

Progress in the rational use of medicines

Report by the Secretariat

1. The present report provides a summary of the major issues related to the rational use of medicines, for coherence and ease of reference. Attention is given to areas underlying the main focus of the resolution EB120.R12 and those for which the Executive Board had requested more information at its 120th session. 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.¹ 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.² 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 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

¹ Document WHO/EDM/2004.5.

² Document A58/14.

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 (792 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
- 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

¹ Document WHO/EDM/2002.3.

- 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

6. Also pursuant to resolution WHA54.11, in order to monitor the pharmaceutical situation in countries the Secretariat has created a second database² 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.

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

² See documents WHO/EDM/2004.5 and WHO/TCM/2006.2.

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 contained in EB120.R12.

9. In discussions at their 118th and 120th sessions, the Executive Board, accepted that irrational use of medicines constituted a serious global public-health crisis, tackling of 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. At its 118th session, the Board explicitly called for a resolution with a specific focus and that did not repeat aspects covered in previous texts.¹ After discussion at its 120th session,² the Board adopted resolution EB120.R12.

ACTION BY THE HEALTH ASSEMBLY

10. The Health Assembly is invited to consider the draft resolution contained in resolution EB120.R12.

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

² EB119/2006-EB120/2007/REC/2, summary record of the sixth meeting of the 120th session of the Board, and summary record of the eighth meeting of the 120th session, section 2.