# EQUITABLE ACCESS TO MEDICINAL PRODUCTS AND MEDICAL EQUIPMENT IN A SITUATION OF SHORTAGE


Recommendation CM/Rec(2023)1
of the Committee of Ministers
to member States

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

# Equitable access to medicinal products and medical equipment in a situation of shortage

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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 applies to 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 equipment should 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.

**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**

This Explanatory Memorandum to the Recommendation CM/Rec(2023)1 on equitable access to medicinal products and medical equipment in a situation of shortage was drawn up under the responsibility of the Secretary General of the Council of Europe. It takes into account the discussions held in the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) and in its predecessor, the Committee on Bioethics (DH-BIO), as well as the remarks and proposals made by delegations. The explanatory memorandum is not an authoritative interpretation of the Recommendation. Nevertheless, it covers the main issues of the preparatory work and provides information to clarify the object and purpose of the Recommendation and to better understand the scope of its provisions.

## Introduction

i. Medicinal products and medical equipment are an essential part of healthcare and contribute significantly to saving lives and improving health. A shortage of medicinal products and medical equipment needed for severe or life-threatening health conditions can result in significant harm to health. The causes of shortage are multi-factorial, including the lack of raw materials, problems in manufacturing, quality control, and logistics, as well as changes in regulatory requirements. Unpredictable events, such as epidemiological outbreaks, armed conflicts, and emergencies caused by climate change, may significantly increase demand and reduce the capacity to guarantee availability.

ii. Considering the severe health consequences of a shortage of medicinal products and medical equipment, it is essential that appropriate measures are taken to prevent these situations from occurring. Where a situation of shortage would occur, it is similarly important to take appropriate measures of preparation and mitigation.

iii. Prioritisation is required to decide who should have access to the medicinal products and medical equipment concerned. However, policies that define and implement priority-setting standards may raise questions concerning the principles on which they are based.

iv. The objective of this Recommendation is to promote equitable access to medicinal products and medical equipment in a situation of shortage and safeguard the fundamental rights of individuals who need them for serious or life-threatening health conditions. More specifically, the Recommendation addresses the general and procedural principles to be followed to ensure equitable access. It also addresses the system that member States should have in place to prevent, prepare for, and mitigate situations of shortage.

v. This Recommendation complements other relevant provisions applicable, contained, in particular, in the Convention for the Protection of Human Rights and Fundamental Freedoms ("European Convention on Human Rights", ETS No. 5), in the Convention on Human Rights and Biomedicine (ETS No. 164), and in the European Social Charter (ETS No. 35) and the revised version (ETS No. 163).

## Drafting of the Recommendation

vi. In the framework of its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025), the Committee on Bioethics (DH-BIO) agreed, at its 17th plenary meeting (3-6 November 2020), to develop guidelines to promote equitable access to vaccines and to treatments and equipment. This decision was taken in the light of the Covid-19 pandemic and the ethical considerations concerning access to vaccines as a scarce resource. It was emphasised that this work should be guided by the principle of equitable access to healthcare as enshrined in Article 3 of the Convention on Human Rights and Biomedicine, requiring Parties, "taking into account health needs and available resources" to "take appropriate measures with a view to providing, within their jurisdiction, equitable access to healthcare of appropriate quality".

vii. Considering the evolutions in vaccine development, the DH-BIO agreed to first prepare a statement focusing on equity in access to Covid-19 vaccines. The “Statement on Covid-19 and vaccines: Ensuring equitable access to vaccination during the current and future pandemics” was issued on 21 January 2021.

viii. At its 18th plenary meeting (1-4 June 2021), the DH-BIO agreed to establish a drafting group on equitable access to treatments and equipment in a context of scarcity, focusing on critical products the scarcity of which could cause serious harm to patients.

ix. In July 2021, a drafting group on equitable access to treatment and equipment in a context of scarcity was established, consisting of the following members: Tomáš Doležal (Czech Republic), Aime Keis (Estonia), Assunta Morresi (Italy), Lyalya Gabbasova and Olga Opanasenko (Russian Federation), Jorge Soares (Portugal), Verina Wild (Germany), Berenice Cruz (Mexico). Tomáš Doležal was designated Chair of the Drafting Group.

