

Progress in the rational use of medicines, including better medicines for children

Rational use of medicines

Report by the Secretariat

1. Members of the Executive Board at its 118th session in May 2006 proposed numerous amendments to the draft resolution contained in the report on the rational use of medicines: progress in implementing the WHO medicines strategy.¹ An informal drafting group considered the proposed amendments but was unable to complete its work. The Board, therefore, agreed to defer further consideration of the matter to its session in January 2007.² This report provides a summary of the major issues, for coherence and ease of reference.³ Attention is given to aspects on which the draft resolution focuses and those for which Board members had requested more information or on which members could reach no consensus. The present consideration of the topic arose from the discussions at the Fifty-eighth World Health Assembly of rational use of medicines by prescribers and patients in the context of the threat of antimicrobial resistance to global health security and the adoption of resolution WHA58.27 on improving the containment of antimicrobial resistance. Many Member States underlined the need for more to be done to rectify the irrational use of medicines, which was a serious global problem.

2. The definition of rational use of medicines was formulated at the Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985, and endorsed by resolution WHA39.27 on the revised drug strategy and resolution WHA54.11 on the revised medicines strategy. The aim of WHO's medicines strategy for 2004–2007, based on resolution WHA54.11, is that people everywhere have access to the essential medicines they need; that the medicines are safe, effective and of good quality; and that the medicines are prescribed and used rationally.⁴ WHO has thus been working to ensure that medicines are used in a therapeutically sound and cost-effective way by health professionals and consumers in order to maximize the potential of medicines in the provision of health care.⁵ Thus, the scope of rational or good-quality use of medicines covers the elimination of their overuse and underuse and lack of adherence to treatment. Monitoring systems within WHO have quantified the

¹ Document EB118/6.

² Document EBSS-EB118/2006/REC/1, summary record of the third meeting of the 118th session of the Executive Board, section 1.

³ For more detail and an overview, see documents A58/14 and EB118/6.

⁴ Document WHO/EDM/2004.5.

⁵ Document A58/14.

serious worldwide irrational use of medicines, and identified that implementation of national policies to encourage rational use is insufficient. Unless these underlying problems are solved, the aims of the WHO medicines strategy cannot be achieved nor can resolution WHA58.27 on improving the containment of antimicrobial resistance be fully implemented.

3. Global sales of medicines in 2004 amounted to about US\$ 550 000 million and 10% to 40% of health budgets are spent on medicines. Evidence suggests that more than half all medicines in developing countries and those with economies in transition, and a substantial proportion of medicines, particularly antibiotics, in developed countries are used inappropriately, thus wasting often scarce resources. The purchase of many medicines through out-of-pocket payments causes severe financial hardship for the poor and disadvantaged in developing countries. In addition, irrational use of medicines results in poor patient outcomes and can cause harm to patients. Antimicrobial resistance, dramatically increasing worldwide as a result of inappropriate overuse of antibiotics, causes significant morbidity and mortality, and has been estimated to cost annually US\$ 4000-5000 million in the United States of America and €9000 million in Europe. Likewise, adverse drug reactions and medication errors, also increasing with overuse of the greater number of drugs available, cause significant morbidity and mortality, and have been estimated to cost £380 million annually in the United Kingdom of Great Britain and Northern Ireland and up to US\$ 5.6 million per hospital per year in the United States of America. Such harm can only be minimized through adequate measures against the irrational use of medicines.

4. To fulfil the monitoring role specified in resolution WHA54.11, the Secretariat has created a database of published and unpublished surveys of medicine use (750 to date) carried out in developing countries and countries with economies in transition since 1990. The data show that, at the primary health-care level in Africa, Asia and Latin America, only about 40% of all patients were treated in accordance with clinical guidelines for many common conditions, and that there has been no improvement over the past 15 years. For example, fewer than half all patients with acute diarrhoea were treated with oral rehydration salts, yet more than half were given antibiotics; just over half the patients with pneumonia were treated with appropriate antibiotics, yet more than half all patients with viral upper respiratory tract infection received antibiotics inappropriately. The data show clearly that the use of medicines in the private sector was often worse than in the public sector. For example, about 40% of cases of acute childhood diarrhoea were treated in accordance with clinical guidelines in the public sector as compared to less than 20% of cases treated in the private-for-profit sector. Less than 50% of surveys were accompanied with interventions to promote rational use of medicines – a low figure for so many countries over a period of 15 years. Most of these interventions were introduced at the local level and only about 20% of them were adequately evaluated for their impact on medicines use. Although some of the most effective and sustainable interventions combine managerial and economic strategies, 75% of the interventions implemented were educational with only 25% being managerial or economic.

