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REPORT FROM THE COMMISSION TO THE COUNCIL

**ON THE BASIS OF MEMBER STATES' REPORTS ON THE IMPLEMENTATION
OF THE COUNCIL RECOMMENDATION (2002/77/EC) ON THE PRUDENT USE
OF ANTIMICROBIAL AGENTS IN HUMAN MEDICINE**

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REPORT FROM THE COMMISSION TO THE COUNCIL

ON THE BASIS OF MEMBER STATES' REPORTS ON THE IMPLEMENTATION OF THE COUNCIL RECOMMENDATION (2002/77/EC) ON THE PRUDENT USE OF ANTIMICROBIAL AGENTS IN HUMAN MEDICINE

(Text with EEA relevance)

1. INTRODUCTION

In November 2001 the Council adopted a Recommendation on the prudent use of antimicrobial agents in human medicine (2002/77/EC) (hereinafter referred to as Recommendation). This Recommendation asks Member States and EEA countries to put in place specific strategies on prudent use of antimicrobial agents aiming to contain antimicrobial resistance. These strategies have to comprise measures in relation to surveillance of antimicrobial resistance, surveillance of antimicrobial use, control and preventive measures, education and training, and research. The Recommendation invites the Commission to facilitate mutual information, consultation, coordination, action and to keep matters covered under review and to submit reports on basis of Member States' reports

Member States and EEA countries were asked to report to the Commission on the implementation of the Recommendation within 2 years of its adoption. All Member States, Iceland, Norway, and Bulgaria have reported to the Commission. This report summarizes the main actions taken at Member State and Community level. It also highlights in conclusion the areas of the Recommendation needing further attention. This report is supported by a Commission Staff Working Paper providing a more detailed technical analysis.

This Recommendation has its main focus on the importance of using antimicrobial agents prudently **in human medicine** to contain primarily the emergence of antimicrobial resistance.

2. SUMMARY OF MAIN ACTIONS AT MEMBER STATE LEVEL

The Recommendation asks Member States to put in place specific strategies on prudent use of antimicrobial agents aiming to contain antimicrobial resistance. Sixteen Member States have a national strategy in place and ten countries are developing such a strategy. These strategies should pursue the following main objectives:

- (a) to establish or strengthen surveillance systems on antimicrobial resistance and use of antimicrobial agents.

Almost all countries have national systems for surveillance of antimicrobial use and antibiotic consumption. Fourteen countries reported to have the ownership of antimicrobial resistance data clearly defined. However, several obstacles for surveillance of resistance and use were reported: primarily the lack of a sustained financial basis, unclear legal status and regulation of privacy issues. Sixteen countries have published a national report on antimicrobial resistance. In a significant number of old Member States and EEA countries a formal collaboration

with veterinary surveillance is established, but in none of the new Member States such a link is reported.

The majority of Member States co-ordinate actions to improve prescribing practices. The scope and target groups vary. In eight countries no co-ordinated actions were reported at all. Although many countries provide some kind of feed-back to prescribers, this seems to consist of more general information and no country provides continuous feed-back on the prescribing practices of prescribers.

- (b) to implement control and preventive measures to support the prudent use of antimicrobial agents and contribute to limit the spread of communicable diseases.

Selling of antimicrobial agents without a prescription is considered a relevant source of inappropriate antimicrobial use in at least seven countries, although no country was able to estimate the current proportion of all antimicrobial agent sold without prescriptions. Sixteen countries have measures in place to enforce regulations for prescription-only use of systemic antimicrobial agents. Such measures are provided by the Community pharmaceutical legislation on medicinal products for human use (Directive 2001/83/EC as amended by Directive 2004/27/EC).

Most countries have nationally accepted guidelines on appropriate use of antimicrobials for surgical prophylaxis, otitis media, sinusitis, tonsillopharyngitis, community acquired pneumonia, urinary tract infections and meningitis. The impact of these guidelines on prescribing practices is only monitored in a few countries.

Twenty-two countries have a national programme for hospital hygiene and infection control in place, and in eighteen it is mandatory for each hospital to have an infection control committee. Only about half of the countries have legal requirements or recommendations about the number of infection control nurses per hospital bed, and have an accreditation procedure for hospitals and/or nursing homes. Only fourteen countries require infection control to be a part of the hospital accreditation procedure, and even less with respect to nursing homes accreditation procedure. Eighteen countries have national guidelines for the control of multi-resistant pathogens, however, this mostly includes only methicillin-resistant *Staphylococcus aureus* (MRSA).