x. The drafting group met on 12 July (online meeting), and on 15 September 2021 (online meeting).

xi. Preliminary draft guidelines, prepared by the Drafting Group, were discussed by the DH-BIO during its 19th meeting (2-4 November 2021).

xii. In accordance with the terms of reference of the new Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO), which took over the responsibilities of the DH-BIO, it was agreed to include the guidelines in a Recommendation on equitable access to medicinal products and medical equipment in a situation of shortage.

xiii. From March to April 2022, the drafting group carried out a targeted stakeholder consultation to elicit comments and suggestions from international organisations and professional and patient organisations with expertise in the field of shortage of medicinal products and medical equipment. On 9-10 May 2022, the drafting group met in Paris, to discuss the outcomes of the stakeholder consultation and review the draft Recommendation.

xiv. The draft Recommendation, prepared by the drafting group in the light of the comments received during the stakeholder consultation and taking into account the comments from delegations, was examined by the CDBIO during its 1st meeting (31 May-3 June 2022).

xv. To discuss in particular the wording of the scope of the draft Recommendation and its Chapter on general principles, a consultation meeting with delegations concerned was organised on 20 September 2022 in Paris.

xvi. The CDBIO, at its 2nd plenary meeting (2-4 November 2022), approved the finalised draft Recommendation with a view to its presentation to the Committee of Ministers for adoption. On 1 February 2023, the Committee of Ministers, at its 1455th meeting at Ministers’ Deputies level, adopted the Recommendation CM/Rec(2023)1 on equitable access to medicinal products and medical equipment in a situation of shortage.

**Comments on the provisions of the Recommendation**

**Preamble**

1. The Preamble of this Recommendation reaffirms the aims of the Council of Europe and the principles embodied in the Convention on Human Rights and Biomedicine (ETS No. 164). It also reaffirms the relevant provisions of the European Social Charter (ETS No. 35) and its revised version (ETS No. 163).

2. The Preamble recalls the principles on which the provisions of this Recommendation are based and in particular underlines the following aspects:

- medicinal products and medical equipment are an essential part of healthcare, and significantly contribute to saving lives and improving living conditions;

- policies and systems to prevent, prepare for, and mitigate shortages of medicinal products and medical equipment are of paramount importance to avoid and reduce harms to patients' health;

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

- 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; and

- decisions on prioritising access to medicinal products and medical equipment should be based on the best available scientific evidence in accordance with defined criteria.

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

**Chapter I – Object, scope and definitions**

***Article 1 – Object***

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

4. The term “equitable access” should be interpreted in accordance with the meaning provided in Article 3 of the Convention on Human Rights and Biomedicine and clarified in paragraph 25 of its Explanatory Report. In this context, “equitable” means first and foremost the absence of discrimination. Although not synonymous with absolute equality, equitable access implies effectively obtaining a satisfactory degree of care. The possibility to ensure “equitable access” depends on medical needs and available resources, which may mean that access cannot be guaranteed for some individuals who need them.

***Article 2 – Scope***

5. The Recommendation applies to access to medicinal products and medical equipment certified through an appropriate regulatory process provided by law. This implies that the conditions and situations of use have been established and the risk-benefit balance is favourable and demonstrated (including for medicinal products authorised for emergency use).

6. The Recommendation only applies to access to medicinal products and medical equipment needed for the medical care of patients with serious or life-threatening health conditions; therefore, their shortage may significantly harm the health of individuals who are in need of them. The Recommendation applies irrespective of the cause of the shortage.

7. The Recommendation does not cover medicinal products and medical equipment, the shortage of which has no significant negative impact on health (e.g., medicinal products used to treat mild to moderate transitory pain).

