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## **AESGP Position Paper**

**Shortages of medicinal products  
for citizens in Europe: the particular case  
of non-prescription medicines**

July 2020

## Executive summary

1. **Self-care plays a crucial role in healthcare, particularly during the pandemic, by helping to reduce the burden on healthcare systems**
  - ♦ Non-prescription medicines and other self-care products were essential to avoid unnecessary visits to healthcare facilities, preventing illness or helping address minor ailments during confinement as well as the symptomatic relief of viral infections.
2. **Self-care products' shortages are rare and have little to no impact on citizens due to the alternatives delivered by a competitive market**
  - ♦ Proactive reporting of medicine shortages should be based on a risk assessment from a patient access perspective.
3. **Self-care products have a fit regulatory framework and a resilient global supply chain, planned to face adversity and ensure continuity, as shown during the Covid 19 pandemic in Europe**
  - ♦ Onshoring of manufacturing sites raises sustainability concerns.
  - ♦ Consider role of EU trade agreements in the context of active product ingredients and other raw materials.
4. **In case of exceptional events, unforeseen circumstances can challenge the EU preparedness for supply disruptions**
  - ♦ Leadership, crisis management plans and coordinated actions are necessary, including flexibility of all actors involved, to prevent and mitigate supply disruptions within the EU, from internal or external origin.

### About

The **Association of the European Self-Care Industry (AESGP)** is a non-profit organisation which represents the manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe, an area also referred to as consumer healthcare products.

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# Self-care plays a crucial role in healthcare, notably during the pandemic, by helping reduce the burden on healthcare systems

Pharmaceuticals are an essential part of health systems, mostly because they are the most affordable and accessible healthcare technology. A global and reliable supply chain ensures the continuous availability of medicinal products to citizens throughout the geography of the European Union as well as globally.

Non-prescription medicines can be acquired directly without a healthcare professional prescription and play an important role in sustainability of healthcare systems. Non-prescription medicines are often the first choice for people as they enable to manage symptoms of a wide range of common health issues, such as headaches, common cold, cough, musculoskeletal pain, allergies, tobacco dependence, heartburn, emergency contraception, gastrointestinal disorders etc. Self-care with non-prescription medicines enables indi-

viduals to carry on normal life and be productive (go to work/school, play sports, care for children, travel, etc.), and contributes to their overall wellbeing.

During the COVID19 pandemic, self-care played a decisive role, avoiding the risk of exposure with unnecessary visits to overburdened healthcare facilities and already exhausted healthcare professionals. The self-assessment and self-management of minor conditions, often supported by the advice of pharmacy professionals, was very significant to face an emotionally stressful period of imposed confinement or voluntary self-isolation. Also, to address milder and non-severe cases of SARS-CoV-2, many patients were advised to quarantine and take symptomatic relief using appropriate self-care products.



## Self-care products' shortages are rare and have little to no impact on citizens due to alternatives delivered by a competitive market

Shortages of medicinal products are a growing issue of concern across the Europe and indeed globally, all the more in the context of the COVID-19 pandemic. Medicine shortages are a multi-factorial issue that can have multiple root causes such as manufacturing, final product quality or supply chain issues (1). The pharmaceutical industry, including self-care industry, having person's health as the primary objective, are committed to avoid medicine shortages and, whenever unavoidable, mitigate the effects on end-users in close collaboration with regulators and healthcare professionals.

(1) <https://aesgp.eu/content/uploads/2020/06/Addressing-the-root-causes-of-medicines-shortages-Final-051219.pdf>





Shortages are of particular concern when they affect medicines for which no or limited alternatives are available, and where interruption of supply will result in a potential risk to public health.

**In case of non-prescription medicines, because substitution is possible (e.g. assisted by a pharmacist) and because alternatives exist in most situations (with same or another active principle for the same objective), any shortage of a product will have little to no impact on the outcomes of self-management.** Shortages on over-the-counter (OTC) products are normally only happening under extreme circumstances, as we have seen with the recent pandemic. Due to dual sourcing, in most cases in the past, companies have been able to manage a shortage in supply of a particular ingredient if limited to one country for a limited period of time.

Because of the low risk of shortages in case of non-prescription medicines, only few European countries monitor these proactively (2). For example, in countries where such data is available, like in Belgium, only 1% of the medicine shortages reported to Belgian Medicines Agency correspond to products with non-prescription medicine status. Likewise, in Spain, reported shortages of non-prescription medicines are

under 5% when compared to medicines subject to medical prescription. **AESGP believes that, as general approach, proactive reporting of medicine shortages should be based on a risk assessment from a patient access perspective, because this would be an effective and proportional use of both regulatory and company resources (3).**

Some non-prescription medicines are listed by the World Health Organization in its Model List of Essential Medicines and none saw ruptures of supply of the European market that impeded people from finding a solution to their self-manageable conditions, even in very recent times.

More than 2.000 companies operate in the self-care sector in Europe. There are more than 200 APIs, available without prescription in Europe, and over 4.000 different products containing those. There is a healthy and effective competition among self-care products, with a high number of medicines containing the same active principle. There are also plenty of therapeutic alternatives to treat the same issue, that people and healthcare professionals can choose from. With this range of products available, it is rare that shortages of self-care products would leave an individual without any treatment options.

## **Self-care products have a fit regulatory framework and a resilient global supply chain, planned to face adversity and ensure continuity**

Europeans benefit from access to affordable non-prescription medicines to manage increasing number of ailments. More than 9,5 billion packs of non-prescription medicines were purchased in 2019 alone. Globalisation of the supply chain – a market reality for the entire pharmaceutical sector – is a success story. **Thanks to its strong regulatory framework for non-prescription medicines, Europe has one of the most reliable supply chains in the world.** It benefits from such globalisation as it is home to a number of key global manufacturing sites of non-prescription

medicines which are then supplied to countries around the world as far as Australia.

***Thanks to its strong regulatory framework for non-prescription medicines, Europe has one of the most reliable supply chains in the world.***

(2) Germany

(3) <https://aesgp.eu/content/uploads/2020/06/Addressing-the-root-causes-of-medicines-shortages-Final-051219.pdf>



Shifting the manufacturing and production of non-prescription medicines and Active Pharmaceutical Ingredients (APIs) to Europe as part of the diversification of the supply chain could be considered as a long-term strategic option, but it is simply hardly actionable in the short-term. **There is no evidence of the impact of such measure on OTC medicines shortages and this option should be weighed against the risk of other parts of the world following the same strategy.** The onshoring of entire production lines and manufacturing sites is a lengthy and costly process that, if done in an uncoordinated and precipitated manner, could be detrimental to people's access to the medicinal products they need, including non-prescription medicines, due to manufacturing and supply delays. It could, therefore, have a further negative impact on accessibility and affordability of non-prescription medicines. In addition, a component of manufacturing

would always remain global, as excipients, solvents, and raw materials composing APIs would still be sourced from third countries.

Securing a well-functioning global supply chain of pharmaceuticals should be the primary objective of the European response to address the problem of medicine shortages. **The possibility of importing increases the potential number of suppliers and possibly the access to surplus stocks, too. Protection, however, concentrates risk domestically, reduces the diversity of potential suppliers and diminishes the pressure of competition and economies of scale. Trade agreements or preferential treatment from supplying countries, ring fencing material goods for Europe, will go a long way in avoiding any future disruptions.**

## **In case of exceptional events, unforeseen circumstances can challenge the EU preparedness for supply disruptions**

In the event of national or international crises that impose measures on trade or import/export activities, unpredictably affect the planning of market supply (e.g. production and transport) to EU Member States. Likewise, in the case of unexpected surges in demand, the

request will surpass the planned supply of a given product to a given market for a given period. Furthermore, under extreme circumstances, there can be situations with manufacturing not at full capacity due to limited availability of employees. These situations hap-



pen in the context of exceptional events such as natural disasters, geopolitical conflicts or public health crises (e.g. pandemics).

Supply disruptions or medicine shortages due to exceptional events could occur and have global effect as a result of:

- Sudden loss of infrastructure and/or manufacturing sites (e.g. natural or man-made disasters);
- Lockdowns of manufacturing sites (e.g. need to deep clean) or restricted access to the facilities;
- Availability of essential human resources impacted by disease or travel restrictions;

- Availability of essential material resources impacted by, for instance, travel restrictions;
- Raw material or final product import/export bans;
- Increased demand for specific pharmaceutical products (even medicines for off-label use);
- Emergency stockpiling by individual citizens, healthcare units, or national reserves.

Product scarcity can be felt and reported at any point of the supply chain, without it impacting on the public demand due to the existing stocks on the several stages of the supply chain (industry, wholesalers, pharmacies, other retailers). Careful planning can drive the supply chain stocks according to the needs of the population and making rational and optimal use of logistics.

## The reality of paracetamol availability during COVID-19 pandemic

During the COVID-19 pandemic, the Pharmaceutical Industry was severely impacted the Indian government's restriction measures put in place for a number of Active Pharmaceutical Ingredients (APIs) and medicinal products. The majority of those measures were lifted shortly after, except for the paracetamol API.

India is one of the major global paracetamol API suppliers, therefore these measures, in place from mid-March to the end of May, severely disrupted supply chain of paracetamol in Europe. During this period, and to ensure the continuity of production, affected companies have mobilised their teams and:

- sourced paracetamol API from **alternative sources**,
- adapted and managed their API stocks according to availability,
- have utilised their **security stocks** to meet increasing demand due to the pandemic
- **focused production** of those paracetamol-based products that were highest in demand and deprioritised those less sought.

While we have seen very few shortages of specific paracetamol-containing products, that emerged due to the peak in demand and shift of production within company portfolio, the Industry was capable by and large to avoid a paracetamol shortage and ensure continuity of supply during these challenging times. This case is an example for which there was no need for additional regulation and where industry contingency and continuity plans were sufficient to ensure stocks while diplomatic channels secured the supply chain.

**Leadership and coordinated actions are necessary during exceptional events, including flexibility of all actors involved, to prevent and mitigate supply disruptions within the EU and globally.** The supply interruptions and surge in demand need to be swiftly pinpointed to reverse the potential threat of shortages or to mitigate its impacts. Political and diplomatic action by the European Commission are required and, during COVID-19, these proved to be effective in leveraging measures both within the European Union and at the international level.