- (c) to promote education and training of health professionals on the problem of antimicrobial resistance and to inform the general public about the importance of prudent use of antimicrobial agents.

Not in all countries health-professional-undergraduates receive education on appropriate use of antimicrobials. However, they receive continuing education on selected issues later in their career. In all countries education is provided by non-sponsored continuing education, and in almost all of them also through sponsoring by the pharmaceutical industry.

All but six countries have performed a campaign in some format in the past five years to raise awareness on topics related to antimicrobial resistance. Campaigns addressed more often health professionals than the general public.

To co-ordinate the implementation of the above strategies as well as for the purpose of information exchange and co-ordination with the Commission and other Member States, the Council recommended that each Member State should have in place rapidly an appropriate intersectoral mechanism. Twenty Member States, two EEA countries, and Bulgaria reported to have an intersectoral mechanism in place and five countries are about to create it. One Member State did not report to create such a mechanism. There are major differences in responsibilities/objectives of these intersectoral mechanisms and considerable variation in legal status and in composition.

3. SUMMARY OF MAIN ACTIONS AT COMMUNITY LEVEL

Antimicrobial resistance is a key priority and the Commission is undertaking and promoting a wide range of activities at Community level, in particular through its public health and research programmes. The Commission has acted on the specific invitations by the Council:

- The Commission has kept the structures and Committees of the Community network¹ up to date of the progress in the area of antimicrobial resistance and has sought its advice in developing a ‘template for reporting’ that the Member States have used to report on the implementation of the Council Recommendation. Members of the Committees have been crucial in coordinating the response of the Member States.
- Considering that there are differences in the information provided by Summary of Product Characteristics (SPC) for already authorised medicinal products for human use containing same antibacterial active substance(s), National competent regulatory authorities in consultation with European Medicines Agency (EMA) are currently undertaking initiatives to evaluate, update and harmonise as appropriate the information provided in SPC. Furthermore the criteria on which application for marketing authorisation for new antibacterial medicinal products for human use are evaluated have been further developed and updated to take fully into account the principle of containment of antimicrobial resistance.
- Following the Council’s invitation, the Commission has called in its workplan 2003 for projects proposing, where appropriate, common methodology and case definitions. The Commission concluded a grant agreement with the European Committee on Antimicrobial Susceptibility Testing (EUCAST). EUCAST has agreed with all stakeholders on a model for harmonising breakpoints for new antibiotics in Europe, and to define epidemiological breakpoints for the measurement of antimicrobial resistance development. It is liaising with European regulatory authorities and with projects within the field of antimicrobial resistance to deliver a platform for pan-European education in matters of antimicrobial susceptibility testing, definition of breakpoints and standardized reference methods.
- As regards to the nature and type of data to be collected for the surveillance of susceptibility of human pathogens and use of antibiotics the Commission has co-funded two large networks that have managed to agree and implement standardized data collection:

¹ Decision 2119/98/EC of the European Parliament and the Council setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, O.J. No L 268, 3.10.1998.

- The European Antimicrobial Resistance Surveillance System (EARSS) is a network of national surveillance systems that currently collects resistance data according to a common protocol from about 800 laboratories from 28 countries. The main function of EARSS is to monitor variations in resistance of indicator pathogens of main public health relevance for targeting interventions and assessing effectiveness of national intervention programmes. All this information is stored in a standardised database available freely on-line on the EARSS web site: www.earss.rivm.nl.
- The European Surveillance on Antimicrobial Consumption (ESAC) implemented a prospective data collection system, based on a validated register of available antibiotic products according to an international classification. Standardised national data are assembled in a European database for international comparison of antibiotic use in relation to antibiotic resistance patterns, socio-economic determinants and general health indicators. Aggregated results of the ESAC project are available on the public ESAC website (<http://www.esac.ua.ac.be>) and the database is accessible for health authorities, scientists and a wider public.
- In addition, the Commission has co-funded a “Selfmedication and Antimicrobial Resistance (SAR)” project to assess the problem of self-medication with antibiotics in Europe. Results show that self-medication with antibiotics is indeed a problem all over Europe and that there are quite a number of countries where a substantial proportion of antibiotics are sold without prescription, commonly referred to as “Over-The-Counter (OTC)” antibiotics.
- Through its Sixth Framework programme for Research and Technological Development, the Commission supports a broad range of research projects of major relevance to prudent use of antimicrobials in human medicine.
- The Commission has set up the ‘Working group on the prudent use of antimicrobial agents in human medicine’ to keep relevant matters under review and has been consulting this working group in collating the Member States’ reports and in developing a proposal on containing healthcare-associated infections.
- Special attention has been devoted over the past years to applicant countries and all of these countries are actively participating in the antimicrobial resistance surveillance networks.
- The Commission and the WHO have signed a Memorandum of Understanding reconfirming their common interest in public health. Antimicrobial resistance is among the agreed priorities and close co-operation with WHO has been ensured for all antimicrobial resistance related networks. The Commission is developing a programme with WHO on strengthening pharmaceutical policies, including rational use of drugs and particularly supporting national programmes to contain antimicrobial resistance through the expansion of projects that link surveillance data to rational prescribing programmes.

