23 April 2024

Critical Medicines Alliance

Working Group 1

Concept note

Strengthening manufacturing capacities in the EU for critical medicines to better prevent and fight their shortages

Introduction

For many years, shortages of critical medicines (including those caused by API shortages) have occurred within Europe and globally, leading to reduced or delayed access to medicines for patients. However, due to multiple and unforeseen reasons, the frequency of shortages seems to have increased[1].

Since the COVID-19 pandemic, shortages of medicines have become more pressing and affected critical medicines in numerous Member States. Hence, the phenomenon has gained more public visibility and the issue of medicine shortages has been prioritised on the political agenda in an even greater number of EU Member States.

Considering the urgency and the growing threat to public health this development represents, the European Commission has proposed a broad set of short-term and longer-term actions in its Communication on addressing medicine shortages in the EU of October 2023, to address shortages of medicines and enhance their security of supply, by providing predictability and a comprehensive and coordinated approach with stakeholders at EU and global level. The key goals are to prevent or mitigate critical shortages at EU level and to assure a particular focus on the most critical medicines for which security of supply needs to be assured in the EU at all times, in normal times, and in times of crisis. In particular, the Communication announced the establishment of a Critical Medicine Alliance, allowing national authorities, industry, civil society representatives, the Commission and relevant EU agencies to come together to develop a set of proposals for coordinated actions at the EU level against shortages of medicines, in compliance with the competition rules and EU's international commitments.

More specifically, the Alliance will pool resources and expertise to enhance the ability to consider how vulnerabilities in the supply chains of critical medicines can be addressed, identify priority areas for action in the medium to long term and propose or highlight structural tools to reduce critical shortages of critical medicines.

The Terms of Reference of the Alliance provide for the setting up of working groups to consider some of the key industrial challenges in this area and make appropriate proposals. The work will build upon the results of the shared vulnerability analysis of supply chain bottlenecks of the medicines on the

[1] According to EU legislation the companies that hold a marketing authorisation have a legal obligation to "ensure appropriate and continued supplies", so that the needs of patients in each Member State are covered.

Union List of critical medicines. This evidence-based process will result in identifying a limited number of critical medicines with the highest risk of shortages and impact on healthcare systems. Through this process, the Alliance would be able to identify appropriate tools to respond to these vulnerabilities in the most optimal way.

Starting from the identification of the root causes of these vulnerabilities, collecting the experience of its participants and, where relevant, outside contributors, Working Group 1 will in particular discuss possible measures to increase manufacturing capacity in the EU for critical medicines with identified supply chain vulnerabilities and/or active pharmaceutical ingredients, and assess whether the increase of such capacity is an appropriate measure to reduce the risk of critical shortages of critical medicines.

The activities will build on evidence and analysis of root causes put forward in the Commission study on medicines shortages and the outcome of the Structured Dialogue 2021-2022 and the Staff Working Document that concluded it, avoiding duplication and repeating steps that already took place.

Aims and Objectives

This working group is established to support the Alliance and advise its Steering Board in identifying and assessing appropriate tools to respond to the supply chain vulnerabilities of critical medicines and effectively reduce their risk of shortages through the possible increase of manufacturing capacity and by improving the resilience of the supply chain of critical medicines (including their APIs) in the EU, via:

- Identifying the challenges and pre-conditions for strengthening the manufacturing capacity in the EU for critical medicines, their active components and critical inputs (and their production).
- The modernisation of the manufacturing facilities and fostering of innovative industrial practices to improve production and manufacturing processes (by automation, yield improvement and other techniques) to ensure availability without disruption, including from a funding, regulatory[2] or standardisation point of view.
- Identifying a set of criteria for a pipeline of investment projects that would facilitate reaching the above-mentioned objectives[3].
- Ensuring that industrial measures and potential financial support demonstrably lead to a reduction of the risk of critical medicine shortages.
- Ensuring the strategies developed would also apply to future critical medicines (including biologics).

[2] Working Group 1 will not discuss the topics covered by the pharmaceutical review proposal or issues which are subject to ongoing legislative processes. Items for discussion can be raised and will be transferred to the relevant EU bodies.

[3] To avoid conflicts of interest and for competition law reasons, it will not be possible for the working group to identify a pipeline of investment projects which could respond to the strategic objectives of the Alliance. This will fall under the responsibility of Commission services.

This approach should also take into account the overall objective of the affordability of medicines as set in the Pharmaceutical Strategy for Europe (2020).