8. The Recommendation neither applies to access to therapeutic products such as human organs, cell, tissues used in the context of transplantation, or human blood and its derivates used in the context of transfusion. In the contexts of transplantation and transfusion, access is guided by specific principles laid down in the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186), the legal instruments elaborated by the European Committee on Organ Transplantation (CD-P-TO) and the European Committee on Blood Transfusion (CD-P-TS).

9. The Recommendation does not apply to access to experimental medicinal products and medical equipment**,** such as those studied in clinical trials, or used under compassionate use schemes and off-label (i.e., indications not authorised in the marketing authorisation). For these products and equipment, the exact conditions for use, and the indications and contraindications are not well-established and the expected risks and benefits are still uncertain.

10. The Recommendation does similarly not apply to vaccines, as these are not normally used to treat serious or life-threatening health conditions. Equitable access to vaccines is guided by specific principles as outlined namely in the "Statement on Covid-19 and vaccines: Ensuring equitable access to vaccination during the current and future pandemics".

11. The Recommendation does also not apply to a situation of shortage of human resources, although the principles outlined here may be relevant to the extent that a shortage of human resources results in a lack of access to medicinal products and medical equipment.

12. Nevertheless, member States may wish to apply part or all of the provisions of this Recommendation to regulating access to other health resources in a situation of shortage when the principles outlined here may be relevant.

***Article 3 – Definitions***

13. The term "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. This implies that the substance or combination of substances are presented in a pharmaceutical form that can be used in or administered to human beings and that the resulting finished product has been approved by an appropriate regulatory process provided by law.

14. The term "medical equipment" refers to medical devices such as diagnostics, instruments, and machines. These devices are subject to a conformity assessment to demonstrate compliance with legal requirements and safety and performance standards.

15. The term "shortage" refers to a situation where there is an insufficient availability of medicinal products or medical equipment relative to the healthcare needs, irrespective of the cause of the shortage.

**Chapter II – General principles**

16. This Chapter lays down the general principles that should guide priority-setting regarding access to medicinal products and medical equipment in a situation of shortage. The Chapter is addressed to all stakeholders entrusted with defining or implementing the priority-setting standards.

17. The principles outlined in this Chapter aim to guarantee equitable access to medicinal products and medical equipment in a situation of shortage. They implement the more general principle of "equitable access to healthcare" as enshrined in Article 3 of the Convention on Human Rights and Biomedicine.

***Article 4 – Non-discrimination***

18. Paragraph 1 states that no person in need of medicinal products or medical equipment in a situation of shortage should be *a priori* excluded from access to them. Priority-setting standards for the allocation of these resources should be based on the principle that every individual has the right to have his/her health protected.

19. Paragraph 2 prohibits discrimination on any ground in the access to medicinal products and medical equipment in a situation of shortage. Non-discrimination is an individual right enshrined in Article 14 of the European Convention on Human Rights. Under this Article, the enjoyment of the rights and freedoms set forth in the Convention must be secured without discrimination on any ground such as "sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status." Other circumstances may negatively impact an individual's access to medicinal products or medical equipment, such as socioeconomic situation, geographical location, gender, ethnic background, legal status, and educational and literacy levels, as well as age, disability, chronic disease, and mental health problems. Priority-setting standards may hold a potential for discrimination if these grounds and circumstances are used as a proxy for increased risk of mortality or morbidity, in this way deprioritising these individuals or groups.

20. Whereas the term "discrimination" has usually a negative connotation in French, this is not necessarily the case in English (where one must use the expression "unfair discrimination"). It has, however, been decided to keep the same term in both languages, as it is in the European Convention on Human Rights, in the case law of the European Court. Discrimination here should, therefore, in French as in English, be understood as unfair discrimination.

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

21. Individuals who already experience disparities in relation to health as well as in access to healthcare can be expected to have an even further decline in health when faced with a shortage of medicinal products or medical equipment. To ensure equitable access, specific attention should therefore be paid to individuals and groups who are systematically disadvantaged in relation to health. These systematic disadvantages may be the result of a variety of factors, including but not limited to economic and social situation, legal status, disability, chronic disease, or age. The aim is to avoid a situation where the application of priority-setting standards would reinforce existing health inequities. This principle can, for instance, be interpreted as requiring that difficult living conditions are considered as a factor in determining the consequences of the lack of access to a medicinal product or medical equipment. This can also be interpreted as requiring positive measures be taken to re-establish a certain balance in favour of those at a disadvantage.

