

## **ANALYSIS OF MEASURES AND INSTRUMENTS TO PROMOTE RATIONAL USE OF MEDICINES IN THE COUNTRIES OF THE EUROPEAN UNION**

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More than 50% of all medicines worldwide are prescribed, dispensed, or sold inappropriately, while 50% of all patients fail to take medicines correctly. Moreover, about one-third of the world's population lacks access to essential medicines. The irrational use of drugs results in wastage of scarce resources and widespread of health hazards. Examples of irrational use of drugs include: use of too many drugs by a patient (poly-pharmacy); failure to prescribe in accordance with clinical guidelines, etc. The problem of the rational use of drugs in developing countries is the worst; people may prefer to spend money on analgesic tablets and particularly injections to relieve their misery and to be able to carry on their normal works of earning livelihood.

The purpose of this work is to analyze measures to promote rational use of medicines in the countries of the European Union.

According to WHO's definition, rational use of drugs requires that patients receive drugs appropriate for 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. The above definition indicates that rational use of drugs, especially rational prescribing, should follow certain criteria as appropriate indication, appropriate drug, appropriate patient, appropriate patient information and appropriate evaluation. Factors contributing to irrational use of drugs include: diagnosis (inadequate examination of patient); prescribing (over-prescribing or under-prescribing); patient adherence (inadequate verbal instructions on drug usage).

The problem of rational use of drug is not only limited to the prescribers, dispensers, and the consumers of drugs, but as well as the manufacturers and sellers. WHO recommends that activities to strengthen the pharmaceutical sector be organized under the umbrella of a national drug policy. In many countries, a national essential drugs program is the mechanism for implementing such a policy, usually with emphasis on drug selection, procurement, distribution, and use in the public sector.

WHO has developed core policies to help promote more rational use of drugs, among them are: a mandated multi-disciplinary national body to coordinate

medicines use; clinical guidelines which consist of systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions; essential medicines list based on treatments of choice; drugs and therapeutics committees in districts and hospitals; problem-based training in pharmacotherapy in undergraduate curricula; continuing in-service medical education as a licensure requirement; supervision, audit and feedback; independent medicine information; public education about medicines; avoidance of perverse financial incentives; appropriate and enforced regulation and sufficient government expenditure to ensure availability of medicines and staff.

Germany was the first country in Europe to introduce a reference price system (Festbetrags system). A scientific institute of a sickness fund (Wissenschaftliches institute der deutschen Ortskrankenkassen) monitors pharmaceutical expenditure and consumption. A key information tool is a report analyzing the development of pharmaceutical prescriptions (Arneiverordnungs-Report) which has been published on a yearly basis for 25 years.

In France monitoring of pharmaceutical expenditure and consumption is done by the Social Health Insurance and the French Medicines Agency (Agence française de sécurité sanitaire des produits de santé), which hosted for some years a department called 'National Observatory for Prescriptions and Consumption of Medicines' producing analysis reports on the development of consumption in a specific pharmaceutical groups. Information campaigns targeted at the general public are regularly organized by the French Social Health Insurance.

In Italy since 2000, the Italian Medicines Agency has been operating a 'National Observatory on the use of Medicines' which monitors and analyses pharmaceutical consumption (e.g. impact of policy measures, comparison to other countries) on a monthly basis. Additionally, yearly reports on pharmaceutical consumption and expenditure are published. At regular intervals, AIFA runs information campaigns targeted at the general public (e.g. a campaign on the rational use of antibiotics and another for promoting generics).

Transparency and the inclusion of all stakeholders (e.g. doctors, pharmacists, and patients) characterize the Danish pharmaceutical system. A rational use of medicines is monitored by the Danish Medicines Agency in the out-patient sector and by the regions, which are the owners of the hospitals in the in-patient sector. When observing pharmaceutical consumption, the Danish Medicines Agency is supported by its Institute for Rational Pharmacotherapy, which was founded in 1999. A major tool is the electronic monitoring system (Odriprax)

which allows the authorities to assess pharmaceutical consumption at the central and local levels as well as at the level of the prescribing doctors.

Key instruments for promoting a more rational use of medicines in Europe include:

1. International non-proprietary name (INN) prescribing: physicians prescribing by the active ingredient name (INN) rather than the brand name.

2. Prescription guidelines: prescription guidelines ensure that the right medicine at the correct dose is given to the right patient at the right time.

3. Pharmaceutical budgets for doctors: when third party payers (sickness funds or national health services) apply this cost-containment measure, the maximum amount of money to be spent on medicines in a specific region or over a period of time is fixed.

4. Generic substitution: when pharmacists substitute a brand name medicine for a generic or another cheaper medicine containing the same active ingredient(s).

5. Prescription monitoring: the act of assessing or observing prescribing practices of physicians applied by payers. It is sometimes accompanied by feedback to prescribers.

6. Information activities targeted at general public: information activities carried out by payers to convey the reasons for rational drug use, e.g. campaign to promote generics.

A number of instruments to promote the rational use of drugs in the EU are targeted at doctors. In 23 of the 27 EU Member States, the payers (social health insurance or National Health Service) have introduced prescription guidelines. In nine Member States these guidelines are obligatory. In nearly all EU Member States the prescribing behavior of doctors is observed by the payers. Still there are some differences among the countries regarding how often this occurs and how institutionalized doctors get feedback and are asked to explain their prescribing behavior. Pharmaceutical budgets for doctors are rather uncommon. This approach is only applied in six of the 27 EU Member States. Only in Czech Republic and Latvia are budgets linked to sanctions.

Generics are seen as important products in the context of promoting the rational use of medicines. Two key measures for promoting generic use are INN prescribing and generic substitution. In the case of INN prescribing, doctors are encouraged to prescribe by INN instead of the brand name. This measure exists in 22 EU Member States. In four countries (Estonia, Lithuania, Portugal and Romania) INN prescribing is mandatory.

Improvements in the role of pharmacists play a major role in promoting the rational use of drugs. Pharmaceutical care is the responsible provision of medication-related care designed to achieve health outcomes that improve or maintain a patient's quality of life. Efficiency and quality of pharmaceutical care by pharmacists has proven to promote the rational use of drugs. In 21 EU Member States pharmacists may substitute an equivalent cheaper product, e.g. a generic or parallel imported product, for a prescribed medicine (in general an original product). In six countries (Denmark, Germany, Finland, Malta, Sweden and Slovakia) pharmacists are obliged to apply generic substitution, unless the patient or doctor opposes substitution, the latter only being possible under clearly defined conditions.

Rational use of drugs remains a challenge both for developing and developed countries. However, public sensitization, policies by the WHO and some developed countries can be emulated to promote the rational use of drugs especially in countries where its effects is enormous.

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