

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL RECOMMENDATION

of 15 November 2001

on the prudent use of antimicrobial agents in human medicine

(Text with EEA relevance)

(2002/77/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Antimicrobial agents are substances produced either synthetically or naturally by bacteria, fungi or plants, used to kill or inhibit the growth of micro-organisms including bacteria, viruses and fungi, and of parasites, in particular protozoa.

(2) The use of antimicrobial agents has greatly contributed to improvements in health. Such 'antimicrobial agents' have been introduced for decades to treat and prevent infectious diseases and infections. However, their use has been accompanied by an increasing prevalence of micro-organisms that have acquired resistance to one or more of these, so-called 'antimicrobial resistance'. Antimicrobial resistance poses a threat to public health, may prolong the suffering of patients, increase healthcare costs and has economic implications for society. Therefore concerted action is necessary at Community level to contain this problem by encouraging the prudent use of antimicrobial agents in human medicine and better hygiene and infection control.

(3) The Council of the European Union on 8 June 1999 adopted a Resolution on antibiotic resistance entitled A strategy against the microbial threat⁽¹⁾. The Resolution

highlights that antimicrobial resistance increases morbidity and mortality due to communicable diseases and leads not only to a diminution of quality of life but also to additional health and medical care costs, and that action needs to be taken at Community level.

(4) The own-initiative opinion of the Economic and Social Committee on the Resistance to antibiotics as a threat to public health⁽²⁾ identified possible initiatives and action that should be taken at Member State and Community level to address the problem of antimicrobial resistance.

(5) There is an association between the growing use of antimicrobial agents and an increase in the prevalence of micro-organisms resistant to those agents, but this relationship is clearly not a simple one. There are many possible factors influencing this relationship, including those related to the organism, to the host and to the mode of use of each drug. However, it is clear that antimicrobial resistance may not necessarily be overcome by the lengthy process of continuously developing new antimicrobial compounds.

(6) To develop strategies for prevention of infections and containment of resistant pathogens, accurate surveillance systems generating valid, reliable and comparable data on incidence, prevalence and modes of spread of resistant micro-organisms as well as on prescription and use of antimicrobial agents must be established throughout the Community. They should form an essential component for an overall surveillance strategy to address the problem of antimicrobial resistance and in particular, to assess the potential link between the use of antimicrobial agents and the development of resistance among these pathogens.

⁽¹⁾ OJ C 195, 13.7.1999, p. 1.

⁽²⁾ OJ C 407, 28.12.1998, p. 7.

- (7) An important step to avoid, or even reverse, further increases in resistant micro-organisms would be to reduce unnecessary and inappropriate use of antimicrobial agents. General principles and methods for the prudent use of these agents in humans must be identified, defined and implemented.
- (8) The European Antimicrobial Resistance Surveillance System (EARSS) and the European Surveillance of Antibiotic Consumption (ESAC) are Community funded monitoring programmes which aim at collecting standardised, harmonised and comparable data on antibiotic resistance and use.
- (9) Improved strategies for hygiene, infection control and infection prevention in hospitals and the community will help to limit the spread of resistant micro-organisms and will be an important step to reduce the quantities of antimicrobial agents used.
- (10) To bring about the necessary changes in prescribers' and patients' behaviour, health professionals and the general public need to be informed on the problem of antimicrobial resistance and associated factors by improved product information, by awareness-raising by adequate information and training during professional education and in-post training, as well as by information measures to the general public and specifically to the patients.
- (11) Support of research will be essential for tackling the problem of the modes of spread of antimicrobial resistance. Research could include *inter alia* the evaluation and cost effectiveness of intervention strategies to optimise antibiotic prescribing in hospitals and the community.
- (12) There is also a relationship between the occurrence of antimicrobial resistance in certain human pathogens and their occurrence in animals and the environment. Coordination between human, veterinary and environment sectors should be ensured and the magnitude of the relationship between the occurrence of antimicrobial resistant pathogens in humans, animals and the environment should be further clarified and therefore this Recommendation does not preclude further initiatives in other areas.
- (13) Measures taken by the Member States in this area, and the way they have taken into account this Recommendation, should be the object of reports at national and Community level.
- (14) In accordance with the principle of subsidiarity set out in Article 5 of the Treaty, any new measure taken in an area which does not fall within the exclusive competence of the Community, such as protection of the public

against the increase of infectious agents resistant to antimicrobial agents, may be taken up by the Community only if, by reason of the scale or effects of the proposed action, the objectives proposed can be better achieved by the Community than by Member States. Antimicrobial resistance, as is the case with communicable diseases, cannot be confined to a geographical region or Member State. Therefore, coordinated action at Community level is required,

HEREBY RECOMMENDS MEMBER STATES:

- I. to ensure that specific strategies exist and are implemented targeted towards the prudent use of antimicrobial agents in the aim of containing the increase of pathogens resistant to these agents. These strategies should be based on the best available scientific evidence and should comprise measures in relation to surveillance, education, information, prevention and control, and research.

These specific strategies should pursue the following objectives:

1. establish or strengthen surveillance systems on antimicrobial resistance and the use of antimicrobial agents in order to:
 - (a) gather reliable, comparable data on the susceptibility of pathogens to antimicrobial agents and the infections caused by them. These data should allow time trend analysis and early warnings and monitoring of the spread of resistance at national, regional, and community level;
 - (b) collect data on prescription and use of antimicrobial agents at the appropriate levels to allow monitoring of overall use involving, among others, prescribers, pharmacists and other parties collecting such data.

