

## Open Strategic Autonomy<sup>1</sup> in pharma – how can we ensure security of supply for patients?

### Executive summary

Europe has taken several measures to prevent shortages of medicines. These include improving transparency in the supply chain, strengthening cooperation between Member States and regulatory agencies, and setting up monitoring mechanisms to identify and anticipate shortages. In addition, the European Union encourages manufacturers to diversify their sources of supply and implement risk management plans. These initiatives aim to ensure a stable supply and protect patients' health. Novartis supports all EU initiatives but alerts on the need to differentiate between causes of shortages.

### Shortages and their multiple root causes

Shortages can be very detrimental to patients. As a company we do everything in our power to mitigate risks and make sure the products reach patients when they need it, and where they need it. Root causes of shortages range from manufacturing and quality problems, such as a contamination of a clean room or the breakdown of a bioreactor, to distribution issues that can include difficulty sourcing active pharmaceutical ingredients and replacement parts for production machinery, or transport disruptions. Natural disasters, strikes, unexpected fluctuations in demand, political sanctions or other geopolitical developments can all have an impact on the supply chain. Covid-19 has shown how resilient our supply chains can be, but also the risk of being dependent on certain regions or countries.

### Resilience of medicines supply chains

As a company, we are closely monitoring the resilience of our supply chains, having a comprehensive process in place to identify, analyse and address risks to ensure business continuity and prevent shortages. Where possible, we make sure to have multiple sourcing to diversify risks from certain regions. We also establish strategic inventories to cover for unpredicted events, so that in case of increased demand, we still have sufficient supply. The following steps form an integral part of our supply risk management:



Diversification of supply chain



Shortage prevention/  
mitigation plans



Safety stocks



Demand forecast

### Is “Made in Europe” the solution?

With the aim of reaching economic and health security, European policymakers are considering localization measures, by promoting European manufacturing and hence reaching (open) strategic autonomy. While autonomy is an important goal, we know that it is not possible to produce everything in Europe, due to natural resources and capacity, which is why an open network of supply partners is crucial to reinforce agility in case one source fails. Localization measures do not necessarily secure the supply for European patients, as quality and manufacturing issues could happen in any region. As Novartis, we therefore support the diversification / multiple sourcing when possible and international partnerships, rather than localization.

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<sup>1</sup> Open Strategic Autonomy is a concept developed by the EU that aims to strengthen the EU's ability to act independently while remaining open to international cooperation. It is a balance between strategic autonomy, which involves reducing dependence on certain partners or supply chains, and openness to trade and collaboration with other countries and regions. This concept applies to various areas, including security, defense, economy and technology as well as healthcare. The idea is to enable Europe to protect its interests while engaging in global partnerships, thus promoting the resilience and sustainability of European systems. This includes initiatives to strengthen research, innovation and local production, while maintaining constructive relationships with other actors on the global stage.

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### **Ensuring the competitiveness of our industry**

In the current geopolitical context, it is important that Europe remains competitive, by supporting its industry. The biotech and pharmaceutical sectors are key to ensure that European patients have access to the most innovative treatments, to improve health and wellbeing of citizens. A robust intellectual property and regulatory framework are at the base of an attractive ecosystem, as well as public and private funding in early research. Other regions have recently introduced incentives for companies to conduct research and clinical trials locally, and Europe should do the same if it does not want to be left behind. The risk of not prioritizing healthcare amongst other sectors will lead for Europe to become a buyer of innovation, instead of a leader.

### **Access and availability for patients**

Medicines have no value if they do not reach patients across the continent. The absorption of innovation by member states is therefore key. Investing in people's health is not only beneficial for patients and their families, but also for healthcare systems and society as a whole. We are committed to working in partnership with EU institutions and member states to find constructive solutions that will accelerate access to life-saving medicines for EU patients.

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