediterranean and the Gulf Cooperation Council. The question of availability of drugs in the Region had also been examined and great benefit had been derived from the reports on essential drugs issued by WHO. In considering the

ethical aspects of the nature and quality of drugs and their effects on patients, health, account should be
taken of the inability of certain countries to regulate their drug production and quality control or to
establish adequate communication networks. WHO should therefore coordinate its work with universities
and help medical faculties to include courses on ethical criteria in their curricula. Furthermore,
international drug research and manufacturing organizations should increase their research on parasitic
diseases in tropical areas, even though such research might not be profitable owing to the poverty of the
countries where those diseases prevailed. In any case, the quality of drugs produced for the developing
countries should be very carefully examined.

His delegation wished to be added to the list of sponsors of the draft resolution.

Dr HAJ-HUSSEIN (Syrian Arab Republic) announced that his delegation fully supported the draft
resolution and wished to be added to the list of sponsors.

Dr MUNOZ PORRAS (Chile) said that his delegation strongly supported the draft resolution, of
which it was a sponsor, and had no objection to the amendment proposed by Greece concerning the role
of universities in promoting the ethical criteria. The draft resolution was very important as a basis for
legislation on the subject or for reforms such as those at present under discussion in the Chilean
Parliament.

Dr MYINT HTWE (Myanmar) fully supported the draft resolution, and stressed the importance of
disseminating the experience of Member States as a means of overcoming the constraints and obstacles
encountered in different situations. He accordingly urged all Member States to take appropriate action as
soon as possible. Such an exchange of experience would also benefit the periodic reviews of the WHO
ethical criteria.

Dr DHANVARACHORN (Thailand) commended the work undertaken by WHO in collaboration
with CIOMS in organizing the Consultation, which had been attended by two participants from Thailand.

In future WHO would undoubtedly face great challenges in helping Member States to introduce relevant
action in line with the ethical criteria, which, although first developed in 1988, were not widely known or
applied.

In Thailand, with technical assistance from WHO, working groups had been formed to consider the
implementation of the criteria and a workshop had recently been convened to develop implementation
guidelines. The Government intended to introduce amendments to the present legislation governing the
promotion of medicinal drugs in conformity with the criteria. It hoped that WHO, the international
community and the pharmaceutical industry associations would provide all possible support and cooperation,
particularly with regard to drug labelling, where it was essential to ensure that all crucial information was
properly and consistently presented to consumers in all parts of the world.

His delegation supported the draft resolution.

Professor PICO (Argentina) stressed the importance of teaching ethical criteria in both graduate and
postgraduate courses for all health team members. The tuition should be sufficiently broad to ensure that
the role played by ethical considerations in the decision-making process was understood by all health
workers without exception. His delegation therefore supported the draft resolution.

Dr ASHLY-DEJO (Nigeria) said that for some years his country had experienced harmful drug
promotion practices including inappropriate advertising. His Government had discovered that certain
imported drugs were fakes or supplied in substandard doses and that some manufacturers ex

ported drugs
that were different to those they distributed in their home countries. Further, there had been a
proliferation of drug products on the Nigerian market, with at one time at estimated 18 000-20 000 products
in circulation, some of doubtful efficacy and quality. The Government had taken a number of steps to
improve the situation including the introduction and implementation of a comprehensive national drug
policy, together with legislation to regulate drug promotion, sales and distribution. An essential drugs
programme had also been developed specifically to promote sound drug practices and drug availability at

primary health care centres, a programme which was working out well with the financial as sistance of the World Bank.

His delegation supported the draft resolution.

Dr KARAGULOVA (Kazakhstan) said that the Director-Generalis report was of great value to the newly independent countries of eastern Europe. Her own country had just recently begun to formulate a pharmaceutical policy and to establish a medicinal drug industry. One of the main challen ges it faced was a tremendous shortage of medicinal drugs: in the past, approximately 98% had been importe d. While it appreciated the information provided by organizations and private firms, Kazakhstan neede d more information from WHO in order to take appropriate action. As a sponsor of the draft resol ution, Kazakhstan hoped that WHO and its Members States would fully implement its provisions, pa ying particular attention to those concerning the development and dissemination of educational materials.

