Vaccines Europe reflections on enhancing supply chain resilience

■ EXECUTIVE SUMMARY

Vaccines Europe is committed to fostering a dialogue towards feasible and sustainable EU-targeted efforts to enhance vaccine supply chain resilience and mitigate shortages in EU Member States while strengthening the vaccine manufacturing footprint in Europe. This paper outlines key vulnerabilities in the vaccine supply chain, approaches employed by vaccine manufacturers to address them and future strategies to strengthen vaccine supply chain resiliency.

Main causes of vulnerabilities in vaccine supply chains:

- Complexities of vaccine development, manufacturing and release processes;
- Packaging complexities in EU limiting supply chain flexibility and potentially hampering access to Member States;
- Challenges in accurate short- and long-term demand forecasting (1-5 years) due to limited dialogue between manufacturers and health authorities regarding the evolution of vaccine recommendations and inclusion into National Immunisation Programs (NIPs);
- Limited global suppliers of several raw materials for vaccines manufacturing;
- External factors outside manufacturers' control, including environmental, geopolitical, policy-related, economic, regulatory and tender-practice related factors.

How are manufacturers addressing issues disrupting vaccine supply chain resilience

Manufacturers are committed to maintaining the supply of vaccines to the community and are therefore implementing when appropriate and feasible a series of measures to reduce potential supply disruptions under their responsibilities, such as:

- Development of shortage prevention plans;
- Diversifying the location of key suppliers;
- Utilising multiple sources for raw materials;
- The number of raw materials and quality control steps required, along with long manufacturing lead times and sterile production requirements are issues which are dealt with at a manufacturer level.

How regulators and policymakers can enhance measures being implemented by vaccine manufactures to ensure vaccine supply chain resiliency:

1. Improve **demand forecast transparency** by maintaining a continuous dialogue between manufacturers and health authorities;
2. Implement successful strategies from the COVID-19 pandemic during non-pandemic periods to reduce delivery times of vaccines to communities (e.g., removing export restrictions for raw materials and vaccines, harmonising global regulatory standards and improving the sharing of epidemiological data).
3. Encourage **stakeholder collaboration** to:
   a. create synergies for deep understanding of the end-to-end vaccine production process
   b. avoid delays and duplication of work
   c. shape future activities in an agile way;
4. Reduce packaging complexities by adopting a common EU packaging and replacing the paper patient information leaflet with an electronic version (ePIL);
5. Invest in a **highly skilled** vaccines manufacturing, supply chain and regulatory evaluation **workforce.**

INTRODUCTION

The underlying principle of vaccine supply chain resilience is that the design of supply chain systems should ensure their capacity to recover critical functions when significant disruptions occur (1). This resilience is based on robust and agile global supply chains. To survive large-scale disruptions, such as geopolitical conflicts, global health threats and catastrophes caused by climate change, a thorough understanding of key vulnerabilities in the supply chain is crucial, alongside the ability to respond with flexibility and agility. **Vaccines Europe is committed to fostering a dialogue towards feasible and sustainable EU-targeted efforts to enhance global vaccine supply chain resilience, mitigate shortages in EU Member States and strengthen the vaccine manufacturing footprint in Europe.**

MAIN CAUSES OF VULNERABILITIES IN VACCINE SUPPLY CHAINS

Vaccines are subject to specific development steps (2), procurement rules (3), manufacturing (4) and testing processes, internal and external national regulatory authority batch release processes and stock requirements (5).

Vaccines are often highly technical, complex biological products with long production lead times owing to the variability in starting materials, and stringent requirements for culture conditions and purification processes. In general, the production lead time for many vaccines is greater than 1 year (from 12 to over 36 months). The production lead times for COVID-19 vaccines were shorter under pandemic conditions (3.5–6 months for viral vector and 2.5–5.5 months for mRNA vaccines) (6). While good manufacturing practices are mandatory, the complexities and strict requirements of daily performance can impact the vaccine supply chain at any time. For example, a manufacturing plant may require materials sourced from some 300 suppliers across 30 countries to produce one vaccine, which involves procuring adequate supplies of more than 100 different critical components (7). Additionally, current paediatric combination vaccines require more than 1200 routine testing controls per batch released. Key differences between vaccines and therapeutics are further summarised in **Appendix Table 1**.