The specific objectives of the working group are to:

1/ Identify the challenges linked to manufacturing and supply of critical medicines in the EU

- Develop a shared understanding of the vulnerabilities in the supply chain of critical medicines using, inter alia, the shared vulnerability assessment, professional expertise from working group members or relevant external contributions (including assessments at national level).
- Identify if these vulnerabilities are country-specific, EU-specific or global.
- Define the key stages of pharmaceutical manufacturing and supply chains where vulnerabilities could be addressed. These may pertain to specific critical medicines or countries or apply universally to all critical medicines with identified supply chain vulnerabilities and falling within the remit of either private or public entities for solving actions.
- Examine if stockpiling as a supply issue mitigation strategy could be performed at EU level, effectively reducing the risk of shortages and improving supply and demand signalling.
- Investigate if EU-based manufacturing/technologies at the identified points in the supply chain could resolve the issues identified for specific critical medicines and effectively lead to a reduction of the risk of critical shortages.
- If so, outline the actions that would be required to develop or improve manufacturing in the EU at the weak points identified in the manufacturing/supply chains.
- Discuss challenges for manufacturing in the EU at the different stages of the medicine manufacturing and supply chain (e.g. environmental regulation, social costs including those for national healthcare systems, regulatory framework).
- Identify and assess the feasibility of measures to address these challenges and assess whether potential support from public and private interventions, including for manufacturing capacity, should be envisaged to effectively address the identified challenges in a coordinated and competitive way and thereby leading to a reduction of the risk of shortages situations.

2/ Identify opportunities for strengthening an EU industrial base for critical medicines and possible components of an EU policy toolbox

The working group should prepare a methodology for identifying which critical medicines with identified supply chain vulnerabilities and steps of their value chain should be prioritised for manufacturing capacity/technology building in the EU (or to preserve existing manufacturing capacities/technologies), where it has been established that this would effectively reduce the risk of shortages situations (as per point 1 above), and critical medicines and value chains steps where it would be advantageous to pursue other strategies (e.g. supply chain diversification) (this action must be performed in cooperation with Working Group 2 as it touches on its objectives).

The complexity of the pharmaceutical supply chains and the variety of critical medicines requires the establishment, where relevant, of a dedicated EU policy toolbox aiming at boosting the resilience of the supply chain and at manufacturing capacity building in the EU of critical medicines and their active components. Such a toolbox could be developed based on a review of the applicable regulatory and financial framework and national policy precedents. The tools in the toolbox should be developed

with a clear assessment and analysis of the impact that they can have on the reduction of the risk of critical shortages of critical medicines.

This could include (this list is indicative):

- Boosting innovation of manufacturing capacity, including research and development of novel greener and/or more sustainable technologies to improve current manufacturing practices or security of supply (such as automation, flow chemistry, yield improvement technologies); with Working Group 2, analyse the impact of the global supply chain on manufacturing capacity within the EU.
- Procurement strategies at national/sub-national level, and joint procurement at EU level (including public reservation of supply or production) with criteria other than price (social, environmental and supply security criteria).
- Financial support, including the mobilisation of EU funding such as cohesion funds, research and innovation funds, investment instruments such as InvestEU or funding mobilisation instruments such as STEP (also to leverage private investment).
- Mobilisation of national/regional funding/IPCEIs[4] in line with State aid rules, in an aligned, strategic manner at EU level to support investments in greener technologies.
- Participation of private investment such as EIB/EIF/HERA Invest.
- Other incentives for investment projects, for future implementation by Member States or Commission services, in cooperation with private sector.
- Skills for the pharmaceuticals, including by cooperating with the relevant partnership in this area.
- Identification of criteria or indicators to ensure that the measures in the toolbox lead to a reduction of risk of shortages situations.

Deliverables

The working group, shall, by end of Q3 2024, provide an initial set of measures and tools with an assessment of the expected impact that each of them is expected to have on the reduction of the risk of critical shortages of critical medicines, to feed into the Strategic Plan to be adopted (Q4 2024) by the Steering Board.

Meetings

The members of the working group will meet on a regular basis (mostly remotely) in 2024. A meeting agenda will be produced ahead of each meeting. As an outcome of each meeting, draft minutes will be produced by the secretariat and shared with the members of the working group and, after validation by the group, with the Steering Board.

Membership

The working group will consist of up to 40 member organisations from the Forum's membership that have applied for participation, selected by the Commission on the basis of their activities or their expertise in relation to the working group's area of work. The working group should be composed of a balanced representation of government, industry and civil society.

[4] Important Projects of Common European Interest

The Commission may restrict discussions related to certain essential strategic tasks affecting security interests of the Union, to member organisations not subject to control by a third country, acting either directly or by way of measures addressed to a third country entity.

Chair

The members of the working group will elect their Chair among representatives of member organisations not controlled by a third country.

Tasks

Members are expected to:

- Contribute to the work of the working group with their expertise and their contacts within their organisation,
- Prepare for and participate in all meetings,
- Co-operate with other members in between meetings,
- Contribute to the drafting of the deliverables of the working group.

Working Group Secretariat

The working group secretariat is provided by HERA. The secretariat, in collaboration with the Chair, will propose an agenda for all meetings.

Finances

There is no compensation for the work of the members participating in the working group.