EUROPEAN COMMISSION

Brussels, 9.4.2010
COM(2010) 141 final

SECOND 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

SEC(2010)399

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(Text with EEA relevance)

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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 the Recommendation. This Recommendation asks Member States and EEA countries to put in place specific strategies for the prudent use of antimicrobial agents with a view to containing antimicrobial resistance. These strategies should include measures relating to the surveillance of antimicrobial resistance and antimicrobial use, control and preventive measures, education and training, and research. The Recommendation invites the Commission: to facilitate mutual information, consultation, cooperation and action; to keep matters covered by this Recommendation under review; and to submit reports on the basis of Member States' reports.

Within two years of its adoption the Commission summarised the main actions taken at Member State and European Union level in a report to the Council on the implementation of the Recommendation (COM (2005)684 final)[1]. The Report indicated that most Member States had taken a variety of actions as requested by the Recommendation. However, it also highlighted numerous areas of the Recommendation where only limited actions had been undertaken and identified others where further attention was needed:

- implementation of national strategies and national action plans;
- setting up of an appropriate intersectoral mechanism with a proper mandate and adequate means;
- collaboration between the human and animal health sectors;
- education of the general public on the proper use of antimicrobial treatments;
- setting up of measures to enforce prescription-only use of systemic antimicrobials or antibiotics;
- appropriate infection control;
- nationally accepted guidelines recommending appropriate antibiotic treatment.

Following this first report on the implementation of the Recommendation, in August 2008 Member States were asked to report to the Commission on the state of implementation as a contribution to the follow up of the Recommendation. The Commission received replies from all Member States and from one of the three EEA/EFTA countries.

Based on the replies this second Report summarises the main actions taken at Member State and European Union level and compares the situation in 2008 with the situation in 2004 when the data for the previous report was collected. This report placed a strong emphasis on the use of indicators to follow up implementation of the action plan. It also highlights in its conclusion the areas of the Recommendation needing further attention. It is accompanied by a Commission Staff Working Paper providing a more detailed technical analysis of the Member States' replies.

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[1] http://ec.europa.eu/health/ph_threats/com/mic_res/com684_en.pdf.

2. SUMMARY OF MAIN ACTIONS AT MEMBER STATE LEVEL

The Recommendation asks Member States to put in place specific strategies on the prudent use of antimicrobial agents with a view to containing antimicrobial resistance. By the end of 2008, sixteen countries had a national strategy in place and eight Member States were in the process of preparing such a strategy. Four Member States had no strategy to report nor were they in the process of preparing one.

Strategies should pursue the following main objectives:

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

All reporting countries had implemented a surveillance system for antimicrobial resistance. In 18 countries there was a surveillance system in addition to participation in the European Antimicrobial Resistance Surveillance System (EARSS) that covers antimicrobial resistance both in the community and in hospitals.

In a significant number of Member States and EEA countries there was an operational link between antimicrobial resistance surveillance and those in charge of outbreak investigation/disease control, as well as collaboration with veterinary surveillance. However, only a few countries had established links with the environment.

Most of the countries had published a national report on antimicrobial resistance and the data were also publicly available.

Health authorities had access to antimicrobial resistance surveillance data in all but two countries. However, there were still obstacles to obtaining rapid and easy access to detailed data owing to problems that were already flagged up in the first report — legal status, data ownership, budget shortage, and poor information and technology support.

Regarding the structure of the surveillance system, the publication of national reports, and operational links with antimicrobial resistance surveillance in animals, progress appeared to be limited when compared with the achievements already reported in 2003. Nevertheless, there had been progress as regards access to surveillance data, with fewer countries reporting obstacles to access data in 2008 than in 2003.

Almost all respondents had national systems for the surveillance of antimicrobial use and antibiotic consumption and all countries participate in the European Surveillance of Antimicrobial Consumption Project (ESAC). Comparisons with the achievements identified in 2003 indicate that progress had been made since the first report. The obstacles to obtaining antimicrobial consumption data had been overcome. The collection of categorised data and links between antimicrobial resistance data and antibiotic consumption data improved. However, in most countries the data were not detailed enough to allow appropriate feedback for prescribers. The obstacles were the same as those involved in resistance surveillance per se. In addition, in only half the responding countries consumption data could be broken down by indication and linked to the resistance data. The collection of more useful data on antimicrobial consumption and prescribing practices seemed to be undermined by the weak legal status of data, including its ownership, and problems with information technology systems. In addition, indicators for the monitoring of prescribing practices were still underdeveloped in several countries

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

Since the previous report many countries have taken positive action regarding the selling of antimicrobial agents without a prescription. While only one country was able to provide data in 2003, in 2008 all respondents provided estimates of the extent of such sales. Eighteen countries reported that this phenomenon was not a significant source of misuse of antibiotics in their country. However, it should be noted that from those countries in which the estimated percentage of antibiotics sold without prescription was from 1% to more than 15% four did not indicate taking measures to enforce the law on prescription-only use for antibiotics. Such measures are provided by the European Union pharmaceutical legislation on medicinal products for human use (Directive 2001/83/EC as amended by Directive 2004/27/EC).