Typically, the total time required to design, build, validate, acquire regulatory approvals and start commercial manufacturing and distribution of a new vaccine takes between 5 and 10 years (5). In times of increased demand, manufacturing capacity cannot be increased quickly owing to the need for unique manufacturing processes and custom-built facilities (5). Validation of new equipment and demonstrating product quality are also required for regulatory accreditation of a new facility.

Packaging complexities

Vaccine packs and leaflets must be produced in different languages, limiting supply chain flexibility and potentially hampering access to EU Member States (5). To reduce pack size and facilitate storage, multi-lingual packs are also limited to a maximum of three languages. As a result, it is estimated that at least 14 different packs are needed for a single presentation of a centrally approved vaccine to cover all EU/EEA countries (5). Therefore, manufacturers need to cluster production based on the country of destination and logistical considerations.

Vaccine supply chains are subject to intrinsic short-term and long-term demand volatility

Lack of transparency in any part of the supply chain can increase the risk of supply shortages, as demonstrated by the COVID-19 crisis (8). Unpredictable global vaccine demand and the absence of early and continuous dialogue between manufacturers and health authorities to anticipate vaccine recommendations and forecast demand significantly contribute to vaccine supply shortages. Some National Immunisation Technical Advisory Groups (NITAGs), such as the UK Joint Committee on Vaccination and Immunisation, conduct horizon scanning to inform policy development, expedite regulatory processes and simplify purchase and supply agreements

followed by deployment at scale to the patient population (9). Many EU countries do not have such mechanisms in place and could therefore benefit by adopting a similar approach to horizon scanning.

External factors outside manufacturers' control also contribute to supply shortages, including:

- **Environmental factors** (e.g., natural disasters, pandemics and epidemics)
- **Geopolitical factors** (e.g., conflicts and trade restrictions)
- **Economic factors** (e.g., demand shocks associated with sudden political or economic changes)
- **Technological factors** (e.g., management platforms for harmonisation of global supply chain)
- **Regulatory factors** (health authority requirements for redundant quality control testing)
    - Several countries perform additional quality testing on vaccine batches which is time-consuming and redundant owing to the stringent quality assurance processes performed by manufacturers. Redundant local testing can reduce the remaining shelf life of a vaccine, potentially resulting in the discarding of expired doses.
- **Tender practices** ('One winner takes it all' practices, meaning that all vaccine doses are purchased from a single supplier)

Further details are provided in **Appendix Table 2**.

HOW DO WE ADDRESS ISSUES DISRUPTING VACCINE SUPPLY CHAIN RESILIENCE?

Manufacturers are committed to maintaining the supply of vaccines to the community and are therefore implementing a series of measures to reduce potential supply disruptions, when possible and appropriate.

Potential issues at the manufacturer level that contribute to vulnerabilities in supply chains include the number of raw materials and quality control steps required, long manufacturing lead times and sterile production requirements. Vaccine manufacturers have multiple mitigation plans in place to deal with these threats, including:

1. **Quality systems:** include following good manufacturing practices, providing adequate training to staff, employing qualified personnel and the validation steps required for new equipment and facilities;
2. **Proactive risk management (multi-sourcing):** involves vaccine manufacturers using multiple sources for raw materials wherever possible to ensure that alternative sources are immediately available should a particular supplier be unable to meet the demand;
3. **Supply continuity plans:** strategies to ensure that the delivery of products will be maintained at acceptable levels following a disruption, including modalities of sourcing raw materials should usual suppliers not be an option;
4. **Fit-for-purpose shortage prevention plans:** a risk management process developed by manufacturers focussing on their manufacturing capabilities, sourcing of raw materials, market trends, marketing activities and the supply of products. This involves identifying any vulnerabilities in the supply chain or risks of an interruption in supply for patients;
5. **Updated business contingency plans:** action plans to help organizations resume normal business operations after unintended interruptions, including threats such as natural disasters, data loss, network breaches and sudden shifts in customer demand.
6. **Diversity of geographical locations of key suppliers:** ensures that manufacturers are not reliant on supplies in the same country/region should disruptions occur (e.g. environmental or political).
7. **Inventory management:** systems designed to monitor stock levels and order demands

Regulators and policymakers can help enable strategies already being employed by vaccine manufacturers and ensure any future policy solutions are proportionate to the risk, carefully considering unintended effects and backed by strong evidence on the nature of shortages.