These surveillance systems should be sustainable with clear regulation of data access and ownership. They should comply with the data protection regulations and guarantee the confidentiality and security of data. These systems should build upon existing national and international surveillance systems, using, wherever possible, internationally recognised classification systems and comparable methods;

2. implement control and preventive measures to support the prudent use of antimicrobial agents and contribute to limiting the spread of communicable diseases by:
 - (a) restricting systemic antibacterial agents to prescription-only use;

- (b) setting guidelines for the use of other antimicrobial agents not subject to requirements for prescription-only use;
- (c) developing evidence-based principles and guidelines on good practice for the management of communicable diseases, to maintain the effectiveness of antimicrobial agents. These practices should include:
- assessing the value of clinical and microbiological criteria for diagnosis of infections, including the use of rapid diagnostic tests,
 - optimising choice of drug, dosage and duration for the treatment and prevention of infections,
 - promoting optimal prescription practices for antibacterial agents subject to prescription-only use,
 - assessment of the need for changes in the guidelines for other antimicrobial agents not subject to prescription-only use;
- (d) establishing and implementing control systems on good practice of marketing of antimicrobial agents to ensure compliance with the evidence-based principles and guidelines on the prudent use of antimicrobial agents for the management of communicable diseases;
- (e) implementing hygiene and infection control standards in institutions (hospitals, child care facilities, nursing homes etc.) and in the community, and assessing their impact in the prevention of communicable diseases and the need for antimicrobial agents;
- (f) encouraging national immunisation programmes to progressively eliminate vaccine preventable diseases;
3. promote education and training of health professionals on the problem of antimicrobial resistance by:
- (a) including teaching principles and guidelines on the appropriate use of antimicrobial agents into undergraduate and postgraduate training and in regular continuous training for physicians, infectious diseases clinicians, dentists, pharmacists and nurses and others in the medical professions;
- (b) enhancing training on hygiene and infection control standards, thereby limiting the spread of microorganisms and thus eventually reducing the need for antimicrobial agents;
- (c) training on immunisation programmes and their role in preventing infections, thereby reducing outbreaks of diseases and thus the demand for antimicrobial agents;
4. inform the general public of the importance of prudent use of antimicrobial agents by:
- (a) raising awareness of the problem of antimicrobial resistance and encouraging realistic public expectations for prescribing of antimicrobial agents;
- (b) launching information initiatives involving the patients on the importance of interventions to reduce the unnecessary use of antimicrobial agents, and on the principles and guidelines on good practice to motivate patients' adherence;
- (c) highlighting the value of basic hygiene and the impact of vaccination programmes on reducing the need for antimicrobial agents;
- II. to have in place rapidly and if possible within one year of the adoption of this Recommendation an appropriate intersectoral mechanism for the coordinated implementation of the above strategies as well as for the purposes of information exchange and coordination with the Commission and the other Member States;
- III. to cooperate with the Commission and the other Member States on:
1. the development of indicators to monitor prescribing practices of antimicrobial agents using the evidence-based principles and guidelines on good practice for the management of communicable diseases;
2. the evaluation of these indicators once developed with regard to potential improvements of prescribing practices and feedback to prescribers;
3. the further development of European surveillance and exchange of information at Community level through the Network on epidemiological surveillance and control of communicable diseases;
4. the information and communication on national research initiatives relating to the containment of antimicrobial resistance, with emphasis on:
- (a) the mechanisms of emergence and spread of antimicrobial resistance among humans and from animals to man;
- (b) the relationship between antimicrobial resistance, resistance mechanisms, clonality, and use of antimicrobial agents;
- (c) the results of intervention strategies in hospitals and the community to improve the prudent use of antimicrobial agents;
- (d) the accuracy of diagnostic tools and the development of rapid and reliable diagnostic and susceptibility testing;

- (e) the development of new modalities for prevention and treatment of infections;
 - (f) the development of alternatives to antimicrobial agents to contain the spread of infections; and
 - (g) the development of new surveillance methods to contain antimicrobial resistance with a view to enhancing their coordination;
5. initiating activities aimed at evaluating and, as necessary, updating the product information (SPC) for antibacterial medicinal products particularly related to indications, dose and dose regimen and prevalence of resistance;
- IV. to report to the Commission on the implementation of this Recommendation within two years of the adoption of this Recommendation and subsequently on request by the Commission with a view to contributing to the follow-up of this Recommendation at Community level and acting as appropriate in the context of the programmes of action in the field of public health,

HEREBY INVITES THE COMMISSION:

1. to facilitate mutual information, consultation, cooperation, and action through the procedures and mechanisms available in the Community Network for the epidemiological surveillance and control of communicable diseases (Decision No 2119/98/EC) in the field covered by this Recommendation;
 2. to establish texts on principles and guidelines of best practice on the prudent use of antimicrobial agents in human medicine having regard to national policies and to the Community requirements for market authorisation and on the quality and content of the Summary of Product Characteristics (SPC), which lays the basis for all promotional activities of an antimicrobial agent, having regard, where relevant, to the activities of the European Agency for the Evaluation of Medicinal Products (EMEA);
3. to propose, where appropriate, common methodology, case definitions and nature and type of data to be collected for the surveillance on the susceptibility of pathogens resistant to antimicrobial agents and the use of these agents;
 4. to develop a strategy for access to surveillance information and volume of antimicrobial use;
 5. to keep matters covered by this Recommendation under review, with a view to its revision and updating, and submit regular reports to the Council on the basis of Member States' reports accompanied, as appropriate, by proposals in order to promote the prudent use of antimicrobial agents in human medicine;
 6. to strengthen participation of applicant countries within the framework of the Network on epidemiological surveillance and control of communicable diseases in the Community, to ensure that the problems of antimicrobial resistance are properly taken into account by these States;
 7. to cooperate with the World Health Organisation (WHO) and other relevant international organisations within the fields covered by this Recommendation.

Done at Brussels, 15 November 2001.

For the Council
The President
M. AELVOET