Most countries had in 2008 nationally endorsed guidelines on the appropriate use of antimicrobials covering the most common infections in the community, such as otitis media, sinusitis, tonsillopharyngitis, community acquired pneumonia, urinary tract infections and meningitis. However hospital guidelines were less frequent and exist in only half of the countries. In addition, the assessment of compliance with guidelines and the evaluation of their impact were still rare, although there had been progress in this respect since 2003.

Twenty-two countries had in place a national programme for hospital hygiene and infection control. In twenty countries it was mandatory for every hospital to have an infection control committee. However, in only three countries did this requirement apply to nursing homes. More than half of the respondent countries had legal requirements or recommendations for the number of infection-control nurses needed in hospitals, but none of the countries had similar requirements for nursing homes. Guidelines for the prevention and control of healthcare associated infections were available in all but three countries. The most commonly addressed topic in the guidelines was Methicillin-resistant *Staphylococcus aureus* (MRSA). Guidelines on multidrug-resistant bacteria in general were always in addition to specific guidelines on MRSA. Guidelines were less frequent in nursing homes than in hospitals. Most responding countries also had recommendations on vaccination against *Streptococcus pneumoniae* infections in both adults and children.

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

Most countries reported that curricula for health professionals included issues related to antimicrobial resistance, hygiene and infection control, appropriate use of antimicrobials, and vaccination programmes. Fifteen countries had in place requirements for non-sponsored continuous education for healthcare professionals, mainly covering hygiene and infection control measures. However, this did not cover all healthcare professions, nor did it solve the problem of the inappropriate use of antimicrobials in every country.

Sixteen countries had implemented awareness-raising campaigns for healthcare professionals on antimicrobial resistance, mainly for medical doctors, and in some also for pharmacists, nurses, and vets.

During the last two years, seventeen countries have targeted the general public with awareness-raising campaigns on antimicrobial resistance, inappropriate use of antimicrobials,

vaccination programmes and their role, and general hygiene measures. Progress since 2003 has been very slow. These campaigns targeted the general public rather than a specific audience, such as patient associations or patients.

In 2002 the Council recommended that each Member State should rapidly establish an appropriate intersectoral mechanism to coordinate the implementation of the above strategies at national level. As well as from national coordination this mechanism should participate in information exchange and coordination between the Commission and other Member States.

Nineteen countries said they had an intersectoral coordinating mechanism (ICM) in place and seven countries were in the process of developing such a mechanism, which they were planning to complete between the end of 2008 and 2010. Two Member States had no plans to establish an ICM. The main improvement since the previous report is the legal status of the ICM. In 2008 the ICM were created by governmental decision in eight countries and in six by regulation. In addition, three countries indicated that their ICM was created by decision of the National Chief Medical Officer or was considered to be an official working group. In most countries the ICM was truly intersectoral with the link between the human and animal health sectors well established through the ICM in almost all cases. It should be noted, however, that ministries of employment, environment, research, and education were seldom represented, and there had been little improvement in the involvement of patient groups since the first report. Nurses and institutions for long-term care were represented in less than half of the ICMs, even though they were important in containing the development and transfer of antimicrobial resistance.

As we are now moving from the strategy development phase to implementation, the questionnaire raises the issue of indicators as tools to follow up the implementation. Twelve countries reported having indicators in place for monitoring purposes. In most cases outcome indicators were used (for antimicrobial resistance, antimicrobial use, prescription, and healthcare associated infections). Five countries indicated the use of structure and process indicators at local and national level (such as the volume of alcohol gel used for hand disinfection, implementation of antibiotic management teams, evaluation of compliance, control of sales of antimicrobial agents and number of research projects).

3. SUMMARY OF MAIN ACTIONS AT EUROPEAN UNION LEVEL

Antimicrobial resistance continues to be a key priority for the Commission, which is undertaking and promoting a wide range of activities at European Union level.

Given the first report's recommendation to address also the spread of resistant microorganisms in health care settings and following a proposal from the Commission, in June 2009 the Council adopted a Recommendation on patient safety, including the prevention and control of healthcare associated infections[2]. The Recommendation aims to ensure that Member States have proper and adequate strategies to improve patient safety in their healthcare systems, including specific proposals to prevent and control healthcare associated infections.

[2] Council Recommendation 2009/C 151/01of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, OJ C 151, 3.7.2009.

