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## CRITICAL MEDICINES ALLIANCE (CMA)

### TERMS OF REFERENCE

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#### 1. CONTEXT AND FOCUS AREA

Critical shortages of critical medicines and their Active Pharmaceutical Ingredients (APIs) are a threat for public health, health care systems and Europe's security. The increasing complexity or globalisation of supply chains can be a potential source of vulnerabilities, including dependencies in medicines supply chains.<sup>1</sup> This was further revealed during the COVID 19 crisis and the Russian aggression against Ukraine.

The EU has a strong and competitive pharmaceutical sector, a global leader in the production of medicines and a major contributor to the EU economy, directly employing some 800.000 people. It is particularly strong in the research and development of innovative medicines. However, the landscape for pharmaceutical manufacturing has evolved in recent decades. Production of inputs for generic medicines has increasingly moved outside Europe, in particular to China and India. Pharmaceutical production in the EU has focused on more complex products, which require high-tech infrastructure, a skilled workforce and sophisticated processes. At the same time, almost 70% of the medicines dispensed in Europe are generics. The high degree of dependency on non-European sources has received increased attention in light of the issues faced in the production ramp-up of COVID-19 vaccines.

The urgency to further develop a coordinated response within the European Health Union has been highlighted on several occasions, notably at the June 2023 European Council. In parallel, the Granada declaration<sup>2</sup> of October 2023 has recalled the need to enhance the economic resilience of the EU and its competitiveness through greater diversification and risk management. The European Parliament has also stressed the need to prioritise such work, notably with an open letter signed by 80 MEPs. The Commission is responding to these calls through determined action. The revision of the pharmaceutical legislation, the strengthening of the EMA mandate as well as the creation of HERA are significant steps to address the above-mentioned challenges and they are already making EU health systems more resilient. But the occurrence of critical shortages of critical medicines show that additional efforts are needed.

The Communication *Addressing medicines shortages in the EU*<sup>3</sup> (the "Communication") sets out a comprehensive toolbox, 'including a set of actions to mitigate these structural risks, notably

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<sup>1</sup> See [https://health.ec.europa.eu/system/files/2022-10/mp\\_vulnerabilities\\_global-supply\\_swd\\_en.pdf](https://health.ec.europa.eu/system/files/2022-10/mp_vulnerabilities_global-supply_swd_en.pdf)

<sup>2</sup> See Commission Communication "Towards a more resilient, competitive and sustainable Europe" (COM(2023) 558) and <https://www.consilium.europa.eu/en/press/press-releases/2023/10/06/granadadeclaratio>

<sup>3</sup> [COM\(2023\) 672 final of the 24/10/2023](#): Communication from the Commission , "Addressing medicine shortages in the EU"

*reinforcing supply by making demand more predictable, encouraging diversification and increased manufacturing for the most critical medicines, as well as EU stockpiling if needed*. This could include actions in the field of health, industrial, trade or innovation policies. The European Council conclusions of October 2023 have endorsed this proposal and called for a swift implementation of the Communication.

In this context, the EMA has published on 12 December 2023 a first chapter of a Union list of critical medicines<sup>4</sup>, which will be subsequently updated. DG GROW and HERA will carry out an analysis of supply chain vulnerabilities (including as over-dependency on a limited number of third country suppliers, limited diversification, limited production capacity) for a first tranche of critical medicines on the Union list by April 2024. The outcome of this work will provide the scope of the mandate of the “Critical Medicines Alliance” (CMA) announced in the Communication and the complementary work of the Executive Steering Group on Shortages and Safety of Medicinal Products (‘the Medicines Shortages Steering Group’ (MSSG)), in anticipation of the proposed pharmaceutical legislation.

## 2. OBJECTIVES

On the basis of the abovementioned scoping exercise, the objective of the CMA will be to **provide an inclusive and transparent consultative mechanism that brings together Member States, stakeholders, especially industry, and the Commission to identify challenges resulting from vulnerabilities and on the most appropriate actions and instruments to address the vulnerabilities in the supply chains of critical medicines in the most optimal way**, with the primary public health goal of reducing the risk of shortages of those critical medicines.