Dr CHINTU (Zambia) supported the draft resolution, including the amendments proposed by Greece. In paragraph 3(2), the words "and understandable" should be added after the word "appropriate"; donated drugs were at times accompanied by information that was not readily understood.

Dr ATTAS (United Republic of Tanzania) said that his country, which was among the sponsor s of the draft resolution, imported nearly all of its medicinal drugs. As a result, Tanzanian health professionals were subj ected to unacceptable and disagreeable approaches from manufacturers, importers and distributors of pharmaceutical products. Even worse, unsuspecting consumers were at times misled by pr omotional material into wasting their limited resources on worthless and potentially hazardous prod ucts. An alarmingly large number of counterfeit and spurious substances were being sold as medicin al drugs. The Government was attempting, with difficulty, to control the problem. Thus, it was essentia l to implement the recommendations contained in the draft resolution.

Dr KIHUMURO-APUULI (Uganda) endorsed the recommendations of the CIOMS/WHO Consultation. Uganda faced urgent challenges in the field of rational drug use and quality control. It had established a national drug authority, which was mandated to elaborate a national medicin al drugs policy, establish a national drug formulary, regulate the importation of drugs and chemical produ cts, oversee the rational distribution of appropriate medicinal drugs by the public and private sectors, a nd monitor the promotion and prescribing of medicinal drugs, and would welcome collaboration with WHO in that connection. He supported the draft resolution, which would allow the Organization to move rapidly ahead in the area of medicinal drug promotion.

Dr ACHOUR (Tunisia) expressed full support for the draft resolution. Thnisia accorded hig h priority to issues relating to medicinal drugs, with particular emphasis on their efficacy and rat ional use. It had three main objectives in that area: to encourage local manufacture of medicinal drugs (40 % of the countryis needs were currently being supplied locally and that figure would soon rise to 60%); to e nsure that authorization to distribute a product in Tunisia was based on the conditions of use in th e country of origin; and to pay particular attention to bodies established to monitor pharmaceutical products and ensure quality control. He called for wide dissemination of the WHO ethical criteria to all Member State s and for a commitment to finding the best means of ensuring the rational use of medicinal drugs.

Dr AZMOUDEH (Islamic Republic of Iran) supported the draft resolution but proposed that i n

paragraph 3 (2), the words "and in particular about their side effects" should be added after "information about drugs".

Dr MUKHERJEE (India) endorsed the recommendations of the CIOMS/WHO Consultation. In India, the technical body representing the pharmaceutical industry was a signatory to the IFPMA Code of Pharmaceutical Marketing Practices and thus had to abide by the norms for ethical promotion of drugs.

Furthermore, advertising of drugs and remedies was controlled in accordance With legislation dating from 1954, which was currently being amended. It had also been proposed that any promotion of new drugs in

r;

