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Organization**

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Rational use of medicines: progress in implementing the WHO medicines strategy

Report by the Secretariat

1. Rational use of medicines requires that “patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.” This definition was formulated at the Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985, the Director-General’s summing-up of which formed the basis of the revised drug strategy endorsed by the Health Assembly in resolution WHA39.27. Such a definition covers the good-quality (i.e. proper and appropriate) use of medicines by providers and consumers, including adherence to treatment. Rational use of medicines has been discussed on several occasions by the Health Assembly in the context of the revised drug strategy and subsequently, the WHO medicines strategy.¹ The Fifty-eighth World Health Assembly considered rational use of medicines by prescribers and patients in the context of the threat of antimicrobial resistance to global health security and adopted resolution WHA58.27 on improving the containment of antimicrobial resistance. Many Member States underlined the need for more to be done to rectify the serious global problem of irrational use of medicines. This report aims to meet the concerns raised by some Member States at the Health Assembly by further considering the rational use of medicines within a broader framework,² and describes progress in promoting such use as part of the implementation of the WHO medicines strategy.

2. Treatment with medicines is one of the most cost-effective medical interventions known, and the proportion of national health budgets spent on medicines ranges between 10% and 20% in developed countries and between 20% and 40% in developing countries. Rational use of medicines for all medical conditions is fundamental to the provision of universal access to adequate health care, satisfying health-related human rights and attaining health-related Millennium Development Goals. 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.³ 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

¹ Resolution WHA54.11.

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

³ Document WHO/EDM/2004.5.



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care.¹ 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, especially for chronic conditions such as AIDS or diabetes. 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, most of this expenditure being in developed countries. Evidence suggests that more than half all medicines in developing countries, those with economies in transition, and a substantial proportion of medicines, particularly antibiotics, in developed countries are used inappropriately, thus wasting often scarce resources. In addition, irrational use of medicines results in poor patient outcomes and can actively harm patients. The purchase of many medicines through out-of-pocket payments causes severe financial hardship for the poor and disadvantaged in developing countries. Inadequate enforcement of laws on prescription-only status, leading to direct sales or sales over the Internet of prescription-only medicines, adds to the problem of irrational use of medicines. The harm is even more damaging in the light of the serious public health consequences of such irrational use. 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 €000 million in Europe. An important factor contributing to inappropriate overuse and unnecessary (and increasing) costs, are promotional activities that are not in keeping with the ethical criteria for medicinal drug promotion adopted in resolution WHA41.17.² A recent survey in 228 medical and pharmacy schools has documented a lack of awareness of those criteria.³ 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. Unfortunately, effective medicines are frequently underused. A recent study of patients with myocardial infarction and stroke in 10 middle-income countries demonstrated that less than 20% of patients received optimal medication therapy.⁴

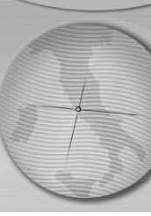
4. To fulfil the monitoring role specified in resolution WHA54.11, the Secretariat has created a database of published and unpublished surveys of medicine use (644 to date) carried out in developing countries and countries with economies in transition since 1990. The data show that, at the primary health-care 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

¹ Document A58/14.

² Document WHO/EDM/PAR/2004.3.

³ Document WHO/PSM/PAR/2005.2.

⁴ Mendis S et al. WHO study on prevention of recurrences of myocardial infarction and stroke. *Bulletin of the World Health Organization*, 2005; **83**(11): 820-828.



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the use of medicines in the private sector was significantly worse than in the public sector. Only 280 surveys (43%) 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 underline 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
- 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 that of promotional activities
- 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 policies, rational use of medicines cannot be attained.

¹ Document WHO/EDM/2002.3.



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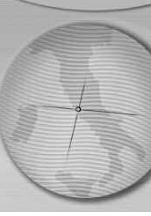
6. Also pursuant to resolution WHA54.11, the Secretariat has created a second database in order to monitor the pharmaceutical situation in countries.¹ This database contains information on pharmaceutical policy from all Member States in 1999 and 2003, which shows that, although several Member States 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 is likely to increase, unless action is taken, for two reasons. First, the use of medicines in developing countries and those with economies in transition is 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. Secondly, many major global initiatives to increase access to essential medicines and to extend treatment of HIV/AIDS, tuberculosis, malaria and other diseases concentrate on access to medicines and do not tackle the fundamental and widespread problem of inappropriate use.