22. To ensure that specific attention is paid to individuals and groups who are disadvantaged in relation to health, they should be meaningfully engaged in developing, refining, and reviewing policies of priority-setting, as outlined in Article 11.

***Article 6 – Prioritisation based on medical criteria***

23. The first paragraph indicates that, before a decision can be taken as to whether an individual should have access to medicinal products and medical equipment in a situation of shortage, an individual medical assessment should first be made. The individual medical assessment is intended to determine the healthcare needs for which the use of the medicinal product or medical equipment concerned is essential.

24. In this medical assessment four elements should be taken into account. The first element is the severity of the individual's health condition, taking into consideration medical urgency and the specific healthcare needed to address the health condition. The second element is the expected effectiveness of the medicinal products or medical equipment for the healthcare of the individual concerned. A careful medical evaluation should be performed of the clinical appropriateness, and proportionality of the use of these resources in relation to the healthcare needs of the individual concerned. The third element is the availability of possible therapeutic alternatives. In a situation of shortage, the concerned medicinal product or medical equipment should only be used if no suitable therapeutic alternative is available. The fourth and final element concerns the consequences for the

health of the individual concerned if that individual lacks access to the medicinal product or medical equipment.

25. The second paragraph sets out the principle for defining and implementing standards of priority-setting for individuals who, on the basis of the individual medical assessment, are considered to be in urgent need of access to the medicinal product or medical equipment concerned. Priority-setting based on defined criteria helps to direct limited resources towards healthcare needs. In a situation of shortage, the term priority-setting is used as a synonym for rationing or allocation. Clear priority-setting standards are of particular importance for the healthcare professionals who are directly confronted with individuals in need of medicinal products and medical equipment.

26. This paragraph states that priority-setting should be guided by the principle of minimising the risk of mortality and, subsequently, the risk of morbidity. This implies that priority access to medicinal products and medical equipment should be provided to individuals for whom they will be more effective, in the light of this principle. This may be interpreted as focusing on the short-term likelihood that the individual concerned survives the acute medical episode. In that interpretation, only those underlying comorbidities that are prognostically relevant for surviving the acute medical episode in question should be considered.

27. The possibility to ensure a comprehensive individual assessment will depend on the time available to evaluate the situation of the individual concerned. Therefore, decisions may need to be taken under uncertainty, especially when the individual concerned requires immediate healthcare.

***Article 7 – Appropriate support and removal of barriers***

28. To ensure equitable access to medicinal products and medical equipment, this article underlines the importance of the removal of barriers and the provision of appropriate support to persons and groups who may be disadvantaged or exposed to higher risk of harm to their health.

29. Examples of individuals and groups concerned include persons with disabilities, with mental health problems, or learning disabilities, as well as those exposed to risks of discrimination or stigmatization, such as individuals belonging to minorities, homeless or living in poverty. Other examples include those individuals with addiction, geographically isolated, deprived of liberty, low-income migrant workers, and individuals without residence or with insecure legal status.

30. Measures to ensure support and the removal of barriers include awareness-raising programmes for healthcare professionals, assistance for individuals with specific needs or who lack a social support network. Other measures include the removal of financial and administrative barriers, disseminating of adapted communication materials, implementation of novel or flexible delivery strategies, and, where possible, removal of other barriers. In accordance with Article 11, these vulnerable groups should be meaningfully engaged in developing, refining, and reviewing policies, so as to take into account their needs, existing barriers, and possible solutions. The measures to ensure support and the removal of barriers should be defined through established protocols.

