

## **From vaccines shortages to sustainable vaccine supply Vaccines Europe Position**

Europe has been a long-standing leader in vaccines. Maintaining this position and ensuring vaccine availability in times of increased demand and supply constraints can only be achieved by a strong industry operating in a stable environment, able to produce vaccines of the highest quality and to innovate to meet future vaccine needs.

Supply and demand sides need to be in balance to ensure a healthy vaccine ecosystem. An ecosystem that recognises the strategic value of the EU vaccine industry in providing prevention against communicable diseases, that ensures the long-term financing of vaccination programmes, that measures the public health outcomes, and that fosters sustainable supply.

Today, the vaccines sector faces unique challenges that raise fundamental sustainability questions. Shortages of medicines, including vaccines are of increasing concern in the EU and globally. The causes are multiple. Finding solutions requires a concerted effort by all key stakeholders.

Vaccines Europe is contributing to finding solutions to this situation. Its member companies are committed to the public health needs of European citizens and citizens of the world. Vaccines Europe calls for the establishment of a European multi-stakeholders platform as put forward by the EU council conclusions on “Vaccination as an effective tool in public health” of December 2014 to enable all key stakeholders to determine how best to mitigate supply issues and to prioritise solutions to improve the sustained vaccines availability for Europe and beyond.

### **What are the supply constraints and why is it difficult to quickly adapt to variable demand?**

The main challenges which are unique to vaccine supply include:

- Increased often unpredictable global demand coupled with challenges to vaccine manufacturers to ensure continuous supply means that disruptions of certain antigens can occur
- It is difficult to respond in the short term to unexpected vaccine shortages due to the complex manufacturing and testing requirements which involve long lead times for vaccine manufacture. Additionally, between 5 to 10 years would be needed to build and license a new facility
- Vaccines are highly technical biological products with complex and lengthy manufacturing, control and release processes. Cycle times can average up to two years or more, with quality control tests representing 70 percent of that time. Unlike the vast majority of the pharmaceutical industry, control testing of each vaccine batch of a vaccine may still include in-vivo methods (animal testing) with their inherent variability and related risks, compounded by the dual (or multiple) batch release testing performed by health authorities
- Increasing and diverse regulatory requirements in Europe and worldwide, notably for post approval changes, lead to significant difficulties in planning and production (including a requirement to continue production of multiple versions of the same product during the change approval period that can take up to 48 months internationally). These constraints significantly reduce supply flexibility in terms of products that can be supplied to specific countries. They also increase lead times that impact vaccine availability for populations
- Diversity of country specific product and packaging requirements creates inefficiencies.
- Uncertain demand coupled with inflexible purchasing mechanisms prevent manufacturers from reacting swiftly when vaccines are scarce; and defeat efforts to more accurately predict demand and plan accordingly
- Lack of dialogue to anticipate national immunisation program plans and implementation

## **What are manufacturers currently doing to improve the situation?**

- Vaccines manufacturers are improving internal processes to increase and optimise capacity. This can include the expansion of existing facilities, optimising production processes or establishment of new production facilities
- Vaccines manufacturers are doing their best logistically to manage the country specific product and packaging requirements and post-approval complexity to avoid supply disruptions.
- Vaccines manufacturers engage actively with pan-European and national authorities on early notification of potential supply disruptions in order to facilitate an appropriate response and mitigation
- Vaccines manufacturers are engaged in an active dialogue with Health Authorities to improve the security of supply

## **Why is Vaccines Europe calling for a European multi-stakeholder platform dedicated to improving vaccines supply sustainability?**

Supply disruptions could be mitigated by ensuring an open dialogue involving all key stakeholders, including European authorities/agencies, scientific experts and vaccine manufacturers to foster a better understanding of the challenges facing the sector and to collectively craft solutions to achieve more sustainable supply conditions for the benefit of public health. As a matter of urgency, the Platform should address ways in which to:

- Reduce duplicate testing and work towards the elimination of animal testing by facilitating faster regulatory adaptation and better scientific collaboration to enable the modernization of control techniques by health authorities in line with Directive 2010/63/EU revising Directive 86/609/EEC on the protection of animals used for scientific purposes adopted on 22 September 2010
- Reduce the number of specific national /regional product and packaging requirements in order to streamline vaccine manufacturing and to optimize existing capacity thereby increasing supply
- Facilitate the transfer of vaccines between EU countries in order to re-allocate vaccines in case of shortages in specific countries
- Harmonise regulatory requirements across countries and regions and, in particular, focus on reducing the lead time for post-approval changes based on science and risk based approach, since this currently is a major supply chain bottleneck
- Work towards mutual recognition for post authorization change approvals by recognized stringent regulatory authorities. This would eliminate the need to maintain in parallel different manufacturing processes for the same product whilst a change is approved by authorities as is the case today. This will help to maximize existing industrial capacities, enhance flexibility and thus increase their supply
- Clarify the obligations related to the notification of shortages to competent authorities in Europe, harmonise the definition of shortages and improve efficiencies through coordination of audit requirements and standards
- When supply is constrained, to ensure the continuity of the programme, encourage the creation of temporary vaccination calendars with the identification of priority groups at Pan-EU and/or national level where necessary
- Introduce more appropriate and flexible purchasing mechanisms and terms which would enable manufacturers to better anticipate and meet public health needs, support sustainable supply (e.g., longer lead times, longer contract duration, split tenders...).
- As multiple supply-chain stakeholders (manufacturers, wholesalers, health care professionals...) are involved in the distribution and administration of vaccines, seek ways to ensure the needs of priority groups are met during periods of constrained supply
- Instigate an early and continuous dialogue between manufacturers and public health authorities that allows both sides to better anticipate the evolution of vaccine recommendations and more accurately forecast vaccine demand

Proper consideration of these proposals will improve sustainability and flexibility of vaccine supply. It should also reduce the need for stockpiling options that might create imbalances and access inequities across Europe.