Key strategies that can help achieve this are outlined below.

1. Improving demand forecast transparency

Mechanisms for an early and continuous dialogue between manufacturers and health authorities at all levels – European, national and regional – must improve to better anticipate the evolution of vaccine recommendations and more accurately forecast vaccine demand.

To accurately predict demand and optimise manufacturing capacity and distribution, it is crucial for manufacturers to access information on community and patient needs and employ a coordinated mechanism for vaccine allocation based on priority territories and timing. The EU and Member States should ensure the necessary regulatory expertise and resources and enhance transparency in the decision-making process regarding vaccine assessment (10). Regular global partner forum discussions with suppliers are essential for transparency and successful planning regarding new policy decisions and program implementation.

Timely epidemiological data can enhance the understanding of vaccine demand, thus increasing resilience and preventing shortages. Continuous dialogue and exchange of scientific data between vaccine manufacturers and the European Centre for Disease Control (ECDC) and Health Authorities (EMA, NCAs, MoH) is critical to avoid potential health crises in the EU (5).

Leveraging data available from different systems such as the European Medicines Verification Systems (EMVS), EMA systems (IRIS & SPOR - substances, products, organisations and referentials), and other sources into the European monitoring system will dramatically expand authorities' visibility and thereby their capacity to take appropriate actions. Existing manufacturing capacity data (and predictive software) could also be better utilised to anticipate demands more effectively (11). Interoperability of these systems will be crucial for their success.

2. Implement successful strategies from the COVID-19 pandemic during non-pandemic times

Successful strategies which helped reduce vaccine delivery times to communities during the pandemic should be employed in non-pandemic periods to ensure supply chain resiliency.

- **Policies that support manufacturing capacities, free trade of raw materials and vaccines, and the freedom to select suppliers are crucial for building resilient global supply chains.**

These policies proved critical during the pandemic, ensuring the supply of raw materials, consumables, and equipment needed for vaccine production and quality testing. Removing export restrictions, opening borders, and ensuring diversified supply chains to allow the free flow of these critical materials are key to maintaining supply chain resilience and securing access to medical goods globally. Global supply chains can be further strengthened by improving distribution channels to help alleviate bottlenecks. For example, official green lanes (or corridors) were created during the pandemic to facilitate customs clearance at border crossings between EU Member States. Pre-arrival documents could also be submitted electronically and import and export declaration forms were simplified.[Error! Bookmark not defined.] Alongside this, dialogue on open supply chains with like-minded countries, at the WTO or bilaterally, will be critical in driving sustainable and globally aligned approaches to the common goal of patient access. Interfering with existing effective manufacturing and supply chains could exacerbate vulnerabilities, delay manufacturing, increase costs, and impose unnecessary burdens on healthcare systems.

- **Harmonising global regulatory standards to streamline processes could provide system-wide benefits, including reducing strain on the manufacturing supply chain.**

Flexibility around regulatory processes and quality aspects, especially the EU variations framework, is one of the most significant enablers for the manufacture and supply of both new and established products. The COVID-19 pandemic demonstrated that rolling submissions, the possibility of electronic or hybrid inspections, conditional marketing authorizations, and the acceptance of the EU common pack and the electronic Patient Information Leaflet instead of the paper version accelerated patients' access to medicinal products. The revision of the EU pharmaceutical legislation is an opportunity to improve the regulatory framework taking into account the lessons learnt from COVID-19 (12).

- **Timely sharing of epidemiological data and information is essential for improved understanding of vaccine demand forecast.**

During the pandemic, surveillance data enabled the rapid development of updated vaccines to target emerging variants. Further strengthening of systems, infrastructure, and policies for sharing data and information on existing and emerging pathogens, could help inform future vaccine demand. Vaccination data systems are also chronically underinvested, lacking coordination and transparency across governmental jurisdictions and between public and private entities. Increased research and development on data sharing techniques, inventory management, and the creation of a framework for the implementation of new technologies are needed to further enhance data transparency (13).