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

31. This Article focusses on the situation where, in light of the principles outlined in this chapter, a person does not have access to life-saving medicinal products or medical equipment. In this situation, other types of healthcare support should be provided, if these are available and appropriate. If no alternative healthcare support is available, the patient should be provided with compassionate and palliative care. As outlined in the Guide on the decision-making process regarding medical treatment in end-of-life situations, drawn up by the Committee on Bioethics in May 2014, the aim is to provide the best possible quality of life.

32. “Palliative care” is specialised medical care of patients with a life-threatening, progressive health condition with a limited prognosis. It is aimed at providing the best possible quality of life through controlling pain and other symptoms of the health condition. “Compassionate care” focuses on providing the necessary support in coping with psychological or social problems and, where appropriate, on providing spiritual support.

33. “Compassionate care” should not be confused with the “compassionate use of a medicinal product.” The latter is a treatment option that, under specific conditions provided by law, allows medicinal products under development to be made available for the medical care of patients with serious or life-threatening health conditions where no satisfactory authorised therapies are available and where these patients cannot enter into relevant clinical trials.

**Chapter III – Procedural principles**

34. This Chapter lays down the procedural principles that should guide the process of defining and implementing priority-setting standards in accordance with the general principles outlined in Chapter II. These procedural principles are essential to ensure that priority-setting standards are defined in a way that guarantees equitable access and are to the greatest extent possible considered as relevant and fair by all affected parties. In this way, they are essential to build and maintain public trust in the fairness of decisions and to ensure their successful implementation.

35. The Chapter is addressed to all stakeholders that may be involved in the process of defining and implementing priority-setting standards, such as competent authorities, professional medical organisations, national ethics committees, hospital ethics committees, and concerned interdisciplinary teams of professionals.

36. The possibility to ensure fulfilment of some of the procedural principles may depend on the time available to complete the process. Especially in cases of urgency, such as caused by unpredictable events and developments, some procedural principles may temporarily be difficult to observe. In that case, these principles should be observed as soon as the situation would allow it.

***Article 9 – Accountability***

37. This article emphasises the importance of accountability as a central procedural principle. Accountability is crucial to ensure that considerations of equity remain at the centre of the decision-making process. Accountability implies that entities at different levels of the healthcare system involved in defining and implementing priority-setting standards take responsibility for the consequences of their decisions.

38. Paragraph 1 states that the respective responsibilities of entities at different levels of the healthcare system should be clearly defined.

39. Paragraph 2 states that information about which entities are accountable at the different stages of priority-setting and implementation should be available to all parties who may be affected by their decisions, including healthcare professionals and the public. This should include information about where and how concerns can be addressed regarding decisions on priority-setting. The mechanisms that allow individuals to express possible concerns should be easily accessible and designed so as to guarantee that concerns will be addressed appropriately.

***Article 10 – Reasonableness and relevance***

40. This article emphasises that, in defining and implementing priority-setting standards, policies should be based on arguments that are reasonable. Paragraph 1 states that this will be the case when appeal is made to the best available evidence. Best available evidence refers to information that is relevant, measurable, clear, objective, and consistent. An evidence-based approach avoids those decisions are based on personal experience, speculation or biased sources. For treatment decisions, the best available evidence is provided by randomised controlled trials.

41. Paragraph 2 states that 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. This should include individuals who might later be disadvantaged by the implementation of these policies.

***Article 11 – Inclusiveness***

42. This article states that the process of developing, refining, and reviewing priority-settings standards should be inclusive so as to ensure that the views of all parties who may be affected by the

resulting decisions are represented. An inclusive process does not only rely on the participation of professional stakeholders, including healthcare professionals, but also on input from the general public and civil society organisations representing groups that may be greatly affected, in particular groups that are disadvantaged or exposed to at a higher risk of harm to their health.

43. Meaningful engagement will guarantee that all parties have the opportunity to articulate the underlying values to be considered. This is especially important since disagreement may exist about the relative significance of certain values. In this way, meaningful engagement in the process of formulating policies is essential in order for these policies to be accepted as legitimate. In addition, the involvement of healthcare professionals, civil society organisations, and the general public will allow the identification of particular needs and barriers that might otherwise remain undetected. This will ensure that specific attention is paid to individuals and groups who are disadvantaged in relation to health in accordance with Article 5, and that appropriate support can be provided, and barriers can be removed in accordance with Article 7.

