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MINISTERS' DEPUTIES Recommendations **CM/Rec(2023)1** 1 February 2023

Recommendation CM/Rec(2023)1 of the Committee of Ministers to member States on equitable access to medicinal products and medical equipment in a situation of shortage

(Adopted by the Committee of Ministers on 1 February 2023 at the 1455th meeting of the Ministers' Deputies)

Preamble

The Committee of Ministers, under the terms of Article 15.*b* of the Statute of the Council of Europe,

Considering that the aim of the Council of Europe is the achievement of greater unity between its members and that one of the methods by which this aim is pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms (ETS No. 5);

Bearing in mind the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine,

ETS No. 164), which requires the Parties to take appropriate measures with a view to providing, within their jurisdiction, equitable access to healthcare of appropriate quality;

Underlining the other principles laid down in the Convention on Human Rights and Biomedicine, in particular the principle of free and informed consent, the protection of persons not able to consent, the respect for private life in relation to health information, and the obligation to carry out any intervention in accordance with relevant professional obligations and standards;

Bearing in mind the European Social Charter (ETS No. 35) and its revised version (ETS No. 163), in particular their Article 11 (The right to protection of health), in the light of its interpretation by the European Committee of Social Rights;

Considering that medicinal products and medical equipment are an essential part of healthcare and significantly contribute to saving lives and improving health and well-being;

Recognising the importance of having in place policies and systems to prevent, prepare for and mitigate shortages of medicinal products and medical equipment;

Noting that health inequities are likely to increase in a situation of shortage of medicinal products and medical equipment and that options to reduce these inequities during such situations may be limited;

Recognising that the principle of equitable access to healthcare remains valid during a situation of shortage of medicinal products and medical equipment, both in an emergency and during routine clinical practice, whatever the cause of the shortage;

Emphasising that a strategy based on multiple criteria may be required to ensure equitable access to medicinal products and medical equipment in a situation of shortage;

Acknowledging the fact that a shortage of medicinal products and medical equipment can significantly harm individuals with serious or life-threatening health conditions;

Emphasising that decisions on prioritising access to medicinal products and medical equipment should be based on the best available scientific evidence, in accordance with defined criteria, and not on individual opinions or best intentions,

1. Recommends that the governments of member States:

a. adapt their laws and practices to ensure the implementation and follow-up of the guidelines contained in the appendix to this recommendation;

b. examine, within the relevant steering committee, the implementation of this recommendation five years after its adoption;

2. Entrusts the Secretary General of the Council of Europe with transmitting this recommendation to the governments of non-member States of the Council of Europe which have been invited to sign the Convention on Human Rights and Biomedicine, as well as to the European Union and other relevant governmental and non-governmental international organisations.

Appendix to Recommendation CM/Rec(2023)1

Guidelines on equitable access to medicinal products and medical equipment in a situation of shortage

Chapter I – Object, scope and definitions

Article 1 – Object

This recommendation aims to promote equitable access to medicinal products and medical equipment in a situation of shortage.

Article 2 – Scope

1. The recommendation appliesto access to medicinal products and medical equipment, certified through an appropriate regulatory process provided for by law, which are needed for the medical care of patients with serious or life-threatening health conditions, in a situation of shortage.

2. The recommendation does not apply to experimental medicinal products and experimental medical equipment.

3. None of the provisions in this recommendation should prevent member States from applying part or all the provisions of the recommendation to other health resources in a situation of shortage.

Article 3 – Definitions

For the purpose of this recommendation:

- “medicinal product” refers to a substance or combination of substances that is intended to treat, prevent or diagnose a disease or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action in human beings;
- “medical equipment” refers to medical devices such as diagnostics, instruments, and machines;
- “shortage” refers to an insufficient availability of medicinal products or medical equipment relative to healthcare needs.

Chapter II – General principles

In a situation of shortage of medicinal products or medical equipment, access to them should be based on the following principles.

Article 4 – Non-discrimination

1. No person in need of medicinal products or medical equipmentshould a priori be excluded from access to them.
2. Any discrimination in terms of access to medicinal products and medical equipment should be prohibited.

Article 5 –Attention to systematically disadvantaged individuals in relation to health

Specific attention should be paid to individuals and groups who are systematically disadvantaged in relation to health, including as a result of economic and social conditions, legal status, disability, chronic disease or age.

Article 6 – Prioritisation based on medical criteria

1. Decisions on access to medicinal products and medical equipment should be based on an individual medical assessment, taking into account the following elements:

- the severity of the health condition of the individual concerned and the healthcare needs to address it;
- the expected effectiveness of the medicinal product or medical equipment;
- the possible therapeutic alternatives;
- the consequences of the lack of access to the medicinal product or medical equipment for the health of the individual concerned.

2. When there is a need for urgent healthcare, priority should be given to minimising the risk of mortality and, subsequently, morbidity.

Article 7 – Appropriate support and removal of barriers

Barriers to accessing medicinal products and medical equipment should be removed and appropriate support should be given to those individuals or groups who may be disadvantaged or exposed to a higher risk of harm to their health.

