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ECL reflections on medicine shortages

Bridging efforts to tackle medicine shortages at the EU level

The European Medicines Agency (EMA) plays an important role in protecting public health in the EU. The Access to Medicines Task Force of the Association of European Cancer Leagues (ECL) welcomes the European Commission's proposal for a Regulation on a reinforced role for the EMA as well as the ongoing study on identifying and addressing the root causes of shortages.

The COVID-19 pandemic has exacerbated the EU's ever-increasing medicine shortages and long-standing drug supply issues, forcing the Agency to become more resilient and better equipped to tackle current and future health emergencies.

By extending the mandate and resources of the EMA, the increasing levels of medicine shortages, which pose severe threats to patient safety and outcomes, could finally be addressed in a harmonised and coordinated manner at EU level.

Cancer leagues wish to highlight the following key aspects:

1. Public health emergencies do not occur only when a chemical or biological agent poses a serious, sudden and unexpected threat to citizens. **Focusing on communicable and infectious diseases** caused by microorganisms that know no borders **is too narrow**. Instead, "**cross-border threats to health" is suggested as a more encompassing term**, which can refer to events that endanger international public health, no matter whether these are caused by communicable diseases, non-communicable diseases, or shortages of medicines and medical equipment that put patients at risk and national health systems under pressure.

2. The **European policy framework in the area of medicine shortages is fragmented** and there is **no single strategy to tackle medicine shortages** but rather, different objectives and instruments are being currently discussed. This prevents effective and coordinated actions to tackle them. It is important to avoid additional bottlenecks and further delays in patients' availability of medicines.

3. National and EU health institutions are currently under pressure and facing major challenges brought by the COVID-19 pandemic. It is important to **efficiently use the tools and resources currently available to communicate shortages and develop further digital infrastructures** around the Single Point Of Contact system (**SPOC**) and Industry Single Point Of Contact (**i-SPOC**) system.

Medicine shortages - a cross-border threat to health

Medicine shortages pose serious risks for patient health which can lead to non-treatment, under-treatment, and possible medication errors from attempts to substitute missing medicines[1]. **A survey conducted by the French League Against Cancer shows that 68% of oncologists estimated that the shortage experienced by their patients will have an impact on the chances of them surviving for another five years**[2]. Hence, a patient-centred approach to managing medicines shortages is required[3].

Definition of 'medicine shortages'

ECL calls on the European Commission to urgently establish clear criteria and a common European definition of 'medicine shortages'. An essential element to a coordinated approach for reporting and managing shortages is the use of a harmonised, legal definition of a shortage. The lack of a common definition has meant that, to date, the detection and coordination of the management of shortages have been inconsistent across the EU.

An EU definition of 'shortage' would allow appropriate interpretation and identification of the phenomenon and the development of appropriate legislative solutions. This would pave the way for a more resilient and predictable pharmaceutical supply chain.

Cancer leagues stress that clear obligations and sanctions should be set alongside the definition of a 'shortage'. This would lay the foundations to act in case a marketing authorisation holder does not fulfil its responsibilities or cause availability issues due to withdrawals**. The definition should be patient-centred and specify time-bound criteria for how long the availability of the product is delayed**.

Forecasting strategies and prevention plans

Cancer leagues welcome the strong emphasis on mitigation plans. However, we miss in the proposal a much-needed focus on the **importance of preventing shortages and addressing possible causes *before* disruptions occurs**. Marketing authorisation holders should be asked to develop both mitigation plans *and* prevention plans. This could find a legal basis in the revision of the Regulation on the role of EMA.

In our view, **the proposed Regulation** as well as the **ongoing policy discussions** at the European level, **are very much focused on medicines shortages that occur during public health emergencies.** The current COVID-19 crisis has brought the issue of medicine shortages to a head, but the number of drug shortages has been escalating for years. In 2019, shortages caused by commercial withdrawals of medicines represented 63% of all shortages in Romania,

[1] https://www.who.int/medicines/publications/druginformation/WHO_DI_30-2_Medicines.pdf?ua=1
[2] https://www.ligue-cancer.net/sites/default/files/docs/infographies_essentielles_en_anglais-.pdf
[3] https://www.who.int/medicines/publications/druginformation/WHO_DI_30-2_Medicines.pdf?ua=1

47% in Croatia, and 37% in Italy[4]. In France, it was estimated that at least 16 % of the shortages notified to the French Medicine Agency resulted from market withdrawals[5]. **The two scenarios of medicine shortages in 'normal' times and shortages during public health emergencies should be both analysed further and have a place in the Regulation**.