5. Over the past 10 years, the Secretariat has worked with partners to fill gaps in knowledge and collect sufficient evidence to make recommendations on how to promote rational use of medicines. The following interventions, which underlie the WHO medicines strategy, are recommended:¹

- establishing a mandated multidisciplinary national body to coordinate policies on medicine use and monitor their impact

¹ Document WHO/EDM/2002.3.

- formulating and using evidence-based clinical guidelines for training, supervision and supporting critical decision-making about medicines
- selecting, on the basis of treatments of choice, lists of essential medicines that are used in drug procurement and insurance reimbursement
- setting up drug and therapeutics committees in districts and hospitals to improve the use of medicines
- promoting problem-based training in pharmacotherapy in undergraduate curricula
- making continuing in-service medical education a requirement of licensure
- promoting systems of supervision, audit and feedback in institutional settings
- providing independent information (including comparative data) about medicines
- promoting public education about medicines
- eliminating perverse financial incentives that lead to irrational prescribing
- drawing up and enforcing appropriate regulation, including regulations to ensure that medicinal promotional activities are in keeping with the WHO ethical criteria adopted in resolution WHA41.17
- reserving sufficient governmental expenditure to ensure equitable availability of medicines and health personnel.

Many of these interventions fall within the technical and financial reach of all Member States. Without such actions, rational use of medicines cannot be attained. Evidence presented at the Second International Conference on Improving the Use of Medicines (Chiang Mai, Thailand, 30 March – 2 April 2004), which was supported by WHO, reaffirmed the effectiveness of these interventions. Many different aspects of health policies and systems can influence how medicines are used, including: insurance; financing; selection, pricing and availability of medicines, and their promotion and regulation; quality-improvement structures such as drug and therapeutic committees for monitoring and supervision; public education; and the availability of adequately trained health-care professionals. Coordination of the many different stakeholders and disciplines concerned, in order to promote rational use of medicines nationwide, is extremely difficult when often no forum nor mandated body to facilitate the process exists. Consequently, the main recommendation of the conference was for countries to have national medicines programmes in order to promote rational use of medicines through coordinated implementation of sustainable multifaceted interventions, scaled up to the national level and with in-built systems for monitoring use of medicines in order to evaluate progress.¹

¹ See <http://mednet3.who.int/icium/icium2004/recommendations.asp>.

6. Also pursuant to resolution WHA54.11, in order to monitor the pharmaceutical situation in countries the Secretariat has created a second database¹ containing information on pharmaceutical policies from all Member States in 1999 and 2003. The data show that, although several Member States are implementing some of the national policies recommended by WHO, a significant number is not using all the available options. For example, of all the Member States that supplied information, less than 60% had monitored the use of medicines in the previous two years; about 50% had undertaken a public-education programme on use of medicines in the previous two years; about 40% supported independent, continuing medical education for prescribers and had established a medicines information centre; 30% to 40% had drug and therapeutic committees in most hospitals and regions; in about 60% clinical guidelines had been updated in the previous five years; just over 70% had a national essential medicines list but only 30% used this list for insurance reimbursement; and only 60% to 70% trained their prescribers in the essential medicines concept, pharmacotherapy, rational prescribing and the application of clinical guidelines.

7. Irrational use of medicines and its detrimental effects are likely to increase, unless action is taken, for two reasons. First, evidence suggests that the use of medicines in developing countries and those with economies in transition is often significantly worse in the private sector than in the public sector, and the private sector is providing an increasing proportion of health-care delivery worldwide. One reason for this may be poorer regulation of the private sector in some countries. Secondly, many major global initiatives to increase access to essential medicines and to extend treatment of HIV/AIDS, tuberculosis, malaria and other diseases concentrate mainly on access to associated medicines. Although these programmes include precautions to ensure rational use of medicines, often insufficient attention and resources have been given to the fundamental and widespread problem of inappropriate use of other medicines.