3. Encouraging stakeholder collaboration to create synergies for strengthened resilience

Developing essential synergies between stakeholders will help ensure a deep understanding of the end-to-end vaccine production process, avoid delays and duplication of work and shape future activities in an agile way.

Effective engagement of multiple stakeholders (vaccine manufacturers, EU agencies, governments, healthcare providers, and patients) is essential for increasing vaccine supply chain resilience (14).

Cooperation through diverse modes of collaboration should be encouraged to allow manufacturers, research institutions and governments to work together to develop vaccines within tight timeframes (11). It is crucial to maintain communication between national, EU, and international health agencies and authorities and manufacturers to ensure fair distribution of vaccines during times of high demand. In the event of a pandemic, it is necessary to quickly increase manufacturing and allocation capacities or repurpose existing capacity while ensuring that vaccines are distributed equitably.

During the COVID-19 pandemic, more than 300 key partnerships (e.g., public-private, private-private, private-academic, etc.) were established. These collaborations bolstered manufacturing capacity, facilitated technology and knowledge transfer, drove historically rapid research and development, and enabled unprecedented manufacturing scale-up to match global demand.

End-to-end collaboration between the private and public sectors could be improved, with adequate public investment and flexible contracts to secure agile industrial capacity, including in the inter-pandemic period.

4. Reducing packaging complexities

Moving to a common EU packaging and replacing the paper patient information leaflet with an electronic version (ePIL) within a short transition period to improve access to vaccines and mitigate shortages.

Vaccines Europe recommends **adopting a common EU packaging** accepted by all EU/EEA Member States and **replacing the paper patient information leaflet with an electronic version (ePIL)** that can be easily updated

and is available immediately in the necessary languages (15). The implementation of these regulatory flexibilities would allow inventory to be redeployed between countries where appropriate in response to critical needs. Having packaging options that allow for late differentiation and timely reallocation during outbreaks, and other surges in demand, would be beneficial from a public health perspective. Furthermore, the replacement of the paper leaflet with an electronic patient information leaflet would allow optimal packaging size and patients to have access to up-to-date information in their language. Further dialogue is needed with regulators and policy-makers currently debating the EU pharmaceutical package to define standard requirements for electronic inserts and create tools to deliver them in innovative formats useful for healthcare providers and citizens.

5. Ensuring a highly skilled vaccine manufacturing and supply chain workforce

Upskilling the EU vaccine workforce and providing greater support to Member States to improve research, development and manufacturing capabilities should be policy priorities.

Member States have varying infrastructure and workforce capabilities for vaccine research and development, manufacturing and regulatory evaluation. As such, there is a need for investment in the upskilling of the EU vaccine workforce. Limited workforce capability can make it more challenging for the industry to innovate and upscale. Policy priorities could focus on facilitating best-practice sharing aimed at upskilling the EU vaccine workforce and providing greater support to Member States (e.g., good manufacturing practice training) to improve research, development and manufacturing capabilities through green/digital transition.

■ CONCLUSION

The main factors impacting vaccine supply chain resilience include long, complex and unpredictable manufacturing and release processes, which are subject to multiple quality controls as part of companies' business practices. Complex global regulatory life cycle management, diverse presentations and package inserts/labels in the EU can also hamper vaccine supply and access. Beyond demand complexity, some vaccine procurement ecosystem specificities, which are defined by high market fragmentation and national tender shaping requirements, could be also addressed to decrease vaccine supply chain complexity. To address the unpredictability of global demand, mechanisms for early and continuous dialogue between manufacturers and health authorities to better anticipate current and future needs, the evolution of vaccine recommendations and more accurately forecast demand are urgently needed. **Addressing these root causes is largely beyond the control of manufacturers alone and will require mutually feasible and sustainable solutions in collaboration between competent authorities, governments and industry.**

To prevent delays in vaccine production and release, it is important to fully understand the end-to-end vaccine production and batch release processes. By doing so, we can optimise collaboration between stakeholders, minimise duplicate efforts, and increase resilience and agility for the future. This will ultimately improve vaccine availability and contribute to better public health.

