



The pharmaceutical supply chain

Current issues and proposed solutions



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5.1.2e

Outline

1. EFCG: who we are and who do we represent
2. Fine chemicals and APIs in Europe
3. The pharmaceutical value chain
4. Drug shortages: root causes and some practical examples
5. Our proposal

EFCG is the voice of the European Fine Chemicals Manufacturers

Our membership:

- **71 member companies** together with our sister association APIC
- **4 national associations**
- **Over 300 fine chemical sites across Europe**
- Membership includes both SMEs and larger companies
- 7 production facilities in the Netherlands



The pharmaceutical value chain is complex



- More than two-thirds* of raw materials and registered started materials for generic pharmaceuticals are currently sourced from Asia.
- One RSM producer can supply several API manufacturers and dozens of different Finished Dosage Form manufacturers
- Most of the processes offshored to Asia are old-generation processes with high environmental impact.

* in volume

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Our members mainly produce the essential **regulated** components of medicines

Registered starting materials



Active Ingredients



Finished Dosage Form



Non Registered starting materials

Inactive Ingredients

European manufacturers are recognized as best in class by US FDA*

- European API producers comply with the highest quality standards and strictest regulations issued by the US FDA and European Medicines Agency (EMA).
- Important investments on equipment and production facilities are required in order for the API manufacturer to optimise production efficiency and yield.
- The European API producers are essential suppliers both for **Innovator** and **Generic Medicines**.



* Testimonial of US FDA 5.1.2e before the US House of Representatives, December 10th, 2019

Drug Shortages: structural causes

Supply Chain issues play a major role in the unavailability of pharmaceutical products:

- **Massive offshoring** of API production and RSMs in the last decade, leaving the EU totally dependent on China for starting materials and APIs, and India for APIs and finished drugs
- Unexpected closures of several production units in China - due to either **serious accidents** or the enforcement of **new environmental laws** – causing severe, unpredictable shortages
- **Procedural delays** in the implementation of changes and improvements to processes
- In case of global shortage, availability of medicines in the EU will be further restricted as we have witnessed during the Covid-19 crisis:
 - Restricted movement of factory workers (e.g. China)
 - Export bans on pharmaceutical products (e.g. India)
 - Export bans and stockpiling within EU member states

US and EU are dependent on China and India for close to 80% of their generic medicinal products.

US and EU API manufacturers have adjusted their capacities, either becoming an alternative source or simply discontinuing

Unpredictability of Supply Chain issue is a major root cause of shortages

Impressive series of Accidents at Chemical Plants.

Example: China

- **3974** Accidents involving Hazardous Chemicals in China between 2006-2017 (*)
- On average 1 accident every day, **1 death every day in 12 years** (*)
- 12 Major accidents in 2019: March 2019, Jiangsu Chemical Explosion, 78 people killed and hundred injured

Stepping up Enforcement on safety & Environment

- 40% of factories were forced to shut down between 2015-2017
- Jiangsu provincial government has a plan **to close 7000 chemical** facilities within 18 months
- **“Domino effect”** where some plants in the same Industrial Park can be closed down without any specific reason

Source:

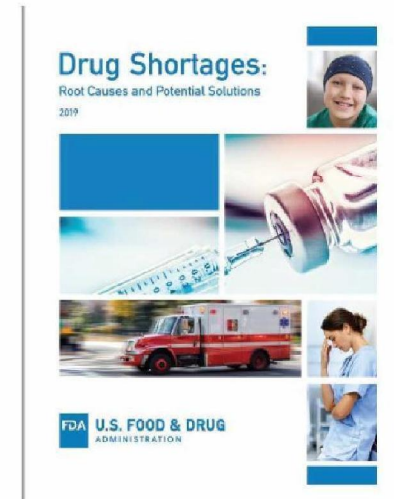
(*) Sustainability 2018, 10, 2935

(**) Navigation the Aftermath of the Jiangsu Chemical Plant Explosion, www.ChinaBusinessReview.com

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Shortages are a global phenomenon

- In the US, the FDA has issued in November 2019 a comprehensive report on the root causes of current drug shortages and recommendations. Since the pandemic, the US multiplied initiatives aiming to ensure US self-reliance.
- In some EU countries where the shortage of critical generic medicines was most acute, national authorities have started working with the pharma supply chain to find root causes and solutions well before the pandemic, stepping up the cooperation during the last two months.



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EFCG proposal to prevent further shortages

1. **Set up a fast-track approval for alternate RSMs:** this will allow quick action in case of future unforeseen events – global pandemics, natural disasters, quality-motivated recalls or closure of some overseas production facilities to name but a few.
 - On this topic, the EMA has issued a temporary guidance on regulatory flexibility to mitigate shortages created by the Covid-19 pandemic
 - We need measures in the future that allow flexibility without any compromise on quality and traceability

2. **Encourage the central role of the EMA** and promote better coordination communication between Member States health authorities on shortages.
 - Updating a registry of critical medicines
 - Maintaining an updated database of shortages

3. **Implement a five to ten-year plan to:**
 - Ensure EU production of critical raw materials and APIs.
 - Invest into **sustainable** technologies produced in Europe, with the aim to reduce the EU's dependency on overseas supplies
 - Promote the **competitiveness** of the EU manufacturing companies
 - Encourage global players to apply the **EU quality and sustainability standards**

EFCG contribution

1. Raising awareness of the issue and its root causes along the supply chain
2. Making an inventory of existing production capabilities in the EU – active or that can be reactivated. This includes an updated set of global market statistics
3. Building an inventory of all critical technologies that can be reshored, linking them to the critical medicines identified by EMA
4. Identifying hurdles to reshoring and the technological upgrades needed in order to bring processes up to EU environmental standards.

Our EU-based member companies have the existing production facilities, the critical know-how, a highly qualified manpower and the highest quality standards.

With the right support, we **CAN** and we **WILL** actively contribute to building a **resilient and sustainable EU-based pharmaceutical supply chain**