The CMA, as an advisory body, will allow national authorities, industry, civil society representatives, the Commission and EU agencies to come together to discuss and find potential solutions to address those vulnerabilities at the EU level, in compliance with the roles and responsibilities defined in the EU pharmaceutical legislation, competition rules and EU’s international commitments.

More specifically, the CMA will pool resources and expertise to enhance the ability to consider how vulnerabilities in the supply chains of critical medicines could be addressed, recommend priority areas for action in the short to medium term and propose or highlight structural tools to address critical shortages of critical medicines. In particular, the CMA will draw on the varied tools available, in order to recommend actions to mitigate structural supply risks, such as how to improve the accuracy of prediction of demand, while recognising that the obligation to do so is with industrial players, facilitate diversification and reinforce supply (to the EU market), including through increased manufacturing capacity of critical medicines.

In the short term, this could include contributing to defining a more strategic use of EU-level procurement tools, including joint procurement or reservation contracts. The CMA could also help in exploring how to diversify global supply chains for critical medicines, by identifying third countries for strategic partnerships, to help coherence and potential synergies between EU and non-EU countries.

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<sup>4</sup> See [https://eur-lex.europa.eu/resource.html?uri=cellar:e3f40e76-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:e3f40e76-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF)

To boost Europe's capacity to produce and innovate in the manufacturing of critical medicines and ingredients, the CMA could coordinate efforts to identify security of supply needs for critical medicines, based on identified vulnerabilities, through strategic projects. In this context, Services of General Economic Interest (SGEI) could be envisaged by Member States to limit the risk of critical medicines shortages at EU level, and the CMA could play a role in promoting a consistent approach across the EU on this matter. Similarly, the CMA could discuss potential new Important Project of Common European Interest (IPCEI) focusing on critical medicines which could enhance the development of innovative and sustainable manufacturing, production technologies and processes for critical medicines.

While the decisions concerning access to finance will be taken by the relevant financings bodies/entities/institutions, the CMA could also contribute to the facilitation of access to finance, including by identifying investment and manufacturing needs, based on vulnerability analysis, and identify or bring together stakeholders around strategic projects that could benefit from EU and national funding possibilities (including EU4Health, STEP, cohesion funding, RRF etc.), ensuring security of supply and potential geographical balance.

Members of the CMA could provide recommendations concerning the future priorities for actions under the EU4Health or Horizon Europe programmes, while the decision-making remains with the relevant bodies and structures. Importantly, the initial work of the CMA could also provide recommendations to the preparation of the strategic priorities of the Commission and the future Multiannual Financial Framework.

In the elaboration of the recommendations of the CMA, key deliverables and milestones should be proposed to ensure that measures taken and commitments made (in particular in the form of financial support) do effectively lead to foreseeable and direct impact.

## **2.1. BROADER IMPACT**

Addressing vulnerabilities in the supply of critical medicines and APIs will require crowding in investments and collaboration between Member States, industry (pharma, chemistry, biotech, finance, logistics) and other relevant stakeholders, including civil society representatives. With industrial policy for medicines as the primary objective, the CMA should also contribute to the industrial competitiveness of the EU, its open strategic autonomy, and its economic security in these sectors. Ultimately, the Alliance will support the overall public health goal by reducing the risk of shortages of critical medicines with identified supply chain vulnerabilities.

## **2.2 COMMITMENTS**

The CMA is based on the following commitments:

- The EU and Member States should indicate their readiness to provide, where relevant, contractual incentives, investments and other forms of support in line with applicable legislation;

- In addition to identifying priorities and developing recommendations for action in line with the objectives of the CMA with other relevant stakeholders, pharmaceutical companies should commit to enhanced transparency and access to necessary and relevant market and supply chain data, to be provided and used in a secure way ensuring that individual commercially sensitive information is not exchanged. This could include, for example, commitment to confidentially share shortage prevention plans (with the Commission and medicines competent authorities), which provide a more structured framework within the pharmaceutical quality system for the industry to focus on shortage prevention.<sup>5</sup>
- Public and private financial institutions, where relevant, should contribute to the achievement of the objectives of the CMA through financing, in particular for public financial institutions through the de-risking of investments which may not prove attractive enough for the private sector.