44. Healthcare professionals, civil society organisations, and the general public should also be meaningfully engaged in creating and disseminating educational tools and in the development and implementation of strategies for communication. This will improve transparency of decisions and ensure that educational tools and communication materials are tailored to the needs of healthcare professionals and the public, in accordance with Article 13.

45. In the process of developing, refining, and reviewing priority-settings standards healthcare professionals, civil society organisations, and the general public should also be meaningfully engaged in a dialogue on aspects relevant to equitable access, as outlined in this Recommendation. In combination with the other provisions set out in this Article, this will ensure that decisions are part of a broader deliberative democratic process involving all groups that may bear the consequences of these decisions. Steps to ensure an effective public dialogue on the conditions for access to healthcare are described in the Guide to public debate on human rights and biomedicine, drawn up by the Committee on Bioethics and published in December 2020.

***Article 12 – Consistency***

46. Paragraph 1 recommends that policies that define and implement priority-setting standards should be applied in a consistent way. This implies that they should be applied to all individuals and groups in accordance with explicit and predetermined criteria, taking into account contextual factors. Individuals and groups who should be treated similarly should therefore not receive different access. The consistent application of policies will also help avoid discrimination against certain groups and individuals, prohibited in accordance with Article 4.

47. Paragraph 2 raises attention to the risks of corruption, arbitrary exceptions, access on the basis of financial means, and activities such as lobbying and political interference. These ways to obtain priority access to medicinal products and medical equipment in a situation of shortage are contrary to the principle of equitable access, and should be prohibited. To that aim, policies should be designed so as to ensure that these interventions are impossible or unsuccessful, including by using terminology that avoids ambiguity and by relying on trustworthy, impartial, and neutral decision-making bodies.

48. Paragraph 3 acknowledges that some flexibility in implementing guidelines might be necessary, especially to account for changing circumstances and factors that may be unique to a local situation. In the light of the principle of consistency, any decision not to follow the guidelines provided should only be taken after careful deliberation and with due respect for the other principles set out in this Recommendation. Such a decision should be clearly documented.

***Article 13 – Transparency and communication of decisions***

49. This article emphasises the importance of transparency and communication in defining and implementing priority-setting standards. Paragraphs 1 and 2 underline the importance of making publicly accessible the objectives of the priority-setting, priority-setting standards, and the reasons why specific priority-setting standards have been chosen. The underlying principles and values should

also be clearly articulated and adequately explained. This approach is essential to allow all stakeholders to understand what and how decisions are taken.

50. In accordance with the provisions of Article 11 on meaningful engagement of stakeholders, information regarding priority-setting should, whenever possible, be provided beforehand. Similarly, in accordance with Article 9, professional stakeholders and the general public should be informed about where this information is made available and how feedback may be given.

51. Paragraph 3 refers to clear, accurate, and understandable information about which persons are prioritised, the reasons for these priorities and how they may change. Attention should be paid to adapting this information to persons with different educational and literacy levels or special language competencies or communication needs. As far as practicable, communication materials should be produced in a variety of formats, translated into all the relevant languages at local and regional levels, and distributed on a variety of easily accessible platforms.

52. Paragraph 4 states that communication should be ensured about the realities of the shortage of medicinal products and medical equipment. This communication should be open and honest, especially in acknowledging remaining uncertainties and the consequences that the shortages may have for the treatment options and the general level of care of persons in need of these resources. Communication plans should ideally be developed in advance, so as to ensure that information will be timely and effectively disseminated to all stakeholders once a situation of shortage arises.

***Article 14 – Review***

53. This article emphasises the need to provide for the possibility of feedback, regular review, and monitoring of measures. Paragraph 1 states that decisions regarding the prioritisation of access should be open to feedback. Responsiveness to concerns raised by stakeholders is essential to ensure equitable access and to promote public trust. To that aim, easily accessible and effective mechanisms should be in place to provide feedback to the entities that are accountable in accordance with Article 9.