8. In resolution WHA39.27 the Health Assembly set the mandate for promoting rational use of medicines. It has subsequently adopted several resolutions on specific aspects, such as medicinal drug promotion (WHA41.17, WHA45.30, WHA47.16 and WHA51.9) and the role of the pharmacist (WHA47.12), and, more generally, essential drugs (WHA43.20, WHA45.27 and WHA47.13), the revised drug strategy (WHA41.16, WHA49.14 and WHA52.19) and WHO's medicines strategy (WHA54.11). Recent knowledge and the existence of evidence-based, practical recommendations, however, demand a new, cross-cutting, sector-wide policy approach to health systems and medicines in order to promote rational use of medicines. Such an approach has not been articulated in any of the previous resolutions. In particular, the national medicines programmes that are needed and recommended (see paragraph 5 above), unfortunately do not exist in many countries. The urgent need to establish such programmes is the focus of this report and the draft resolution below.

9. In their discussion of the matter at the 118th session of the Executive Board, members accepted that irrational use of medicines constituted a serious global public-health crisis, tackling which needed a focus on health systems and policies. Such an approach by WHO would require a new mandate for the Organization in order to facilitate the flow of increased resources to this area. Member States at the Fifty-eighth World Health Assembly² and Board members mentioned the need for a broad resolution on the rational use of medicines; the Board explicitly called for a resolution with a specific focus and

¹ Document WHO/EDM/2004.5.

² Document WHA58/2005/REC/3, summary record of the eighth meeting of Committee A, section 2.

that did not repeat aspects covered in previous texts.¹ The recommendation to establish national programmes for monitoring medicine use and coordinating the implementation of sustainable, nationwide, multifaceted interventions (see paragraph 5 above), targeting providers and consumers in both the public and private sectors, would meet these concerns. The Board did not complete its consideration of the draft resolution and the proposed amendments, including this recommendation. In deferring further consideration, it requested a revised draft resolution and additional information.

10. The draft resolution below incorporates the amendments proposed by Board members. Since the informal drafting group convened to consider the text had not completed its work, there remain some inconsistencies. The original draft resolution² urged Member States “to ensure national coordination of the use of medicines, where possible by establishing a mandated multidisciplinary body, involving civil society, to monitor medicine use, and to promote and coordinate the implementation of a national programme for the rational use of medicines”. Such national programmes would include core strategies, particularly those listed in paragraph 5 above, implemented by Member States in a progressive manner according to their individual situations. The revised draft resolution remains broad in urging Member States to consider establishing national programmes, in paragraphs 1(2) and 1(6), but is not sharply focused since no agreement was reached on what strategies such national programmes should adopt nor how such programmes should be managed. Thus, all reference to monitoring the use of medicines, the fundamental activity for any programme to promote rational use of medicines, has been deleted. The recommendation to establish a national multidisciplinary body for coordinating a national programme has become consideration for establishing such a body. The text retains a narrow selection of the strategies mentioned in paragraph 5 (above): clinical guidelines, training health professionals, and regulation of drug promotion, but some have been inserted within square brackets (essential medicines lists, and drug and therapeutic committees) and others are not mentioned (promoting systems of supervision, audit and feedback, making continuing medical education a requirement of licensure, and avoiding perverse financial incentives). Recommendations to the Director-General have been narrowed since all reference to supporting Member States to establish national programmes for monitoring the use of medicines and coordinating implementation of strategies to promote rational use of medicines has been deleted, as has mention of providing support to Member States in order to establish national bodies for coordinating national programmes. The recommendation to promote research on promoting rational use of medicines has been retained but reference to promotion of research on the development of national monitoring systems, essential to monitor the impact of interventions but often absent, has been removed.

¹ Document EBSS-EB118/2006/REC/1, summary record of the fifth meeting of the 118th session of the Executive Board, section 4.

² Document EB118/6, paragraph 10.

ACTION BY THE EXECUTIVE BOARD

11. The Executive Board is invited to consider the following draft resolution:

The Executive Board,

Having considered the report on progress in the rational use of medicines, including better medicines for children,¹

RECOMMENDS to the Sixtieth World Health Assembly the adoption of the following resolution:²

The Sixtieth World Health Assembly,

Having considered the report on rational use of medicines: progress in implementing the WHO medicines strategy;

Recalling the report by the Secretariat on rational use of medicines by prescribers and patients, discussed at the Fifty-eighth World Health Assembly;