### 2.3 INTERLINKS WITH THE WORK OF OTHER EXISTING FORA

The CMA will not replace existing fora and will have a specific mandate for a defined period.

Due to its consultative nature, the CMA will not interfere with the mandate nor duplicate the work of the MSSG, including its role in the management of shortages of medicines and the management of critical medicines<sup>6,7</sup>. In anticipation of the proposed pharmaceutical legislation, the MSSG will make recommendations *“on appropriate security of supply measures to marketing authorisation holders, the Member States, the Commission, or other entities. Such measures may include recommendations on diversification of suppliers and inventory management”*. The CMA will consider the work of the MSSG and inform the MSSG of CMA recommendations accordingly.

The members of the Alliance could also cooperate with the group of National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR), especially by contributing to the development of guidance on procurement practices to strengthen security of supply.

The CMA will take into account the work of the Joint Industrial Cooperation Forum (JICF) in the field of addressing bottlenecks of medical countermeasures and will use the expertise of its members to substantiate its work specifically in matters related to critical medicines.

The CMA will not interfere with, nor discuss, any Commission proposals.

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<sup>5</sup> [Good practices for industry for the prevention of human medicinal product shortages \(europa.eu\)](https://eur-lex.europa.eu/resource.html?uri=cellar:e3f40e76-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_2&format=PDF), [https://eur-lex.europa.eu/resource.html?uri=cellar:e3f40e76-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC\\_2&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:e3f40e76-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_2&format=PDF)

<sup>6</sup> [EUR-Lex - 32022R0123 - EN - EUR-Lex \(europa.eu\)](https://eur-lex.europa.eu/resource.html?uri=cellar:e3f40e76-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF) and

<sup>7</sup> [https://eur-lex.europa.eu/resource.html?uri=cellar:e3f40e76-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:e3f40e76-e437-11ed-a05c-01aa75ed71a1.0001.02/DOC_1&format=PDF)

### 3. FIRST DELIVERABLES OF THE CMA

#### 3.1. IDENTIFICATION OF RELEVANT ACTIONS TO ADDRESS IDENTIFIED VULNERABILITIES IN THE SUPPLY CHAINS OF CRITICAL MEDICINES

The CMA will recommend priority areas for action for the critical medicines identified as having supply chain vulnerabilities requiring recommendations, within the scope of the Alliance, in the vulnerability assessments and make recommendations to improve their security of supply and therefore better prevent shortages (also including their APIs), without prejudice to the MSSG mandate. Such recommendations may also be of strategic and overarching nature and may not specifically target the resolution of identified vulnerabilities in the supply chains of particular critical medicines.

These recommendations should in turn enable the Commission to take necessary measures, including the development of the right incentives for the various actors of the medicinal products supply chain and ensure the strengthening, extension, modernisation or reshoring of manufacturing capacity through public-private investments involving, wherever relevant, EU funding. Each of these recommendations should be accompanied by an assessment of the expected quantifiable impact that it will be expected to deliver in terms of critical medicine shortage mitigation or prevention.

Based on the above, the CMA Steering Board<sup>8</sup> **will draw up a multi-year set of actions (Strategic Plan)** with proposed milestones and corresponding deadlines, to be endorsed by the CMA Forum, guiding the Commission, the Member States and industry should these be chosen for implementation by respective parties. The CMA Forum will also evaluate every 2 years if the strategic plan remains adapted to inform the strengthening of supply chains of critical medicines and APIs and mitigate or prevent shortages of those critical medicines.

Timeline/ actors: by Q3 2024, Commission, Steering Board and CMA Forum for validation

### 4. CONSULTATION

Beside the above-mentioned tasks, the Commission may consult the CMA on matters relating to policies related to the focus described above, and more generally relating to critical medicines.