Since the rise of antimicrobial resistance has been traced to the use of antibiotics in both human and veterinary medicine, the Commission has been working since the first report towards the development of initiatives which would be relevant for both sectors.

Thus, the Directorate-General for Health and Consumers has established a technical intra-service platform to exchange information and enhance the coordination of activities between public health and animal health. The work of this group aims to encourage a joint approach to monitoring AMR in humans and animals with support from the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), and the European Food Safety Authority (EFSA). As result of these activities, in November 2009 the Commission published a Staff Working Paper on antimicrobial resistance[3]. The purpose of this paper is to inform the Parliament and the Council on the progress made by the Commission in monitoring and controlling antimicrobial resistance in human and veterinary medicine and to start an exchange of views on follow-up and possible further actions. This joint approach has been strengthened by the establishment of closer cooperation between the different EU Agencies working on antimicrobial resistance. Following a joint request by the Commission departments, the ECDC, EFSA, EMA and the Scientific Committee on Emerging and Newly Identified Health Risks worked together to provide a common state of play on antimicrobial resistance[4].

In addition to these initiatives, the Commission has been addressing antimicrobial resistance through the funding of several European-wide projects within the framework of the Public Health Programme 2003-2007:

EARSS — the European Antimicrobial Resistance Surveillance System (2003-2006) aims to maintain a surveillance and information system that links national networks as well as to monitor health threats caused by AMR in Europe www.earss.rivm.nl. EARSS is in the process of being integrated into ECDC activities.

ESAC — the European Surveillance of Antimicrobial Consumption (2004-2007) aims to consolidate the collection of antibiotic consumption data. Moreover, in-depth consumption data for ambulatory care, hospital care, and nursing homes were investigated and a pharmaco-economic evaluation was carried out. Some data derived from this project could be assessed in relation to resistance patterns and incidence of disease and could also be used as guidelines for treatment http://www.esac.ua.ac.be . ESAC is in the process of being integrated into ECDC activities.

EUCAST — the European Committee on Antimicrobial Susceptibility Testing (2004-2007) establishes the surveillance of pathogens resistant to antimicrobial agents by defining common reference methods which permit comparison of results, thus providing a common basis for interpreting AMR data across Europe. This project has established a standing committee for European susceptibility testing and breakpoint setting. http://www.eucast.org.

BURDEN — Burden of Resistance and Disease in European Nations (2007-2010) is a project which aims to provide comparable information on the burden of disease and resistance across Europe and to generate awareness and understanding among policy-makers and communities

[3] Reference to be included
[4] Reference to be included

at large. This project will also include a case study of MRSA in intensive care units and general wards in hospitals www.eu-burden.info.

E-BUG PACK — Development & Dissemination of an Antibiotic & Hygiene Education Pack (2006-2009) for schools, based on a successful UK project. Targeted at 9-16 year-olds, this project aims: 1. to increase awareness of the benefits of antibiotics as well as prudent use; 2. to teach how inappropriate use can have adverse effects on 'good bugs' and on antimicrobial resistance; 3. to improve hand and respiratory hygiene, thus reducing the spread of respiratory, gastrointestinal and skin infections and decreasing the demand for antibiotics.

ABS International — implements Antibiotic Strategies (ABS) for Appropriate Use of Antibiotics in Hospitals in Member States of the European Union (2006-2008). Implemented in 9 Member States, it aimed to prepare a training programme for national ABS experts and to develop standard organisational tools for hospitals to ensure appropriate antibiotic use.

IPSE/HELICS — is an international network for the collection, analysis and dissemination of valid data on the risks of nosocomial infections in European hospitals. HELICS' routine data collection continues to be supported in Work Package 4 of the project.

Through its Sixth and Seventh Framework Programmes for Research and Technological Development, the Commission supports a broad range of research projects of major relevance to the prudent use of antimicrobials in human medicine. Several European-wide projects have been funded, focusing on areas such as the development of evidence-based patient management, guidelines for respiratory infections and the control of healthcare associated infections. In the latest call, the impact of antibiotic therapy on the human host was addressed in several of the selected proposals as well as the clinical validation of diagnostic tests. In addition to the Framework Programmes, other related initiatives, such as European Technology Platforms, consider the issue of AMR. Moreover, the Joint Technology Initiative on Innovative Medicines provides an instrument for a public-private partnership that can play a role in tackling the AMR issue.

European Union actions against antimicrobial resistance, which promote the prudent use of antimicrobial agents in human medicine, have been further strengthened since the first report with the creation in 2005 of the ECDC.