medical or related journals should correspond to the package insert and promotional liter ature, which was
subject to approval by Indiais drug control agency. Such advertising should be in harmony with the goal
of the rational use of drugs.
He supported the draft resolution.
Professor SHAIKH (Pakistan) said that Pakistan had a strict system for registering drugs and medical
devices. It was also endeavouring to prevent the promotion and use of spurious or counter feit drugs and
of irrational combinations of drugs and had recently established a high-level committee t o assist in the
implementation, monitoring and evaluation of the rational use of medicinal drugs.
Pakistan strongly supported the draft resolution and particularly favoured periodic revie w of the
criteria and measures to promote relevant education for health professionals at all level s. It was also
important to adopt effective strategies to ensure the exchange between Member States of i nformation
regarding ethical criteria.
Dr SANGALA (Malawi) said that Malawi supported the draft resolution and wished to be incl uded i
as a sponsor. In the spirit of the draft resolution, donations of medicinal drugs should be labelled in the
official language of the recipient country. -
Dr SHRESTHA (Nepal) endorsed the 19 recommendations of the CIOMS/WHO Consultation and supported the draft resolution, including the amendments proposed by Greece.
Dr MAREI (Egypt) endorsed the comments of the delegate of Saudi Arabia. Developing countr ies
were being used by international corporations as research sites. He therefore endorsed th e WHO ethical
criteria and the rational use of medicinal drugs. Egypt supported the draft resolution an d wished to join
the list of sponsors.
Professor WOJTCZAK (Poland) said that the WHO ethical criteria were invaluable for all co untries
and, in particular, for countries undergoing economic and social transformations.
Poland supported the draft resolution, including the amendments proposed by Greece and Is rael and
wished to be added to the list of sponsors.
Dr KAMARA (Sierra Leone) supported the draft resolution together with the amendments prop osed
by Greece. The elaboration of the ethical criteria was yet another demonstration of the O rganizationis
leadership in the field of health.
With the assistance of WHO, his Government was currently reviewing its health legislation . Like
other developing countries, Sierra Leone faced a serious problem with counterfeit drugs. Medicinal drugs
distributed through the national health service were provided exclusively by UNICEF and W HO. However,
private enterprises procured drugs from various sources. The ethical criteria would help to maintain strict
standards.
Third World countries were constantly faced with a scarcity of foreign exchange. It was t hus in their
interest to produce essential drugs locally. He hoped that WHO would continue assisting c ountries in that
respect.
His country wished to join the list of sponsors of the draft resolution.
Dr MELONI NAVARRO (Peru) said that his country wished to become a sponsor of the draft resolution; it also endorsed the amendments proposed by Greece and Israel. Of particular relevance to
Peru was paragraph 6 (1), subparagraph (f), which referred to support for Member States i n strengthening
drug regulatory capacity and mechanisms regarding the labelling and promotion of medicina l drugs.
Dr KANAAN (Lebanon) endorsed the comments of the delegates of Saudi Arabia and Pakistan a nd

supported the draft resolution, together with the amendments proposed by Greece and Iran.
WHO should consider the possibility of involving CIOMS in assessing for the use of new me
dicinal
drugs, and in the continuous appraisal of existing drugs, with particular emphasis on ess
ential drugs, which
should be subject to international ethical criteria.

Research in medicinal drugs should be directed towards finding drugs for specific diseases rather than supporting research interests of the medical profession and the pharmaceutical industry.

Dr NGEDUP (Bhutan) said that there was no medicinal drugs promotion in his country because all drug needs were met through the essential drugs programme. The few private pharmacies that did exist were regulated by that programme and the trade board. However, his Government was in the process of elaborating a medicinal drugs act and establishing a drug control administration.

He welcomed the Consultation% recommendations; perhaps the ethical criteria could be transformed into models to be incorporated into national drug policies.

Bhutan supported the draft resolution and wished to join the list of sponsors.

Professor OKELO (Kenya) said that his country was a sponsor of the draft resolution. In his view, explicit reference to the problems associated with donated drugs should be included in the text.

Dr BANKOWSKI (Council for International Organizations of Medical Sciences), speaking at the invitation of the Chairman, said that all the participants in the joint CIOMS/WHO Consultation had agreed on one fundamental principle: to help those who were in need of assistance. That had resulted in a spirit of consensus which, hopefully, would lead to more concrete action.

The draft resolution under consideration was only the beginning and should lead to further and more effective activities in the field of medicinal drug promotion, on the basis of ethical criteria.

He appreciated the efforts of all those who had collaborated in the Consultation and in preparing the resulting report. In particular, he wished to thank the WHO Division of Drug Management and Policies, the International Federation of Pharmaceutical Manufacturers Associations, the World Federation of Proprietary Medicine Manufacturers, the United States F 00d and Drug Administration, the International Organization of Consumers Unions and, for their financial support, the Governments of Australia, Canada, the United Kingdom of Great Britain and Northern Ireland, the Netherlands and Switzerland.

That cooperation was a concrete example of how partners were working together on a global agenda for bioethics. CIOMS was willing to collaborate with WHO on any initiatives in that field.