8. In resolution WHA39.27 the Health Assembly set the mandate for promoting rational use of medicines. The Health Assembly 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 demand a new, cross-cutting, sector-wide, policy approach to health systems and medicines in order to promote rational use of medicines. There is mounting evidence that these practical and effective recommendations prevent unnecessary deaths and illness and reduce global expenditure on medicines.

9. Irrational use of medicines not only causes serious harm to patients through suboptimal treatment outcomes and unnecessary side effects, admissions to hospital and death, but also wastes huge amounts of scarce resources. Practical, evidence-based recommendations on how to counter irrational use now exist but unfortunately many of them are not being acted on, even though such policies needed to be implemented to guarantee progress towards ensuring universal access to essential medicines. Tackling the public health crisis of irrational use of medicines requires a new mandate and increased resources. The following draft resolution takes a cross-cutting health-systems approach to promoting rational use of medicines, emphasizing national strategies known to be effective, and prepares the ground for progress towards health-related Millennium Development Goals and fulfilling health-related human rights.

¹ Document WHO/EDM/2004.5.



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ACTION BY THE EXECUTIVE BOARD

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

The Executive Board,

Having considered the report on rational use of medicines: progress in implementing the WHO medicines strategy,¹

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

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 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;²

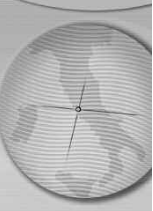
Acknowledging the progress made in monitoring the use of medicines and identifying effective interventions to promote rational use of medicines;

Wishing to promote rational use of medicines by providers and consumers as a prerequisite for achieving equitable access to essential medicines;

Aware that irrational use of medicines continues to be an urgent and widespread problem with serious consequences in terms of poor patient outcome, adverse drug reactions, increasing antimicrobial resistance and wasted resources;

¹ Document EB118/6.

² Document WHO/EDM/2004.5.



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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 have neither a full national programme to promote rational use of medicines nor a mandated multidisciplinary national body to monitor medicine use and to develop and coordinate the implementation of such a national programme;

Aware that many major global initiatives to increase access to essential medicines do not address the fundamental and widespread problem of irrational use of medicines;

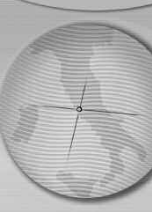
Concerned that insufficient political attention and economic investment is being directed towards tackling the problem of irrational use of medicines by prescribers, dispensers and consumers;

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

Convinced that it is time for governments, the health professions, civil society, the private sector and the international community to pledge their commitment to ensuring that sufficient investment is made for promoting the rational use of medicines,

1. URGES Member States:

- (1) to invest sufficiently in human resources and provide adequate financing in order to ensure more appropriate use of medicines in both the public and the private sector;
- (2) to ensure national coordination of the use of medicines, where possible by establishing a mandated multidisciplinary national 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 as part of a medicines policy congruent with national health structures and available resources;
- (3) to develop and strengthen existing training programmes on rational use of medicines and ensure their incorporation into the curricula for all health professionals;
- (4) to enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor drug promotion, and to develop and implement programmes that will provide independent, nonpromotional information about medicines;
- (5) to develop and implement national medicines programmes to improve medicine use, with an emphasis on multifaceted interventions targeting both the public and private health systems, and involving providers and consumers;
- (6) to expand to national level, sustainable interventions successfully implemented at local level;



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2. REQUESTS the Director-General:

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

(2) in collaboration with governments and civil society, to expand and strengthen WHO's technical support to Member States in their efforts to establish mandated multidisciplinary national bodies to monitor medicine use, and to promote and coordinate the implementation of national programmes for the rational use of medicines;

(3) to promote research, particularly on development of national monitoring systems and sustainable nationwide interventions, and on promotion of rational medicine use at all levels of the health sector, both public and private;

(4) 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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