SUPPLY CHAIN

UNDERSTANDING THE IMPACT OF THE EU PHARMACEUTICAL LEGISLATION REVISION

As a biopharmaceutical leader in research, development, and manufacturing of innovative therapies and biosimilars, ensuring a reliable supply of medicines to patients is essential to Amgen's mission to serve patients. Irregularities in the medicine supply chain can have a significant impact on patients and healthcare providers.

The current EU pharmaceutical legislation directly affects the manufacturing, quality, supply of medicines, as well as their environmental impact.

We hope that the upcoming revision of the general pharmaceutical legislation will:

- **SUPPORT GLOBAL TRADE** for a reliable supply without enforcing local manufacturing
- **ENCOURAGE HOLISTIC SUPPLY CHAIN MANAGEMENT** to be proactive & preventive
- **GIVE AUTONOMY TO ALL ACTORS THROUGHOUT THE SUPPLY CHAIN** according to their responsibility
- **HARMONISE REQUIREMENTS ACROSS MEMBER STATES** to promote equal access and resilience without additional import testing

AMGEN'S SUPPLY CHAIN

RELIABLE, AGILE AND GLOBAL

Amgen has a track record of maintaining a reliable supply chain by identifying, preventing and managing risks holistically. We continue to supply >25[1] products around the clock under the current legislation.

>10
STORAGE LOCATIONS ACROSS EUROPE
including warehouses and logistics service providers

A RESILIENT NETWORK
of own and contract manufacturing plants across the world

100 M. EUR
Invested to upgrade our manufacturing facility in Ireland[3]

ROBUST SUPPLY CHAINS: KEY TO PREVENTING SHORTAGES

Ensuring a secure and proactive global supply chain for medicines is essential to provide consistent access for patients. Current EU regulation sets out strict requirements to monitor quality, to trace medicines throughout their production & distribution, and to prevent shortages. However, these may make operations less agile. Rigid requirements could inhibit quick responses & the ability to anticipate, which ensure supply in a changing market.

REDUCE DUPLICATE QUALITY CHECKS

Most medicines coming from outside the EU are subject to additional quality analysis before going to market, even when it disrupts supply & they are from trusted sources.

GIVE AUTHORITY TO LOCAL MANUFACTURING SITES, LABS & STORAGE AREAS

Facilities already have comprehensive inspections in place, but have limited autonomy as they must be open to inspections from different authorities at all times.

SHARE KNOWLEDGE ACROSS THE WORLD

Everyone involved must be fully qualified to manufacture and distribute medicines but there is a very limited exchange of knowledge among different parties* throughout the supply chain.

HOW LEGISLATION CAN IMPROVE MANUFACTURING, QUALITY, ENVIRONMENT & SUPPLY

Ensuring reliable access of medicines for patients is key, driven by an end-to-end supply chain. Suppliers, manufacturers and distributors are able to identify, prevent and respond quickly to any risk. Therefore it is important that EU pharmaceutical legislation enables and enforces all actors in the supply chain to take responsibility to reduce the risk of shortage.

KEY CONSIDERATIONS FOR THE REVISION OF THE EU PHARMACEUTICAL LEGISLATION

1 ALLOWING PROACTIVE MANAGEMENT OF INFRASTRUCTURE, STOCK & BUSINESS

Legislation should enable suppliers to use transparent risk management by limiting administrative burdens on people responsible for bringing treatments to patients, (e.g., manufacturers and Marketing Authorization Holders MAH).

2 UPDATING REGULATORY EXPECTATIONS ALLOWING APPROPRIATE AND RISK-BASED MANUFACTURING, QUALITY CONTROL, & SUPPLY

Including feasible reporting requirements, as applicable. Eliminate inspections of imported medicines when received from trusted regions to allow delivering medicines to patients faster. EU regulation should account for reliance (e.g., on PIC/S participating authorities) based on a necessary balance of risk and flexibility needed to provide continuous supply and to allow patients access to new medicines.

3 LINKING EU PHARMACEUTICAL REQUIREMENTS TO EXISTING LEGISLATION IS CRUCIAL

High environmental standards are already met throughout the medicine lifecycle (e.g., required waste treatments, REACH)[3]. To support competitiveness, innovation and sustainability in medicine production, the pharmaceutical legislation update must align itself with existing policy.

4 HARMONISING EXPECTATIONS ACROSS ALL EU MEMBER STATES TO PROMOTE EQUAL ACCESS

Under the current regulation, Member States can impose additional restrictions also on suppliers, leading to unequal access across countries. We call on the EU institutions to collaborate and provide guidance by supporting Member States to harmonise and standardise requirements applicable across the Union, as well as to monitor Member State performance. We are seeing a more complicated supply chain with uncertainties resulting in a higher risk of shortages even if financial ownership is fully transparent within the same holding.

For more information, contact Nicholas Cosenza
Senior Manager, External Access Engagement European Union Government Affairs at ncosenza@amgen.com

AMGEN®

1. Amgen Products, Amgen, accessed 24 May 2022, https://www.amgen.com/products
2. Fierce Pharma, Dec 21, 2021, Accessed 19 September 2022, https://www.fiercepharma.com/manufacturing/amgen-to-spend-100m-to-build-new-vial-filling-line-at-dublin-site-source
3. Environmental Sustainability, Amgen, accessed 24 May 2022, https://www.amgen.com/responsibility/healthy-planet/environmental-sustainability/sustainable-by-design/product-sustainability

*Agents, brokers, distributors, re-packagers, re-labellers, parallel trades, hospital groups, government warehouses etc.