Mr LOPEZ LINARES (International Organization of Consumers Unions), speaking at the invitation of the Chairman, said that IOCU had more than 180 branches in some 70 developing and industrialized countries and was a founder member of Health Action International (HA1). IOCU and HA1 were dedicated to the full implementation of WHOls revised drug strategy and had consistently supported the efforts of WHO, its Member States and other institutions, to promote the more rational use of drugs.

IOCU had also collaborated with WHO in a number of other areas, including the development of educational strategies and training materials. It had also participated in the WHO/CIOMS Consultation.

WHO in turn had participated in many activities organized by IOCU and HAI.

Since the publication of the first model list of essential drugs in 1977, WHO had played an important part in encouraging the availability of essential drugs and their rational use. Its Revised Drugs Strategy had raised international awareness and had led many countries to introduce comprehensive national drug policies. However, a gap still existed between the resources available for drugs and growing demand.

Economic constraints had led to reduced government expenditure on health, privatization of health services,

and the introduction of payment by the consumer in public health institutions which had led to a weakening of the public health sector in many countries. Special problems confronted the newly emerging economies of central and eastern Europe and the countries of the former Soviet Union. Moreover, high drug prices continued to concern consumers worldwide.

Other international agencies, such as the World Bank and UNICEF, bilateral donors and nongovernmental organizations were becoming increasingly involved in work on drugs and their policies required overall coordination under the leadership of WHO. Now more than ever it was essential that WHO should continue to play a key part in promoting the principles of the revised drug strategy and should act as a focus for the necessary cooperation between other bodies. Without such leadership, there was a danger that the work of international agencies and of donors might conflict with public health goals and become less focused on equitable access to essential drugs and health care services.

IOCU and HA1 had noted with interest the Director-General% report on the implementation o
f
WHO'S revised drug strategy (document A47/8) and welcomed the many supportive interventio
ns by
Member States about WHOls work on pharmaceuticals. Those interventions confirmed WHO'S ma
ndate
to provide leadership coordination in that area and to implement all the components of th
e revised drug
strategy. He welcomed support by countries for the draft resolutions before the Committee
.
HA1 and IOCU had been working for many years to improve the standard of drug promotion.
Unethical drug promotion continued in both developing and developed countries, and countr
ies acting to
introduce policies to improve the standards of information provision and to control drug
promotion often
met with opposition. For example, it had recently been reported that one pharmaceutical i
ndustry
association had attempted to prevent a Member State from introducing generic labelling le
gislation. Yet
resolution WHA46. 19 had called on governments "to enact rules and regulations as necessa
ry to ensure that
international nonproprietary names (or the equivalent nationally approved generic names)
used in the
labelling and advertising of pharmaceutical products are always displayed prominently".
The ethical criteria provided a model which governments could adapt and use as a basis fo
r legislation
to control drug promotion and to ensure that it was consistent with national health polic
ies. They could
also be used by health professionals, consumers and industry in developing standards and
evaluating drug
promotion.
The report of the CIOMS/WHO Consultation contained some useful recommendations which
identified specific actions to be taken by governments, industry, WHO, medical profession
als, consumer
organizations and medical journals to ensure that the quality of information about a drug
was of as high
a standard as the quality of the drug itself.
IOCU and HA1 would continue to work to achieve equitable access to essential drugs and to
idefend
consumersl rights to independent information on safe, effective and appropriate drug use.
They would
continue to monitor drug promotion and compliance with the ethical criteria and work to c
reate critical
awareness among consumers. All those efforts would require increased collaboration with W
HO and others
working to promote rational drug use.
Dr REINSTEIN (World Federation of Proprietary Medicine Manufacturers), speaking at the
invitation of the CHAIRMAN, said that WFPMM was the worldwide organization of non-prescri
ption
medicine manufacturers with member associations in 45 countries, both developed and devel
oping. It had
represented the non-prescription medicine industry at the successful CIOMS/WHO Consultati
on, which
had resulted in substantial agreement on the major issues and actions to be taken, in spi
te of the normal
tensions which existed among the various parties.
At the ninety-third session of the Executive Board, he had mentioned that WFPMM had inten
sified
efforts to encourage the formation of national associations of non-prescription medicine
manufacturers -
one of the recommendations of the Consultation. Efforts had also been increased to update
the national
voluntary codes of advertising practice of members. National industry associations develo
ped codes of
advertising practice to which their member companies agreed to adhere. Those codes were b
ased on the
WFPMM guidelines for national codes of advertising practice and the WHO ethical criteria
for medicinal
drug promotion. Thus, they supported the complementarity of self-regulation by industry a
nd national

regulation by governments, which had been recognized by the Consultation. All public advertising was regulated by law in developed and most developing countries, and self regulation by industry added to the controls.