APPENDIX

Table 1. Key differences between vaccines and treatments

Rationale for use: Vaccines are medicinal products intended to elicit an immune response for prevention, including post-exposure, prophylaxis, and for the treatment of diseases caused by infectious agent. The role of therapeutic drugs is to manage/cure an already present condition, slowing down or stopping its progression, or to alleviate symptoms.
Vaccine complexity: Vaccines are almost always highly technical, complex biological products, which have implications for the global and EU research, innovation, development and manufacturing ecosystem (4).
Longer production lead times: Owing to biological variability in basic starting materials, the cell/microorganism itself, cell/microbial culture requirements, and purification processes. The complexity is further amplified in the case of combination products that contain multiple antigens. In general, the production lead time of vaccines ranges from 18 to 24 months. However, there are vaccines for which the lead time is even higher, up to 36 months (e.g. pertussis-containing vaccines, meningococcal and pneumococcal conjugated vaccines). Only for several vaccines the lead time is lower than 18 months (e.g., monovalent hepatitis B vaccine) (6).
Benefits of use: Individual and population-based benefits, including herd/community immunity, outbreak control, pandemic prevention, disease control/elimination/eradication, antibiotic use reduction and reduction of healthcare resource use and cost (16).
Market access: Multidisciplinary National Immunisation Technical Advisory Groups (NITAGs) will provide recommendations in relation to approval, implementation and public funding of a vaccination as part of National Immunisation Programmes (17).
Time to population access: Across the EU, the median time from marketing authorisation to population access (national recommendation and reimbursement) for innovative vaccines is 6 years (18). The average time to reimbursement for innovative treatments across countries in the EU/EEA is 531 days (19).
Cost and funding: Vaccination is one of the leading cost-effective interventions providing a significant return on investment. Still, EU countries spend on average only 0.5% of their healthcare budget on immunisation (20) – the budget which covers not only the cost of vaccines but the cost of the implementation of vaccination programmes (needles and syringes, alcohol wipes, ensuring cold chain, waste removal and salary for staff, education, communication activities, programme monitoring).
Vaccine hesitancy: The reluctance or refusal to vaccinate despite the availability of vaccines has been identified by WHO as one of ten global threats to health, posing risk reverse progress made in tackling vaccine-preventable diseases (21).

Table 2. Factors affecting global supply chains

Environmental	• Natural disaster • Extreme weather • Pandemic • Epidemic (local, regional)
Geopolitical	• Political Instability • Trade restrictions • Terrorism • Corruption • Piracy • Counterfeiting • Wars, conflicts
Policy	• Request to localise or regionalise manufacturing to manage market requirements to protect local supply (i.e., stockpiling, shortages prevention plan) • Immunisation financing (e.g., tender, purchasing policies) • Mandatory technology transfers (i.e., IP waiver)
Economic	• Price volatility • Border delays • Currency fluctuations • Energy shortages • Demand shocks (e.g., outbreaks) • Sustainability and capability of manufacturing investments*
Technological	• ICT disruptions* • Infrastructures failures* • Malware and other cyberattacks* • Harmonized global supply chain management and data collection platforms
Regulatory	• Post-approval changes** • Global redundant QC testing as HA requirements • Multiplication of SKU presentations that are not justified • Missed opportunity to digitalise patient information while ensuring patient safety and health literacy
Process	• DTP in vivo testing challenges (i.e., intrinsic "volatility") • DTP in vivo testing challenges (i.e., internal processes)* • Manufacturing lead times* • Predictability of certain manufacturing steps and QC testing outcomes* • Critical Components shortages (e.g., vials, disposable)* • Capability to ramp up in terms of capacity* • Temperature control conditions and possibility of failure* • Facilities complexities* • Expiration prior to use (i.e., short shelf life) *

***Under marketing authorisation holder control**

**** Shared control by the marketing authorisation holder and regulatory authorities**

Abbreviations: HA, health authority; ICT, information and communications technology; QC, quality control; SKU, stock keeping unit

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