Recalling resolutions WHA39.27, WHA41.16 and WHA47.13 on the rational use of drugs, WHA41.17, WHA45.30 and WHA47.16 on ethical criteria for medicinal drug promotion, WHA43.20 and WHA45.27 on the WHO Action Programme on Essential Drugs, WHA47.12 on the role of the pharmacist, WHA49.14 and WHA52.19 on the revised drug strategy, WHA51.9 on cross-border advertising, promotion and sale of medical products using the Internet, WHA54.11 on the WHO medicines strategy, and WHA58.27 on antimicrobial resistance;

Recognizing the efforts of WHO in collaboration with governments, universities, the private sector, and nongovernmental organizations, in areas related to health care delivery systems and health insurance programmes to improve the use of medicines by prescribers, dispensers and patients;

Aware of the core components of WHO's strategy for promoting the rational use of medicines;³

Wishing to promote evidence-based rational use of medicines by providers and consumers [in order to contribute significantly to achieving equitable access to essential medicines];

Aware that irrational use of medicines continues to be an urgent and widespread problem [especially among the private health sector in developing countries] with serious consequences in terms of poor patient outcome, adverse drug reactions, increasing antimicrobial resistance and wasted resources;

¹ Document EB120/7.

² See document EB120/7 Add.1 for the administrative and financial implications for the Secretariat of this resolution.

³ Document WHO/EDM/2004.5.

Acknowledging that successful implementation of previous resolutions on antimicrobial resistance cannot be achieved without addressing the global problem of irrational use of medicines;

Recognizing that many countries do not have a stringent drug regulatory authority nor a full national programme/body to promote rational use of medicines;

Emphasizing that global initiatives to increase access to essential medicines should adhere to the principle of rational use of medicines, and especially patient adherence;

Concerned that insufficient attention and resources are being directed towards tackling the problem of irrational use of medicines by prescribers, dispensers and consumers;

Emphasizing the need for a comprehensive, sustainable, national and sector-wide approach to promote the rational use of medicines;

[Recognizing the importance of financing drugs and methods of provider payment have major impact on rational use, and that appropriate policy on financing health care is required;]

[Recognizing the perverse incentive of itemized fee for service where the prescriber also sells the medicines (provider payment) on irrational use of drugs, which requires comprehensive health reform;]

Convinced that it is time for governments, the health professions, civil society, the private sector and the international community to pledge their commitment, including adequate resources, to promoting the rational use of medicines,

1. URGES Member States:¹

(1) to invest sufficiently in human resources and provide adequate financing in order to strengthen institutional capacity to ensure more appropriate use of medicines in both the public and the private sector;

(2) to consider establishing and/or strengthening, as appropriate, a national drug regulatory authority and a full national programme and/or multidisciplinary body, involving civil society and professional bodies, to promote the rational use of medicine;

[(3) to develop, strengthen and implement, where appropriate, the application of an essential drug list into the benefit package of the existing or new insurance funds;]

(4) to develop and strengthen existing training programmes on rational use of medicines and ensure that they are taken into account in the curricula for all health

¹ And regional economic integration organizations, where appropriate.

professionals and medical students, including their continuing education, where appropriate;

(5) to enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, [including those through direct to consumer and Internet sales,] to monitor drug promotion, and to develop and implement programmes that will provide independent, nonpromotional information about medicines;

(6) to develop and implement national policies/programmes to improve medicine use, including clinical guidelines [and essential medicines lists], with an emphasis on multifaceted interventions targeting both the public and private health systems, and involving providers and consumers;

[(7) to consider to develop, and strengthen where appropriate, the role of the hospital Drug and Therapeutic Committee to promote the rational use of drugs;]

(8) to expand to national level, sustainable interventions successfully implemented at local level;

2. REQUESTS the Director-General:

(1) to strengthen the leadership and evidence-based advocacy role of WHO in promoting rational use of medicines;

(2) to strengthen, as appropriate, WHO's support to Member States in their efforts to establish and/or strengthen institutional capacity in promoting rational drug use in both public and private sector;

(3) to strengthen the coordination of international financial and technical support, in terms of rational use of medicines;

(4) to promote research, particularly on development of sustainable interventions for rational medicine use at all levels of the health sector, both public and private;

(5) to promote discussion among health authorities, professionals and patients on the rational use of medicines;

(6) to report to the Sixty-second World Health Assembly, and subsequently biennially, on progress achieved, problems encountered and further actions proposed in the implementation of WHO's programmes to promote rational use of medicines.

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