Important studies to determine what could be effectively communicated to consumers about non-prescription medicines in advertising had indicated that, contrary to what had been thought by the drafters of the WHO ethical criteria in 1988, public advertising was an ineffective way of communicating detailed information on medicines. All parties at the Consultation had agreed that detailed information on when and how to use the medicine should be provided on the label and/ or the leaflet which came with the product and which was thus available at the moment the medicine was about to be taken. Detailed information in advertising simply reduced the effectiveness of the main message which was: the name of the product, what it could be used for and an express invitation to read the label or leaflet as appropriate.

Even in the most developed countries, detailed information in advertising of medicines to the public was not effective and at least one important developed country had now withdrawn a requirement for such information in television advertising in favour of a simple message that consumers should read the label

and leaflet and consult a pharmacist or physician. Studies to monitor the current impleme ntation of the ethical criteria with regard to advertising to the public would therefore produce a disto rted conclusion, since the advice concerning such advertising currently indicated that it should contain informa tion on major precautions, contraindications and warnings.

One of the gratifying aspects of the Consultation had been the opportunity to meet, in a neutral and non-confrontational setting, representatives of all other interested parties. That had re sulted in informal interactions which should lead to cooperative efforts to further improve the usefulness a nd the implementation of the ethical criteria for the promotion of non-prescription products. WF PMM looked forward to continuing its efforts to advance the recommendations of the Consultation as t hey applied to non-prescription medicines, in collaboration with all interested parties.

Dr ARNOLD (International Federation of Pharmaceutical Manufacturers Associations), speaki ng at the invitation of the CHAIRMAN, said that he was now in a position to give further inf ormation on the progress which had been made in revising the IFPMA Code of Pharmaceutical Marketing Pract ices. A draft of an extensively revised Code was currently being considered by IFPMA member assoc iations and would be discussed by the IFPMA Council when it met in June 1994. In the light of comment s received the Council would submit a definitive text of the revised Code for consideration at the I FPMA Assembly on 31 August 1994. Acceptance of the terms of the Code by member associations on behalf o f their member companies, wherever they did business was a statutory obligation and a condition o f membership of the Federation. Federation members represented a large proportion of the worlds produc tion of prescription medicines and included virtually all the research-based sector.

The adoption of the revised Code would be a major step forward in self-regulation in that the Code would be more detailed and more responsive to current circumstances. For example, it woul d address in detail the question of congresses and symposia. National codes would, if necessary, be br ought into line to ensure that they were in no way less stringent than the revised IFPMA code.

An effective self-regulatory code, perhaps backed up by enforceable legislation to deal w ith serious abuses by companies falling outside the scope of the Code, was the most cost-effective wa y to achieve high overall ethical standards of promotion. IFPMAls action in revising its Code was fully in keeping with the spirit of the WHO ethical criteria and the wishes of the Health Assembly.

IFPMA was also working to extend its membership and thus the scope of operation of its Co de and, to that end, was in active discussion with a number of national associations in eastern E urope, South-East Asia and southern Africa.

Periodic reports on the operation of the Code would continue to be given wide circulation , including to WHO, thus fulfilling the intention of paragraph 6 (1), sub paragraph (c) of the draft resolution before the Committee.

Professor CALDEIRA (representative of the Executive Board) thanked speakers for their val uable contributions.

Ethical approaches were becoming increasingly important and the nature of the discussions of such a diffith and controversial matter at the CIOMS/WHO Consultation at the ninety-third sess ion of the Executive Board and at the current meeting of the Committee was therefore very encouragin g. He hoped

that, in the future, criteria could be developed in relation to other medical health technologies, such as medical devices and equipment.