54. Paragraph 2 states that, in addition, interim and retrospective review processes should be introduced to provide regular opportunities for improving policies. In the light of changing circumstances and new evidence it may be necessary to adapt priority-settings standards or their implementation. Regular review ensures that priority-setting remains up to date with the latest developments of the shortage situation, as well as consistent with best evidence.

55. Whether access to medicinal products and medical equipment is equitable may also depend on the measures taken to address the situations of shortage. Paragraph 3 therefore states that situations of shortage and the measures to address them should be closely monitored to evaluate whether equitable access is ensured, and the principles laid down in guidelines are observed.

**Chapter IV – System for prevention, preparation and mitigation**

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

56. This article states that it is essential that member States 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. It is essential that situations of shortage of medicinal products and medical equipment are as much as possible prevented. Member States should therefore take appropriate measures to prevent these situations from occurring. Where a shortage would occur, appropriate measures should be taken to prepare for and mitigate them. Member States should ensure that in this system, all measures are defined and implemented in accordance with the principle of equitable access to healthcare of appropriate quality.

***Article 16 – Prevention***

57. Paragraph 1 states that measures in place for the prevention of situations of shortage of medicinal products and medical equipment should include methods for predicting future needs in different scenarios.

58. Paragraph 2 clarifies the information that should be used to this end. It should not be limited to historical data on the marketing and use of medicinal products and medical equipment, since forecasts made on the basis of these data only may reinforce health inequities. Therefore, data used for predicting future needs should also include epidemiological data, clinical and public health practices, and available healthcare infrastructure and their capacities, as well as data directly relevant from the perspective of inequity, such as sociological data and data on health inequities.

***Article 17 – Preparation***

59. This article emphasises that, as soon as a situation of shortage of medicinal products and medical equipment can be expected, measures for the prevention of such situation should immediately be taken to address possible adverse consequences for the health of the individuals concerned. The measures should be based on a regular assessment of the healthcare system's capacities, including available infrastructure and resources, and planning to control the risk identified.

***Article 18 – Mitigation***

60. This article states that, when a situation of shortage emerges, the strategies prepared in accordance with Article 17 should be implemented to minimise the impact and duration of the shortage. These strategies of mitigation should include monitoring the availability of medicinal products and medical equipment and conserving those available. The assessment of available suitable alternatives to medicinal products and medical equipment, and the re-allocation of medicinal products and medical equipment in accordance with healthcare needs, should be foreseen.

***Article 19 – Information***

61. This article stipulates that healthcare professionals and the general public should be provided with timely information about shortages of medicinal products and medical equipment, the possible therapeutic alternatives, and the risks involved in purchasing products and equipment from unofficial supply channels and in unauthorised use.

62. This information should be clear, accurate, and understandable. Attention should be paid to adapting this information to persons with different educational and literacy levels or special language or communication needs. As far as practicable, communication materials should be produced in a variety of formats, translated in all the relevant languages at local and regional levels, and distributed on a variety of easily accessible platforms. Messages should be regularly repeated and provided by trusted voices operating in partnership with local communities.

***Article 20 – Responsibilities***

63. This article emphasises that the entities which are involved in defining and implementing measures of prevention, preparation for, and mitigation of situations of shortage of medicinal products and medical equipment should take responsibility for the consequences of their decisions. Their respective responsibilities should be clearly defined. This implies that information should be provided about which entities can be consulted to address concerns regarding measures of prevention, preparation for, and mitigation of situations of shortage of medicinal products and medical equipment. The mechanisms that allow individuals to express possible concerns should be easily accessible and designed so as to guarantee that concerns will be addressed appropriately.

***Article 21 – International co-operation***

64. This article encourages close cooperation at international level with a view to most efficiently preventing, preparing for, and mitigating situations of shortage of medicinal products and medical equipment. Faced with a complex and globalised production and distribution chain, coordinated action based on harmonised standards should be considered so as to guarantee timely measures to appropriately address situations of shortage.