EU Consultation: Pharmaceuticals – safe and affordable medicines (new EU strategy)

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The COVID-19 pandemic has shown how reliant the EU is on third countries when it comes to pharmaceuticals. However, the pandemic has also shown that the Commission can identify processes to simplify or fast-track methodologies for regulations without compromising compliance, most especially when it comes to mitigating medicines shortages and to ensure efficient distribution of medicines within the Member States. In the light of these recent developments, the Commission has already stated their determination to launch an initiative to “repatriate pharmaceuticals”. As such, Fecc acknowledges the steps the Commission has taken so far in order to support the industry and encourages the EU Institutions to move further in this direction.

Fecc looks forward for this support to continue and expand post COVID-19. This would alleviate the regulatory burden significantly, especially for the SMEs which are suffering a lot from regulatory complexity, combined with substantial resource constraints, while not compromising the EU’s health, safety and environmental standards.

Supporting the industry is paramount to ensure medicine affordability, safety, and availability within the region. The EU and other national governments are currently offering a lot of regulatory and financial support for pharmaceutical stakeholders when it comes to research and development. However, support from the sector must include a wider part of the supply chain. A main issue for the European pharmaceutical sector is the cost to the manufacturer due to overlapping regulations. Fecc requests the Commission to consider the effects of these overlaps on the level playing field in the pharmaceutical industry, most especially for the SMEs.

The EU expects high-quality medicines from its local manufacturers and the same should be expected from all third countries that conduct trade with the EU. Fecc calls for the Commission to increase monitoring and stricter enforcement when it comes to trade and imports of pharmaceuticals.

Pharmaceutical quality (safety) and quantity (availability) must go hand-in-hand and without these considerations, the Commission may find it challenging to ensure that the EU pharmaceutical industry remains competitive. Through this new EU Pharmaceutical strategy, collaborations between the industry, academia and public bodies could be developed further in support of the EU Pharmaceutical sector and neighbouring value chains. We would be happy to engage further with all regulators in the pursuit of sustainable, future-oriented solutions in this area.

To access the Fecc's response on the EU Commission's website, please click here.