He drew particular attention to the comments which had been made regarding the need to give adequate, correct and appropriate information both to patients and to prescribers, the need for more education both at university and other levels, the references to a periodic review of the criteria, and the unification of appropriate drugs promotion.

Dr AN'IEZANA (Assistant Director-General) thanked all members of the Committee for their encouraging comments on the Director-Generalls report (document A47/7). The report highlighted the right to impartial balanced information for patients, prescribers and all interested parties in the community and indicated that the dissemination of information was of great importance not only to all delegations but also to WHO in its future activities.

He assured delegates that WHO would do its utmost to follow up the 19 recommendations of the CIOMS/WHO Consultation both at headquarters and regional office level. The periodic review, to which reference had been made by several delegations, was very important, particularly as nothing was static in the field of pharmaceuticals and drugs. As the Australian delegate had implied, there was a need to make appropriate provision in budgetary terms both for the current and the next biennium and the intention was to do so from the outset in a way which would enable the Secretariat to support activities in as efficient a manner as possible. Support for national governments was part of the raison dare of WHO and the Organization could be counted on to do its utmost to implement the ethical criteria.

Reference had been made to the very important subject of donations. The international community should not only implement the recommendations of the draft resolution but should endeavour to harmonize and standardize goodwill donations among nations so as to avoid difficulties for recipient countries.

Reference had also been made to the need for harmonization and uniformity of information worldwide. Many groups of countries were already working towards that end and WHO would follow-up and disseminate information on their activities. Finally, be emphasized the commitment of the Secretariat to do the best it could both from the point of view of the allocation of resources and of coordination with its partners both governmental, intergovernmental and nongovernmental organizations in that important task.

The CHAIRMAN said that a revised version of the draft resolution incorporating the proposed amendments and the names of additional countries willing to be included as sponsors would be circulated.

Maternal and child health and family planning for health (resolution WHA46.18) (continued)

The CHAIRMAN recalled that, at its fifth meeting, the Committee had considered the resolution on quality of care recommended by the Executive Board in resolution EB93.R11, and had proposed a number of amendments, so that it now read as follows:

The Forty-seventh World Health Assembly,

Noting the report by the Director-General on maternal and child health and family planning:
current needs and future orientation;

Recalling resolutions WHA32.42 on maternal and child health, including family planning; WHA32.3O on primary health care and monitoring health for all; and WHA46.18 on maternal and child health and family planning for health, and WHA45.5 on strengthening nursing and midwifery serv1ces;

Noting that the Organization has successfully developed and adapted a number of management and evaluation methods that involve the participation of all levels of the health system and community, that can be rapidly applied to a wide range of service delivery problems, and that may provide guidance on action needed to improve the functioning and performance of maternal and child health and family planning services;

Noting also that several divisions and programmes within WHO are engaged in these fields and that there is a need for a comprehensive, unifying strategy for action and research in the broad area of reproductive health;

Recognizing that enormous progress has been made in many aspects of maternal and child health, as evidenced by the great increase in immunization coverage, accessibility and use of family planning services and numbers of trained attendants at childbirth;

Concerned nonetheless that in many countries such increases in coverage are not having th
e
expected effect because of poor quality of care and performance of health systems;
Emphasizing that rapid progress in the health of mothers and the newborn and in family
planning can be assured by improving the quality of care and the performance of the exist
ing services
and staff;
Recognizing that a number of different international, national and nongovernmental
organizations are providing technical and financial support at country level,

