

## CoR INTERREGIONAL GROUP ON HEALTH & WELL-BEING

Thursday, 18 April 2024, 13h30-14h30

“Addressing medicines shortages in the EU”

### Minutes

#### **13.30 Welcome, introduction by the Chair, Birgitta Sacrédeus**

**Jean-Luc Vanraes**, Municipality Council of Uccle – European CoR member and Member of the European CoR Interregional Group on Health and Wellbeing, welcomed all the participants on behalf of the Interregional Group’s Chair, **Birgitta Sacrédeus**, explaining that the purpose of the constitutive meeting was to discuss the recent European Committee of the Regions Opinion on "Addressing Medicine Shortages," currently under discussion within the CoR Commission for Natural Resources, and gather comments from stakeholders.

#### **13:35 Presentation of the CoR’s Opinion on “Addressing medicines shortages”**

**Erika Von Kalben**, Vice-President of the State Parliament of Schleswig-Holstein, European CoR Member (Greens, Germany) and Rapporteur of the European CoR’s Opinion on “Addressing medicines shortages”, opened the panel by stressing how Europe is globally dependent on medicine production and sourcing raw materials. In this regard, the opinion calls for greater commitment from the next legislature on this issue. Specifically, there is a need for more diversification among supply partners as currently Europe’s medicine production relies on foreign countries (e.g., referring to China and India). The report also focuses on the need for accessible and available medicines across Europe, promoting a more European and less nationalistic approach. This can be achieved through a data collection system that monitors the needs of individual countries and existing stocks, in order to then consider a harmonized strategy.

#### **13:45 Stakeholders’ views on medicines shortages – with focus on the role of regions**

**Gloria Ghéquièrre**, Advisor at the Cabinet of the Deputy Prime Minister and Minister for Social Affairs and Public Health, Belgium, highlighted that many of the medicines used are produced in countries such as China and India, causing a dependency issue as well as frequent shortages or difficulties in sourcing for European countries. An interesting debate has arisen, especially at the competence level: the Commission believes this is a matter of competence for the Member States, while some countries believe it requires greater European harmonization. For example, in 2022, under the French presidency, the Versailles Declaration was drafted, in which European leaders committed to

supporting sustainable European medicine production at affordable prices, accelerating the registration of European suppliers, funding research and development, and building production capacity for critical products. In 2023, a non-paper was developed by Belgium to introduce a solidarity mechanism among Member States based on the exchange of medicines in urgent cases, but it had limited effects considering that in 96% of cases shortages concern generic medicines. However, these tools have not always had concrete effects and have not prevented an increasing outsourcing of production to non-EU countries.

Mention was also made of the absence of the Critical Medicines Act, since the Commission considered that there was not enough political and time space during the legislative term to produce a legal act. To address this gap, the Commission has established a Critical Medicines Alliance to prevent and address potential critical shortages of such drugs. The Alliance will bring together stakeholders and work to strengthen cooperation between the Commission, national governments, industry, and civil society. In particular, it will identify issues, establish priorities, and suggest possible solutions to the problem of medicine shortages in the EU by developing recommendations and providing advice to the Commission, Member States, and other European decision-makers. The Critical Medicines Alliance, open to all companies and organizations, as well as Member States, their agencies, healthcare professionals, patients, and other stakeholders, will last for five years, and the publication of the first recommendations on actions to improve the supply of critical medicines is expected by the fall of this year.

**Ylva Reisnert**, Senior EU policy advisor, Region Skåne Brussels Office, presented the case of the Swedish region of Skåne in relation to medicines shortages. The Swedish plan to prevent and manage medicine shortages involves the participation of multiple stakeholders working synergistically and at various levels to improve system efficiency and resilience. In particular, companies are required to report to the Medical Products Agency if there are risks of medicine shortages. These reports are compiled into a list and publicly shared so that everyone is aware of them. Representatives from the medical and pharmaceutical sectors, and the Agency discuss potential shortages of essential products weekly to be able to act in advance in case of high risk. For this purpose, there is also a forum for comparison and discussion on trends and risks of disruption in the production and distribution chain of medical products and devices on a large scale to provide a broad spectrum and multilevel view of the current situation and potential future scenarios. Regarding cooperation, individual regions collaborate with each other to manage any shortages of critical medicines and strive for redistribution of available products if one of them encounters difficulties. Analysing the European framework, among the steps that the Commission could take in the coming years, it is desirable that anti-competitive measures are used cautiously, balancing punitive measures with incentives and

conditions that allow companies to maintain a wide range of products on the market. Furthermore, it is important to minimize the risk of medicine shortages, both for new medicines and for those that have been on the market for a longer time and are less profitable.

#### **14:00 Open debate and Q&A**

During the Q&A session, **Ms. Ghéquierè** referred to a pilot project for monitoring stock levels and supply chains. The aim is to create a database that can be used to intervene and address shortages of medicines, devices, and medical personnel. If successful, the project could be expanded to other countries and eventually adopted at the European level. Regarding Pharma Legislation and the shortage prevention plan, she explained that there is indeed some limitation on the inclusion of medicines in the list of critical medicines, as some Member States are concerned that this may make the European market less attractive. Regarding the establishment of strategic partnerships, the EU must coordinate with other actors (e.g., the USA and Japan) in order to diversify production and ensure the availability of all products, splitting the burdens. Reference was also made to the Zero Pollution Act, which poses new challenges for companies on how to be sustainable and competitive. Regarding monitoring activities, **Ms. Von Kalben** hopes for a paradigm shift, moving the focus from monitoring what is produced to monitoring what is needed.

#### **14.30 End of the meeting**