In order to assess and monitor the antimicrobial resistance risk, the epidemiological surveillance activities in this field envisaged under Decision 2119/98/EC[5] and Decision 2000/96/EC[6] have continued, with the added value of the ECDC, which is now responsible for the running of the surveillance networks. Every year the ECDC publishes data on antimicrobial resistance and antimicrobial use in the EU in its Annual Epidemiological Report on communicable diseases.

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5 Decision No 2119/98/EC of the Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, OJ L 268, 3.10.1998

6 Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under decision No 2119/98/EC of the Parliament and of the Council, OJ L 28, 3.2.2000

In addition the ECDC has set up a network of antimicrobial resistance National Focal Points from Member States and EFTA-EEA[7] countries aimed at strengthening EU collaboration on this issue. It is also implementing a specific programme on antimicrobial resistance and healthcare associated infections in cooperation with the Commission, the other European Union Agencies and the Member States. As a result, the ECDC will help the Commission to foster best practice on the prevention and control of healthcare associated infections, promote training opportunities and assist Member States to develop infection-control training and curricula for infection-control staff and healthcare workers.

In order to ensure a coordinated and balanced approach between veterinary and human medicine, cooperation has been established with EFSA on antimicrobial resistance surveillance in the field of EFSA's competencies. Cooperation with other EU agencies includes the publication of a joint ECDC/EMA study on the need for new antibacterial drugs[8] and a joint ECDC/EFSA/EMA/SCENIHR study on the state of play of antimicrobial resistance in the EU[9].

As part of the drive to increase awareness among the general public and improve education of healthcare professionals, in 2008 the European Antibiotic Awareness Day (EAAD) was initiated as a European public health initiative coordinated by the European Centre for Disease Prevention and Control. This annual event aims to raise awareness about the risks associated with the inappropriate use of antibiotics and how to take antibiotics responsibly.

4. CONCLUSIONS

Significant progress has been achieved since the publication of the first report. Most Member States have taken a variety of actions, as requested by the Recommendation and further underlined in the first implementation report. However, there are still numerous areas of the Recommendation where only limited improvement has been attained. It is important that all the Recommendation's provisions are adhered to by the Member States. Based on the findings identified in this report, the areas on which future work could be focused include:

- Improving the enforcement by the Member States of the Council Recommendation, addressing current concerns:
    - Rapid development and efficient **implementation** of **national strategies** and **national action plans** in all Member States and associated countries taking into account the Council Recommendation on patient safety, including the prevention and control of healthcare associated infections.
    - Greater involvement of nursing homes and representatives of institutions for long-term care when setting up action plans and guidelines regarding antimicrobial resistance and healthcare associated infections.

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7 European Free Trade Association — European Economic Area countries

8 ECDC/EMA study, 'The Bacterial Challenge: time to react', September 2009, http://ecdc.europa.eu/en/publications/Publications/0909_TER_The_Bacterial_Challenge_Time_to_React.pdf.

9 Reference to be included

- **Collaboration between the human and animal health sectors** on antibiotic resistance and antibiotic use at national and European Union level, particularly in all those countries where this has not yet been established.

- External assessment of national programmes.

- Actions to **ensure that each Member State has an appropriate intersectoral mechanism in place with a suitable mandate and the means** to coordinate the implementation of the strategies foreseen in the Recommendation. It would be useful to evaluate the functioning of the various intersectoral mechanisms.

- Fostering monitoring and evaluation at Member State level

    - Develop and use indicators to monitor the implementation of the Council Recommendation and assess the impact of national action plans and the efficiency of measures.

    - Develop mechanisms and indicators to assess the impact of national guidelines.

    - Strengthen surveillance networks on antimicrobial resistance and antibiotic use in order to improve access to the surveillance systems' data on antimicrobial resistance and the use of antimicrobial agents by policy makers, professionals and the public.

    - Improve the collection of comprehensive data on antimicrobial consumption and prescription practices.

    - Develop a feedback mechanism on prescription practices and the use of antibiotics for prescribers and decision makers.

    - Promote the use of indicators to monitor the implementation and efficiency of measures and to disseminate relevant information to the public.

- Improving at Member State level education of healthcare professionals and the general public

    - Involve patient groups in the implementation of the strategies and action plans being planned.

    - Improve non-sponsored continuing education for all healthcare professionals in all countries. Educational programmes should cover all aspects of antimicrobial resistance (hygiene, appropriate use, etc.).

    - Raise awareness among all healthcare workers and the general public.

    - Optimise European Antibiotic Awareness Day.

- Cooperation at EU level and European Union actions

    - Strengthen cooperation on the links between antimicrobial resistance in humans and in animals and food.

- Address the global dimension of antimicrobial resistance. Action cannot be limited to the EU level and links with international partners and EU external actions are vital (ie. strengthening pharmaceutical policies and health systems in developing countries).

- Monitor the environmental impact of the use of antimicrobials.