### 5. MEMBERSHIP ELIGIBILITY CRITERIA

The work of the CMA shall be without prejudice to the legal framework of EU's funding instruments and shall be in compliance with the competition rules and EU's international commitments.

The following membership eligibility criteria shall apply:

- 1) The CMA is open to all public and private entities with relevant activities in the area of research, production, distribution, delivery and use of medicines industry (pharma, chemistry, biotech, finance, logistics and all relevant stakeholders, including the civil society representatives) and which meet the eligibility criteria including companies and associations, healthcare professional organisations, healthcare organisations, social partners, education and training providers,

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<sup>8</sup> See section 6 below

research and technology organisations, distributors, investors, civil society organisations, and representatives of EU Member States, regional and public authorities. Legal entities, which do not have such activities themselves, but through their members (for example, industry associations), may become “Member Organisations”, subject to the relevance of the legal entities activities to the objectives of the CMA.

- 2) An organisation’s membership of the CMA will be conditional on the signature and compliance with a CMA’s Declaration, including a code of conduct and competition compliance programme.
- 3) In the event of a change during the membership which might put into question the fulfilment of the eligibility criteria, the relevant legal entity shall inform the European Commission sufficiently in advance, which shall assess whether these eligibility criteria and conditions continue to be met and shall address the potential impact on the organisation’s membership of the CMA.
- 4) Member Organisations who no longer act in accordance with the principles set forth in the CMA Declaration, or are no longer capable of doing so, upon request of the Commission, shall no longer be invited to participate in any meetings of the CMA and may be replaced for the remainder of their term of office.
- 5) Prior to the signature of the CMA Declaration, applicants shall provide all relevant information necessary for the assessment of fulfilment of the eligibility criteria to the European Commission, this includes:
  - a) Practical utility to the CMA: the entity shall describe its relevant existing or planned activities including in the European Economic Area of practical utility to the CMA (Focus areas and deliverables).
  - b) Signature of Competition Compliance Programme : the alliance will safeguard competition by reporting on meetings, discussions, information exchanged, and agreements reached and making these available to the Commission on request. The competition compliance programme will be incorporated in the code of conduct that members have to sign when joining.
  - c) Compliance with EU Data Protection rules and respecting security of sensitive information: the entity shall provide assurances in this regard, and that it shall not provide any information related to the CMA and related projects to third parties, except general information about the CMA’s work that may be disseminated to non-members and exclusively upon specific request of the European Commission.
  - d) a written commitment that it has and will ensure in the future to have, no conflict of interest whatsoever with the CMA’s objectives or with specific objectives of the project groups to which it participates.

These criteria will be assessed on a case-by-case basis by Secretariat of the CMA, on the basis of information provided by the applicant. In case of concerns, such assessment may result in a refusal by the European Commission of the application of a given eligible organisation or its participation rights restricted.

The entities which are not subject to control by a third country, acting either directly or by way of measures addressed to a third country entity, are normally presumed to respect criteria (c).

Without prejudice to membership, the Commission, for instance upon proposal of the CMA Steering Board, may restrict discussions related to certain essential strategic tasks affecting security interests of the Union, be it in project groups or European Critical Medicines Forum’s agenda points, 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.

## 6. GOVERNANCE

The governance of the CMA will respect the key principles of expertise, cooperation, relevance to the objectives of openness, transparency.

- Openness: the CMA will be open to all interested parties who can actively contribute to its objectives and are able to demonstrate it, subject to the conditions outlined in section 4 above. A call of interest will be launched in this regard early 2024.
- The Declaration that potential members will be asked to sign should clarify that they agree with the objectives of the CMA and that they will be expected to contribute actively. A continuous membership review process could be considered.
- Transparency will be ensured by publishing the output documents and providing further information (membership, working methods) through a dedicated website. With regards to the activities of the CMA will prepare and duly keep records of, the reports on meetings, discussions, information exchanged, and agreements reached and making these available to the Commission on request.
- The measures developed and proposed as part of the recommendations of the Strategic Plan would need to be accompanied by key deliverables and milestones.