Article 8 – Respect for the dignity of persons excluded from access

When a person cannot access life-saving medicinal products or medical equipment, that person should, where available and appropriate, be provided with alternative healthcare support or with compassionate and palliative care.

Chapter III – Procedural principles

The following procedural principles should be observed when defining and implementing priority-setting standards in accordance with the principles laid down in Chapter II.

Article 9 – Accountability

1. Responsibilities in defining and implementing priority-setting standards should be clearly defined.
2. Healthcare professionals and the public should be informed about which entities can be consulted to address concerns regarding decisions on setting priorities for access to medicinal products and medical equipment.

Article 10 – Reasonableness and relevance

1. Policies for prioritising access to medicinal products and medical equipment should be based on the best available evidence, relying on relevant, measurable, clear, objective and consistent parameters.
2. Measures should be taken to ensure that the evidence taken into account is considered as relevant and fair to the greatest extent possible by all affected parties including those who might later be disadvantaged by the implementation of the policies.

Article 11 – Inclusiveness

Healthcare professionals, civil society organisations and the general public, including vulnerable groups, should be meaningfully engaged in:

- developing, refining and reviewing policies for prioritising access to medicinal products and medical equipment, with a view to identifying needs, barriers and the values at stake;
- creating and disseminating educational tools;
- developing and implementing strategies for communication; and
- dialogue on issues relevant to equitable access to medicinal products and medical equipment.

Article 12 – Consistency

1. Policies for prioritising access to medicinal products and medical equipment should be applied consistently, taking into account contextual factors.
2. Policies should be designed to prevent corruption, arbitrary exceptions, access on the basis of financial means, activities such as lobbying and political interference.
3. Flexibility in implementing these guidelines at local level should be permitted after careful deliberation.

Article 13 – Transparency and communication of decisions

1. The objectives of priority setting, and the criteria and reasons for it, should be publicly accessible.

2. Underlying principles and values should be clearly articulated and adequately explained.

3. Information regarding priority setting should be clear, accurate, understandable and tailored to the needs of the target audience. Communication materials should be suitable for audiences with different levels of education, language competence and communication needs.

4. Open and honest communication should be ensured about the reality of shortages of medicinal products and medical equipment and their impact on the level of care.

Article 14 – Review

1. Mechanisms should be available to provide feedback on decisions regarding the prioritisation of access to medicinal products and medical equipment.

2. Interim and retrospective review processes should be introduced to take into consideration new evidence and developments.

3. Monitoring of measures taken to address situations of shortage should be ensured in order to evaluate compliance with the principles set out in these guidelines.

Chapter IV – System for prevention, preparation and mitigation

Article 15 – System to prevent, prepare for and mitigate situations of shortage

Member States should take appropriate measures to ensure that there is a system in place, to prevent, prepare for, and mitigate situations of shortage of medicinal products and medical equipment.

Article 16 – Prevention

1. Measures taken to prevent situations of shortage should include methods for forecasting needs under different scenarios.

2. Information to this end should not be limited to historical data on the marketing and use of medicinal products and medical equipment, but should also take into account:

- data on epidemiology;
- data on clinical and public health practices;
- data on available healthcare infrastructures and their capacities;
- relevant sociological data; and
- data on health inequities.

Article 17 – Preparation

When a situation of shortage can be expected, measures should immediately be taken to address possible adverse consequences for the health of the individuals concerned. This will involve a regular assessment of the healthcare system's capacity and planning to control the identified risks.

Article 18 – Mitigation

When a situation of shortage emerges, strategies should be implemented to minimise its impact and duration, while maintaining the principle of equitable access to medicinal products and medical equipment. These strategies should include:

- monitoring the availability of the medicinal products and medical equipment concerned;
- conserving available medicinal products and medical equipment;
- assessing the availability of suitable alternatives to the medicinal products and medical equipment concerned; and
- reallocating the medicinal products and medical equipment concerned in accordance with healthcare needs.

Article 19 – Information

1. Timely information should be provided to healthcare professionals and to the general public on a shortage of medicinal products and medical equipment and possible therapeutic alternatives, as well as on the risk of purchasing products and equipment from unofficial supply channels and of unauthorised use.

2. Information should be clear, accurate, understandable and tailored to the needs of the target audience.

3. Communication materials should be suitable for audiences with different levels of education, language competences and communication needs.

Article 20 – Responsibilities

Responsibilities for developing and implementing measures to prevent, prepare for and mitigate situations of shortage of medicinal products and medical equipment should be clearly defined.

Article 21 – International co-operation

International co-operation should be encouraged to facilitate the prevention, preparation for, and mitigation of situations of shortage of medicinal products and medical equipment.

Related documents
CM(2022)192-add2final
[1455/4.1b] Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) - b. Explanatory Memorandum to Recommendation CM/Rec(2023)1 of

the Committee of Ministers to member States on equitable access to medicinal products and medical equipment in a situation of shortage

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