1. URGES all Member States:
(1) to give priority to assessing and improving the quality of care for women and childre n in
district-based health systems, as part of a global approach to family health;
(2) to adapt and apply standard protocols for the diagnosis and clinical management of th e
common problems encountered in services for the health of mothers, infants and children;
(3) to strengthen health centres so as to ensure a high level of nursing and midwifery ca re,
and to provide regular supervisory, managerial and logistic support to peripheral health posts,
community health workers and trained traditional birth attendants applying local strategi es for
the health of mothers and the newborn;
(4) to give priority to assessing and improving the quality of basic and continuing nursi ng and
midwifery education;
(5) to reorient training curricula to community-based and problem-solving approaches, and to ensure that health workers are made aware of the attitudes and needs of women and othe r
members of the community within a context of coherent implementation of population polici es;
2. REQUESTS the Director-General:
(l) to continue to provide technical support and guidance to Member States in the further development, adaptation and application of indicators of quality of care in maternal and child
health and family planning and other aspects of primary health care;
(2) to continue to prepare guidelines and training material and devise approaches that improve the quality of care through standardized case definition, diagnosis and case management for the major health problems affecting mothers, the newborn, infants and children, and providing the necessary supervisory support, including monitoring and evalu ation;
(3) to ensure that the components of maternal and child health care and family planning a re
promoted and provided to Member States in a coherent and integrated manner, and that they correspond to national priorities and demand;
(4) to seek to improve in-country coordination mechanisms, where appropriate, between all concerned agencies and organizations, to support national leadership and to make optimal use
of available human and material resources;
(5) to report to the Executive Board and to the Health Assembly in 1995 on ongoing activities to develop a comprehensive strategy for research and action in the broad field of
sexual and reproductive health.
The resolution recommended by the Executive Board in resolution EB93.R11, as amended, was approved.
The CHAIRMAN recalled that, at its fifth meeting, the Committee had also considered the r esolution
on traditional practices harmful to the health of women and children recommended by the E xecutive Board
in resolution EB93.R10. He invited the Committee to consider a revised version of that re solution,
incorporating the amendments proposed, which read as follows:
The F orty-seventh World Health Assembly,
Noting the report by the Director-General on maternal and child health and family plannin g:
current needs and future orientation;
Recalling resolutions WHA32.42 on maternal and child health, including family planning; WHA38.22 on maturity before childbearing and promotion of responsible parenthood; and WHA46.18 on maternal and child health and family planning for health;
Reaffirming its support for the United Nations Convention on the Rights of the Child, and United Nations Economic and Social Council resolution 1992/251 on traditional practices a ffecting
the health of women and children;
Recognizing that, although some traditional practices may be beneficial or harmless, othe rs,
particularly those relating to female genital mutilation and early sexual relations and r eproduction,
cause serious problems in pregnancy and childbirth and have a profound effect on the heal th and

development of children, including child care and feeding, creating risks of rickets and anaemia;
14

Acknowledging the important role that nongovernmental organizations have played in bringing
these matters to the attention of their social, political and religious leaders, and in establishing
programmes for the abolition of many of these practices, particularly female genital mutilation,
1. WELCOMES the initiative taken by the Director-General in drawing international attention
to these matters in relation to health and human rights in the context of a comprehensive approach
to womenls health in all countries, and the policy declarations to the United Nations Special
Rapporteur on traditional practices by governments in countries where female genital mutilation is
practised;
2. URGES all Member States:
(1) to assess the extent to which harmful traditional practices affecting the health of women
and children constitute a social and public health problem in any local community or sub-group;
(2) to establish national policies and programmes that will effectively, and with legal
instruments, abolish female genital mutilation, childbearing before biological and social
maturity, and other harmful practices affecting the health of women and children;
(3) to collaborate with national nongovernmental groups active in this field, draw upon their
experience and expertise and, where such groups do not exist, encourage their establishment;
3. REQUESTS the Director-General:
(1) to strengthen WHO,s technical support to and cooperation with Member States in
implementing the measures specified above;
(2) to continue global and regional collaboration with the networks of nongovernmental
organizations, United Nations bodies, and other agencies and organizations concerned in order
to establish national, regional and global strategies for the abolition of harmful traditional
practices;
(3) to mobilize additional extrabudgetary resources in order to sustain the action at national,
regional and global levels.
The resolution recommended by the Executive Board in resolution EB93.R10, as amended, was approved.
2. FIRST REPORT OF COMMITTEE A (Document A47/48)
Dr AL-SHABANDAR, Rapporteur, read out the draft first report of Committee A.
The report was adopted.
The meeting rose at 11h30.