All stakeholders should join the CMA by signing up to a declaration that includes its main objectives and targets, a commitment to the basic principles and the main elements of the governance structure.

The CMA will fully comply with EU competition rules, in both its setting-up and its activities. Its Members shall subscribe to the competition compliance programme.

The governance of the CMA will be structured at 3 levels: the CMA Forum, the CMA steering board and the CMA working groups.

### 6.1. CMA FORUM

- The CMA Forum is open to all Member Organisations based on eligibility criteria (cf section 5).
- The aim of the Forum will be to discuss high level policy issues related to the CMA, seeking involvement of high-level representatives from within its Membership.
- Member States, the European Medicines Agency and the European Parliament are also invited to participate to the Forum.
- The Forum will meet at least once per year.
- The European Commission will act as a facilitator of the Forum and organise its meetings.

### 6.2. CMA STEERING BOARD

- The CMA Steering Board
  - prepares the Forum,
  - ensures consistency and integration of the work of the different working groups and with the other existing structures,

- based on their input, it maintains a roadmap of the implementation of the actions proposed by the CMA,
  - supports the European Commission in facilitating, communicating, and monitoring the work of the CMA, as well as validating its outputs.
- It is chaired by a high-level representative of the European Commission.
- The European Commission organizes the work of the CMA Steering board and provides its secretariat.
- Members of the CMA Steering Board are appointed by the European Commission, on the basis of voluntary applications and based on objective criteria. The composition of the CMA Steering Board is as follows:
  - 1 representative of the Ministry in charge of Public Health and 1 representative of the Ministry in charge of Industrial policies, corresponding to the current trio Council Presidency (i.e. in 2024 6 representatives, 2 of ES, 2 of BE and 2 of HU)
  - 5 representatives of the industry chosen among the candidates from Member Organisations originating from industry;
  - 2 representatives of patients/consumers, and healthcare professionals chosen among the candidates from Member Organisations originating from these sectors;
  - A representative of the Medicines Shortage Steering Group;
  - A representative of the EMA;
  - Chairs of the CMA' working groups
- The members of the CMA Steering Board shall designate two Vice chairs for a mandate of 1.5 years. Exceptionally, to align with the rotation of presidencies, the first two vice-chairs will be mandated until end of 2024, until the start of the next trio of presidencies in 2025.
- The CMA Steering Board prepares and endorses the Strategic Action Plan (cf section 3.1), and may adopt opinions, recommendations or reports on behalf of the CMA. The CMA Steering Board shall do so by consensus. In the event of a vote, the outcome of the vote shall be decided by simple majority of the members. Members who have voted against shall have the right to have a document summarising the reasons for their position annexed to the opinions, recommendations or reports (minority opinion).
- Endorsements and adoptions of opinions, recommendations or reports may not necessarily represent the views of the Commission.
- The CMA Steering Board shall adopt its rules of procedure by simple majority of its members.

### 6.3. CMA WORKING GROUPS

- The CMA Steering Board may propose the setting up of working groups of the CMA on suggested specific topics listed in Annex 2.
- Working groups are set up by, and their membership is defined by, the European Commission. Member Organisations, part of the CMA Forum, may apply for participation

- on the basis of their activities or their expertise in relation to the working group’s area of work. Their representatives shall have the appropriate expertise in the field.
- Working groups elect their Chair among representatives of Member organisations not controlled by a third country. They may adopt opinions, recommendations or reports, by way of consensus. In the event of a vote, the outcome of the vote shall be determined by simple majority of the members. Members who have voted against shall have the right to have a document summarising the reasons for their position annexed to the opinions, recommendations or reports (minority opinion).
- Observers and their representatives may be permitted, with the agreement of the Commission, to take part in the discussions of a given working group and provide expertise. However, they shall not have voting rights and shall not participate in the formulation of recommendations or advice of the working group.

The Commission reserves its right to act as an observer to all working groups of the CMA and provide guidance where relevant. It will act as secretariat for the working groups, in collaboration with the Chair.

In Annex 2 below are suggested working groups topics and tasks that could be used as the basis for the elaboration of the working group by the CMA Steering Board, without prejudice to additional ones or changes to their remit.