4. CONCLUSIONS

Most Member States have taken a variety of actions as requested by the Recommendation. However, there remain numerous areas of the Recommendation where only limited action has

been undertaken. It is important that all the provisions in the Recommendation are being adhered to, in particular:

- A quick development and efficient **implementation of National Strategies and National Action plans** should be a priority.
- The status, organisational structure, composition, funding and understanding of the responsibilities of the ‘intersectoral mechanism’ reveal major differences. Actions should be taken to **ensure that each Member State has in place an appropriate intersectoral mechanism with appropriate mandate and means** to coordinate the implementation of the strategies foreseen in the Recommendation. The functioning of the different intersectoral mechanisms could usefully be evaluated.
- Much has been done on surveillance of antibiotic resistance in indicator bacteria and on surveillance of antibiotic use at national and EU level, fostered by initiatives and EU-wide projects with Community funding. However, **data can often not be broken down to a lower level (hospitals, single diseases) where it is needed for local policies.**
- **Also feed-back on prescribing practices should be improved.** This should be a point for attention for the ‘intersectoral mechanisms’.
- **Collaboration between human health and animal health sector** on antibiotic resistance and antibiotic use should be fostered in all countries where this has not been established yet.
- The Commission funded SAR-project identified that in seven countries, systemic antibacterial medicinal products are still obtained without a prescription and that self-medication with antibiotics should be tackled appropriately in many Member States in particular through **education of the general public** about the risks of self-medication. All countries should have clear **measures in place to enforce prescription-only use of systemic antimicrobials or antibiotics.**
- All countries should have **nationally accepted guidelines in place recommending appropriate antibiotic treatment**, at least for the most common human infections. The impact of these guidelines on prescribing practices should be assessed regularly.
- It is highly recommended that each hospital/nursing home ensures **appropriate infection control**. Institutions should have its own infection control system/committee in place or ensure that relevant tasks are undertaken by other appropriate existing bodies. Countries should consider making infection control part of an accreditation or other quality control procedure for hospitals and possibly nursing homes.
- EU-wide **exchange of best practice** of all relevant issues should be promoted. Examples of good practice concerning antimicrobial resistance, vaccination campaigns and hygiene/infection control should be discussed and exchanged between Member States.
- Recital 1 of the Recommendation defines ‘antimicrobial agents’ indicating that the scope of resistance monitoring should include bacteria, viruses, fungi, and parasites, in particular protozoa. The focus of most **surveillance activities** undertaken until now, has been on

antibacterial resistance and **should be enlarged to include data on antivirals and antiparasitic agents.**

- As laid down in the Regulation establishing the Centre for disease prevention and control (ECDC)², in particular in Articles 5 and 11, the **ECDC will have an important role to operate European surveillance also in the area of antimicrobial resistance.** The ECDC should be able to assist the Commission in the future preparation of implementation reports and of recommendation proposals.
- This report aimed to summarise main findings from the Member States' reports and highlighting those provisions in the Recommendation that may need particular attention. The information contained in the Member State reports provide more detail and may be of interest to health professionals, international institutions such as WHO, and the general public. **Providing public access to the Member State reports** should be encouraged by the Member States.
- One additional concern is the **global dimension of the antimicrobial resistance problem.** Given the migration and trade flows from outside Europe and the exposure to resistant microbial strains from other continents, action can not be limited to the EU level and attention is necessary for links with EU external actions such as strengthening pharmaceutical policies and health systems in developing countries.

This Recommendation focussed on the importance of using antimicrobial agents prudently in human medicine to contain primarily the emergence of antimicrobial resistance. Not only emergence, but also spread is an important driver of the problem of resistance. Therefore the Commission is currently preparing an **appropriate initiative in the area of infection control.**

² Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control. OJ L142/1, 30.04.2004.