Parliamentary Assembly
Assemblée parlementaire
https://pace.coe.int

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Doc. 15801
20 June 2023

Securing safe medical supply chains

Reply to Recommendation[1]: Recommendation 2243 (2022)
Committee of Ministers

1. The Committee of Ministers has carefully examined Parliamentary Assembly Recommendation 2243 (2022) "Securing safe medical supply chains". The recommendation has been brought to the attention of the governments of the member States and forwarded to the relevant committees for information and possible comments.[2]

2. On a general note, the Committee of Ministers fully supports initiatives aiming at enhancing preparedness and response of healthcare systems to public health emergencies as well as mitigating situations of medicine shortages with the ultimate goal of ensuring equal access to and continuity of care. The Committee of Ministers welcomes the Assembly's recommendation and shares the observation of "increased shortages of medical products that have the potential to jeopardise the functioning of public health systems and affect the exercise of the right to protection of health, which is intrinsically connected with the right to life".

3. In this respect, the Committee of Ministers informs the Assembly that it recently adopted Recommendation CM/Rec(2023)1 on "Equitable access to medicinal products and medical equipment in a situation of shortage" to safeguard the fundamental rights of individuals who need them for serious or life-threatening health conditions. In this recommendation, it is recognised that 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. External events, such as epidemics, armed conflicts, and emergencies caused by climate change, may significantly increase demand, and reduce the capacity to guarantee availability of medicinal products and medical equipment. The Committee of Ministers underlines that the recommendation requests that appropriate measures should be taken to ensure that, at the national level, there is a system in place, to prevent, prepare for, and mitigate situations of shortage of medicinal products and medical equipment, in accordance with the principle of equitable access to healthcare of appropriate quality.

4. The Committee of Ministers would also point out that a continuous reflection has been carried out by the CDBIO and its predecessor, the Committee on Bioethics (DH-BIO), on ways to be better prepared and resilient to future threats as evidenced in the statement, *inter alia,* on "Covid-19 and vaccines" and through webinars and other events organised by the CDBIO such as the Conference on "Social Resilience and Health Equity: A human right prospective for better resilience and preparedness", held online on 22 February 2022.

5. Given that the causes of disruptions in the medical supply chains are multidimensional and, over the years, the issue of medicine shortages has received growing attention from numerous key actors operating in both the public and private sector, the Committee of Ministers notes that initiatives in this area need to take account of activities carried out at international and European level with a view to developing co-ordinated approaches. It recognises in particular the importance of a close working relationship with the WHO with which the CDBIO has a long-standing co-operation and of supporting the development of regional production chains for vaccines and health products in low- and middle-income countries**.** The CDBIO is also committed to

1. Adopted at the 1469th meeting of the Ministers' Deputies (14 June 2023).
2. The Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) and the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH).

co-operation with other international organisations and bodies as outlined in its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025). It is recalled that the Council of Europe is an associated member of the UN Inter-Agency Committee on Bioethics (UNIACB) where it exchanges information and co-ordinates relevant activities with UN agencies.

6. Finally, in response to the call of the Assembly, the Committee of Ministers invites member States, which have not yet done so to consider ratifying the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (CETS No. 211, the “Medicrime Covention”). Given the potential increase in the numbers of counterfeit medical products linked to medicine shortages, this convention plays a crucial role in supporting countries worldwide in the fight against the falsification of medical products and similar crimes and safeguarding public health. The Medicrime Convention is the first coherent international legal instrument of global scope clearly establishing that the introduction of counterfeit medical products into the licit supply chain are crimes under international law. The Committee of Ministers recalls that a Handbook for parliamentarians was published back in 2015 to encourage member States to sign, ratify and implement the Medicrime Convention, the Council of Europe's main instrument for combating the counterfeiting of medical products and similar crimes, in order to put an end to this form of crime and protect public health. In addition, a feasibility study was published in December 2021 for the “Establishment of a 24/7 network within the framework of the MEDICRIME Convention report” which aims to support Council of Europe member States and other countries in examining the feasibility of creating a network of national focal points available 24/7, to contribute, *inter alia*, to securing the supply chain of medical products through operational and judicial co-operation against the counterfeiting of medicines and other similar offences threatening public health.