## 7. MONITORING AND EVALUATION (COMMISSION, MS, STAKEHOLDERS)

The initial duration of the CMA will be 5 years (starting from the date of the first meeting of the CMA Forum), renewable upon mutual consent of the CMA forum and the Commission.

The monitoring of the CMA will be carried out by the CMA Steering Board, with an annual report of the elements included in the **strategic plan** to be shared with different bodies, including MSSG, NCAPR, HERA Board and the High-Level Group on Competitiveness. The Commission will ensure good communication within the bodies that compose the CMA.

## 8. RULES OF PROCEDURE

The CMA Forum shall adopt its rules of procedure by simple majority of its members.

## 9. PROTECTION OF PERSONAL DATA

The European Commission DG HERA will publish on the Register a privacy statement providing information about the processing and the protection of personal data. The European Commission is committed to protect personal data and to respect privacy. The European Commission collects and further processes personal data pursuant to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data.

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## ANNEX 1

### SUMMARY TIMELINE AND NEXT STEPS (2023-25)

	<b>Action</b>	<b>Actors</b>	<b>Timeline</b>
1.	Agreement on TOR principles + launch invitation to MS (health & industry ministries) via HERA Board / HLWG on Competitiveness and Growth + permanent representations	Commission	Q4 2023
2.	Official call for interest for participation to the CMA and the CMA Steering Board	Commission, MS, CMA stakeholders	(16?) Jan 2024
3.	Selection of the participants to the CMA and the CMA Steering Board	Commission, MS	Q2 2024
4.	First meeting of the CMA Forum, official launch of the work of the CMA	Commission, MS, CMA stakeholders	Q2 2024
5.	First meeting of the CMA Steering Board	Commission, CMA Steering Board	Q2 2024
6.	Setting up of the working groups	Commission, CMA Steering Board	Q2 2024
7.	Identification of relevant actions to address identified priority vulnerabilities in the supply chains of the first group of critical medicines	Working groups	Q3/Q4 2024
8.	Elaboration of the Draft Strategic Plan	CMA Steering Board	Q4 2024
9.	Presentation of the Draft Strategic Plan to the CMA Forum for consultation	CMA Steering Board, CMA Forum	Q4 2024
10.	Adoption of the Strategic Plan	CMA Steering Board	Q4 2024
11.	Monitoring and evaluation	Commission, CMA Steering Board	From 2025



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## ANNEX 2

### SUGGESTED WORKING GROUPS

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- ***Working Group 1: Strengthening manufacturing capacities in the EU.***

The Working Group should identify rationale, challenges and make proposals to increase manufacturing capacity for critical medicines with identified supply chain vulnerabilities (including APIs), where the increase of manufacturing capacity is an appropriate measure, including by supporting existing facilities or incentivising the establishment of new production facilities, supporting strategic projects etc.

- ***Working Group 2: Strategic stockpiling, procurements, including joint procurement and tools***

The working group should look at a possible more strategic use of EU stockpiling, joint procurement and other contractual or to prevent critical shortages of critical medicines. This group should take existing national stockpiles and company contingency stocks into consideration (including where those are recommended by MSSG). The group can also contribute to the development of guidance for procurement practices to strengthen security of supply, working in close cooperation with other groups, such as NCAPR. Additional measures, in line with state aid rules, such as services of general economic interest or IPCEI or European coordination of services of General Economic Interest can be discussed in the Alliance, without prejudice to the relevant selection fora such as the Joint European Forum for IPCEIs.

- ***Working Group 3: Diversification of supply, international partnerships and cooperation***

The working group should look at the international dimension of strengthening security of supply of critical medicines, including through diversification of supply chains.

- ***Working Group 4: Data sharing and Transparency***

The working group should elaborate and propose establishing mechanisms for transparent information exchange (in line with competition rules) among CMA members, regulatory bodies, and other relevant stakeholders to enable early warning, forecasting, proactive decision making ahead of supply disruption.

Each of the working groups should also consider and assess possible investment and financial needs.