Already in early 2017, a number of players involved in the drug supply chain issued a **joint statement** on information and medicinal product shortages calling **for greater transparency and availability of (i) medicines shortage data**, (ii) **early detection, and assessment of potential shortages**, (iii) consistency of reporting, (iv) increased access to the information available across the supply chain, (v) improved data infrastructure, and (vi) collaborative governance processes.

We are aware that medicine shortages are dealt with at the national level by competent authorities. Nevertheless, **in recognition of the important and growing impact of shortages across Europe, this issue should be defined and treated as a cross-border health threat**.

National initiatives aimed at fighting medicine shortages **such as forecasting, planning, and mitigation plans should be** encouraged and **coordinated by the European Commission. EU-level strategic stockpiling of critical medicines** and other health equipment at high risk of shortage would **avoid competition for scarce resources** among EU Member States.

Aiming for complementary policy and legislative actions

Cancer leagues note that **conversations about the EU pharmaceutical supply chain management are ongoing at different levels and in different settings**. We, therefore, **call on the European Institutions to align the various ongoing legislative actions and avoid contradictory policy actions**.

The **European Commission** is (i) conducting a study on identifying the root causes of shortages, (ii) looking at the new European Health Emergency Preparedness and Response Authority (HERA) as a plausible stakeholder that could oversee the pharmaceutical supply chain. At the same time, **Members of the European Parliament** are currently working on (iii) amendments to extend the role of the EMA in tackling pharmaceutical shortages and address this longstanding issue. Moreover, the **proposed Regulation** lays on the foundations of the pharmaceutical legislation, including the Directive 2001/83/EC that is currently under evaluation.

It is essential that EU institutions, EU Agencies, Head of Medicines Agencies (HMA), **and national bodies are aligned and complement each other's work**. This is especially important in case of emergency and supply bottlenecks, in order to **avoid additional administrative and legal complications that would ultimately lead to further delay in patients' access to medicines and healthcare services**.

Harnessing the potential of digital infrastructure

[4] https://www.quechoisir.org/action-ufc-que-choisir-penuries-de-medicaments-devant-la-responsabilite-criante-des-laboratoires-les-pouvoirs-publics-doivent-sortir-de-leur-complaisance-n84943/

[5] https://www.quechoisir.org/action-ufc-que-choisir-penuries-de-medicaments-devant-la-responsabilite-criante-des-laboratoires-les-pouvoirs-publics-doivent-sortir-de-leur-complaisance-n84943/

Besides the definition of shortages, **the criteria for reporting shortages differ greatly between the EU Member States**. National reporting systems should be streamlined and centralised in an EU-wide interface.

To achieve this objective, **digital tools and statistical modelling can contribute to the establishment of a methodology for forecasting medicines' national demand and streamlining demand forecasting across the EU Member States**. The previously established EU single point of contact network (SPOC) and then the Industry Single Point of Contact (i-SPOC) systems turned to be effective instruments to swiftly communicate possible shortages and minimise the impact on patients' health[6]. These digital tools would not only address shortages but also prevent them by (i) streamlining communication channels, (ii) reducing time-consuming procedures, (iii) making the system more transparent, and (iv) increasing accountability. **The SPOC and i-SPOC systems should converge to the benefit of all stakeholders.**

Finally, **ECL urges policymakers, the EMA, and HMA to further engage with cancer leagues, patients, and the wider civil society, by involving all the stakeholders in discussions around medicine shortages**. The EMA has been a forerunner in this regard, and its capacity to embed patient involvement in regulation needs to be safeguarded and expanded. Cancer leagues' involvement is essential to provide data and insights on shortages at the national and regional level and to add value to the Agency's work.

About ECL Access to Medicines Task Force

Established in 2016, the ECL Access to Medicines Task Force connects 30 national and regional cancer societies in 25 European countries, representing over 570 million Europeans. It aims to make safe and effective medicines available to all cancer patients in Europe, by insisting on accessibility, availability, affordability and increased transparency related to medicine prices, ultimately leading to sustainability of healthcare systems. The Task Force strongly believes in the power of constructive dialogue. We urge all stakeholders to push for accessibility to high quality treatments, improving both survival and the quality of life of cancer patients.

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[6] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines