Teva Q&A on security of supply

July 2020

FOR MORE DETAILS, PLEASE REFER TO
TEVA POSITION PAPER ON MEDICINES SHORTAGE

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What is the definition of shortage? Is there a common definition?

In July 2019, EMA and HMA published a guidance for marketing authorisation holders on detecting and reporting medicine shortages. The guidance is based on a harmonised definition of a shortage, as agreed by all national competent authorities and EMA.

The EMA and Heads of Medicines Agencies have agreed on the following definition of a shortage: "a shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level".

Such a definition remains very high level and vague and leaves a lot of flexibility to each Member State to interpret it and apply it in slightly different ways. For this reason, despite the existence of a common definition, in practice, several definitions are used at national level.

It is therefore crucial to make sure that **a single and more comprehensive definition is defined among the EU27** to avoid a fragmentation of the single market and 27 different approaches to tackle medicines shortage.

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Why are medicines shortages happening?

Medicines shortages occur for various reasons

- Cost containment measures
- Lack of market predictability
- Price pressure
- An onerous and rigid regulatory framework

All these factors are challenging access to generic and biosimilar medicines, especially for very old inexpensive essential drugs and putting the sustainability of our sector at stake, ultimately increasing the chances for medicines shortages to occur.

In order to tackle medicines shortages in a sustainable way, it is crucial to look at their root causes, assess them carefully and find concrete solutions for each one of them, by **implementing sustainable economic, regulatory and industrial policy at all levels.**

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What are the root causes of medicines shortages?

Root causes of shortages are numerous. They cover areas such as

- Manufacturing and quality issues
- Economic related issues (e.g., market conditions, unsustainable tender practices and pricing policies)
- Supply chain issues

They are the results of complex supply dynamics involving the Marketing Authorisation Holders (MAHs) but also every other actor of the supply of medicines and APIs (Active Pharmaceuticals Ingredients).

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Is Teva experiencing shortages of its own products?

It does occur that we experience shortages of certain of our medicines. However, **our key focus at Teva is to ensure that patients get access to the right treatments** when they need them. That is why we put in place all necessary actions in order to achieve that goal and mitigate the effects of any potential shortage of products in our portfolio.

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How is Teva getting organized to tackle medicines shortages?

Teva believes that the effective detection, notification and communication of shortages is key to mitigate the potential impact of either temporary or permanent out-of-stocks.

We have, therefore, **specific processes and tools** to ensure that we are adequately preventing or mitigating out-of-stocks. We have also defined which medicines are of strategic importance to health and to Teva and which require specific increased measures to limit potential shortages.

Teva has already a robust organization to monitor and address supply issues.

Teva has set up a Shortages Task Force aiming at:

- **Ensuring full compliance with EU guidelines** for detection, notification, and communication of drug shortages
- **Providing agreed advice to improve internal processes** to avoid drug shortages such as an SOP describing Drug Shortage Management
- **Providing input** for health authorities and policy makers

The Task Force has reviewed each of the key processes to better manage and anticipate out-of-stocks and for each of them has identified **several concrete actions that were put in place**

From a manufacturing point of view, Teva performs risk assessment and manufacturing optimization initiatives for critical medicines (e.g., site transfers)

From a regulatory point of view, Teva is already engaged in reducing drug shortages by a variety of regulatory mitigating actions. The interactions with authorities can be a deciding factor and the response time and requirements can have an impact on the availability of alternative products (e.g., importation, repackaging, alternative dossier registration), hence the importance to have permanent regulatory flexibilities and optimization measures

From a supply chain point of view, Teva monitors market dynamics (e.g., use of artificial intelligence), assesses and adapts demand forecast in relation to priority medicines (e.g., prioritization of shipping)

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Are medicines shortages handled at national or European level? What is the best option?

We are currently observing the development of national plans and legislations which will fraction the European market and make it more complicated for the industry and other concerned stakeholders of the supply chain to mitigate and prevent shortages.

In some countries, Marketing Authorisation Holders (MAHs) are being asked to face disproportionate, impractical, unrealistic and too broad measures like stockpiling and penalties. Such requirements only lead to more complexity, increasing risk of supply disruption rather than addressing root causes of shortages and rewarding security of supply.

As one company alone cannot tackle the complexity of the underlying factors responsible for shortages, **we welcome pan-European led initiatives which reflect the way the pharmaceutical company supply chain is organised and the need to preserve the integrity of the single market.** These pan-European initiatives should address, constructively and genuinely, the complexity of the multi-dimensional challenges posed by shortages of medicinal products.

Teva believes that the most sustainable way to address shortages is to set up **a pan-European coordination with all concerned stakeholders to ensure:**

- harmonisation and monitoring of shortages
- addressing their multiple root causes to prevent them
- supporting the industry to mitigate shortages when they occur

In this context, we also believe that **a single pan-European harmonised notification and reporting system, focusing on the pan-European critical list of products,** covering both Centralised and National Marketing Authorisations, would be beneficial in the handling of medicines shortage. **Harmonised definitions at pan-European level** are also needed for the same reasons.

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Some countries decide to stockpile medicines and to apply sanctions in case of failure to supply. Is that the right approach? Why?

Teva strongly opposes those types of short-term and quick fix measures, and calls on the policy makers, regulators, industry and relevant stakeholders of the pharmaceutical supply chain to **tackle the root causes, moving from mitigating to preventing shortages from happening.**

Teva strongly encourages member states to revisit any plan to introduce or implement mandatory stockpiling and unproportioned penalties associated to a national critical medicines list.

Indeed, extra stockpiling raises several questions and concerns among which:

The lack of proportionality of the stockpiling requirement (e.g., French and Dutch current requirements) and penalties (e.g., French new provisions) which are not adapted to the multi causal context and the root causes of shortages

The scope is too broad and not adapted to the criticality of products concerned (e.g., French and Dutch current requirements), making the stockpiling requirement impracticable (as regards to already limited stock capacities and/or specific storage conditions) or leading to waste (e.g., products with short shelf life and/or difficult storage conditions)

Unrealistic implementation timelines and requirements (e.g., industry has limited manufacturing capacity which cannot be changed overnight)

Extreme stockpiling requirement (e.g., France / The Netherlands) could also **impact availability of the concerned medicines in other European markets,** moving stocks from one market to the other to comply with the requirements, hence potentially paving the way for additional shortages

As a result, companies will assess the complexity, risk and the cost of supplying the market and may decide to withdraw the products from certain markets in case of economic risks, which may ultimately worsen the out-of-stock situation.

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What can be done to prevent medicines shortages from happening ?

There are several measures that could be taken in order to prevent medicines shortages:

Optimize the EU Regulatory Framework via digital tools

Enhancing regulatory cost efficiency and fit-for-purpose regulatory measures, can be achieved by **making the most of the telematics tools at pan-European level.** These tools, while providing the same high regulatory standards, can reduce the administrative cost to perform basic regulatory administrative work for the industry but also for the regulators. It will foster greater economic resilience and therefore, provide accessibility to affordable medicines.

On variations more specifically, Teva calls for the **targeted amendment of the EC Variations Regulations 1234/2008 and Variations Classification Guideline to be considered as soon as possible** to modernize the current variations system and to reflect the evolution in technology and regulatory needs. This will ensure smoother and faster processes which will help to mitigate and prevent medicines shortages.

Support Market Conditions that reward security of supply

The European Union and member states need to put the right economic framework in place which **rewards investments in medicines quality and security of supply.**

At a national level, we encourage authorities to ensure predictable pricing and reimbursement policies, setting up "stability" pacts with the generic and biosimilar industry, allowing to find common ground on the need to sustain the healthcare system and providing incentives to sustain essential medicines, also by promoting measures to increase the uptake of generic and biosimilar medicines.

At the EU level, in the context of the existing EU Procurement Directive, **we call on the Commission to specifically look at developing guidance to best implement the MEAT** (Most Economic Advantageous Criteria) **criteria for pharmaceutical products** for the market where tender practices are used.

In this context, it is important to:

- adjust the number of tender winners according to the market, product and country characteristics
- use lead times that guarantee a steady supply of medicines and
- reward investments increasing the supply chain robustness and therefore security of supply (for example, multiple API sources - currently, registering an alternative source of API can take up to 12 months as part of security of supply)

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What can be done to mitigate medicines shortages once they occur?

In the context of the Covid-19 crisis, **the European Commission is advising to implement regulatory flexibility covering procedures for stock transfer, changes in suppliers of APIs** (e.g., the designation of new manufacturing sites).

In the same spirit, **we believe it would be beneficial to mitigate medicines shortages to have more permanent regulatory flexibilities to be applicable for MAHs** (see more details on the individual regulatory measures in our position paper).

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What are the key learnings from the Covid-19 health crisis in terms of tackling medicines shortages?

The management of the Covid-19 crisis showed that manufacturers had contingency plans in place avoiding any major disruption for critical products.

It also showed that national hoarding and stockpiling undermine the industry's ability to deliver equitable supply in all markets.

This has been recognised in the context of the European Commission Guidance on Optimisation of Supply of Medicines published on April 8th and presented by Mrs. von der Leyen.

The Guidelines clearly stipulate that "Stockpiling practices in anticipation of possible shortages can further contribute to the actual appearance of such shortages" and are calling to avoid national stockpiling.

Through Covid-19, it has become clear that **EU and national coordination to ensure equitable supply of medicines is important,** and avoiding shortages requires dialogue, demand visibility and close cooperation between governments/ regulators and all actors.

Following the Covid-19 health crisis, **Europe will have to face an economic crisis** which will challenge even further access to medicines.

Therefore, in order to ensure access and sustainability of healthcare systems in the long term, **it is crucial to maintain a concrete action-oriented dialogue with the industry and relevant healthcare supply chain stakeholders.**

In this context, Teva is therefore calling for all concerned stakeholders to join **a focused, action-oriented High Level Pharmaceutical Forum led by the European Commission** and involving Ministers of Health and policy makers, regulators, payers, industry and other concerned stakeholders of the Healthcare supply chain.

The key objective would be to share the learnings from the Covid-19 situation and draw the conclusions to establish a pan-European and effective policy framework to prevent shortages in the long term and ensure a well-functioning, sustainable and competitive industry that continues to act as a catalyst to enable sustainable and equitable access to medicines for patients.