



## ECL welcome the reflection paper on forecasting demand for medicinal products in the EU/EEA

The [Access to Medicines Task Force](#) of the Association of European Cancer Leagues (ECL) welcomes the [reflection paper on forecasting demand for medicinal products in the EU/EEA](#) jointly developed by the European Commission, the European Medicines Agency (EMA), and the Head of Medicine Agencies (HMA) and issued on 3 June 2021.

The [EU Executive Steering Group on Shortages of Medicines Caused by Major Events](#) supports the strategy of forecasting demand for human medicines used in the EU and at the national level in exceptional circumstances like the COVID-19 pandemic.

**ECL strongly encourage demand-forecasting not only during crisis but also in non-emergency situations, as medicine shortages negatively impact on treatment outcomes and patient safety, no matter what caused them.**

## 6 Principles

THAT CAN BE APPLIED BOTH IN NORMAL TIMES AND DURING PUBLIC HEALTH EMERGENCIES

1. **Epidemiological models, historical information** and **horizon scanning** are essential to **determine** the **quantity of medicines** that will be **needed** should a disruption of the pharmaceutical supply chain occur;
2. The ultimate purpose of demand forecasting is to inform the planning of the manufacturing of medicines, **no matter the cause that impacts the production process**;
3. The demand forecast should **cover at least a period of 6 months** so that manufacturing sites can respond to the demand before it becomes impossible to meet;
4. EU institutions should **support coordinating national initiatives aimed at fighting medicine shortages** by forecasting, planning, and implementing mitigation plans.
5. **Harmonised and centralised reporting** will not prevent the occurrence of shortages per se, but improved information sharing through timely and standardised reporting may **improve understanding of the nature and causes of shortages**;
6. It is essential to **harmonise the level of data granularity** and the **criteria** to assess the supply chain.

Amandine Courtin, Advocacy Manager at the French League Against Cancer (Ligue contre le cancer) and ECL Medicine Shortage leader commented: *"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. Hence, a patient-centred approach to managing medicines shortages is required, no matter the cause."*

# 6 Cancer leagues' priorities

## TO TACKLE MEDICINE SHORTAGES

Timing and the extent of data available are critical to prevent first and then tackle medicine shortages. To this end, cancer leagues call on the EU institutions to:

1. **Increase supply chain transparency;**
2. **Improve information sharing** between manufacturers, the EMA, and national institutions;
3. **Strengthen the obligation to promptly notify shortages.** A system of obligations and sanctions should be put in place, as this would increase accountability and responsibility across the supply chain;
4. **Plan a minimum amount of critical medicinal products** that should be available in each country's supply chain to assure continuity of supply to patients at any given moment;
5. **Consider medicine shortages as a cross-border health threat, no matter the cause,** including withdraws from the market of much-needed medicines;
6. **Medicines that are not available to patients after 72 hours from their request, should be considered in shortage.**

We conclude by echoing the views expressed in the [reflection paper on forecasting demand for medicinal products in the EU/EEA](#) that **forecasting demand for medicines is essential for a resilient medicines supply chain** and that it should follow an integrated approach considering the following elements:

1. what will be needed **for treatment of patients;**
2. what will be needed to **restore planned minimum stock levels;**
3. what is currently **available in the stocks** held by e.g. hospitals, wholesalers and manufacturers.

## About ECL

The Association of European Cancer Leagues (ECL) is a non-profit, pan-European umbrella organisation of national and regional cancer societies, currently representing 30 cancer leagues in 25 European countries.

The [ECL Access to Medicines Task Force](#) aims to make cancer medicines available for all cancer patients in Europe by insisting on accessibility, sustainability of the healthcare system and transparency of medicines prices. Today, 29 national/regional cancer leagues, representing over 500 million citizens, have signed the Task Force's Declaration of Intent.

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