EUROPEAN MEDICINES AGENCY
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Protecting public health in times of crisis

Multistakeholder workshop on EMA's extended mandate

An agency of the European Union

9 November 2022
EMA/196821/2022

Multistakeholder workshop on EMA's extended mandate – protecting public health in times of crisis

On 1 March 2022 a new mandate for a reinforced role of EMA came into application (Regulation (EU) 2022/123)1 (1). This extended mandate provides a framework for the Agency's activities in the context of the preparation and management of public health emergencies and major events. The goal of this new mandate is to enhance the capacity of the EU to react quickly, efficiently, and in a coordinated manner to these health threats.

The new mandate foresees a reinforced role for EMA in the monitoring and mitigation of shortages of medicines and medical devices, in particular of those on critical lists during major events and public health emergencies. It provides the legal basis which allows the Emergency Task Force (ETF) to provide advice on development of medicines and support their authorisation and monitoring; to coordinate independent vaccine effectiveness and safety monitoring studies and to enhance clinical research by supporting the conduct of clinical trials. The new mandate also transfers the task of supporting the 'EU Expert Panels' for scientific assessment of certain high-risk medical devices (MDs) and in vitro diagnostics (IVDs) to EMA and requires EMA to invest in and leverage real world evidence to support crisis preparedness and response. In accordance with the new mandate, the Agency will also set up, by February 2025, the European Shortages Monitoring Platform (ESMP), an interoperable IT platform at the EU level to enable monitoring and reporting of shortages of medicinal products.

The mandate builds on structures set up during the COVID-19 pandemic, where EMA has been at the forefront of the EU's efforts to fight the Covid-19 pandemic.

On 1 April a workshop took place, bringing together all stakeholders, including industry and patient organisations, to inform them about the new mandate and its impact, as well as provide them a platform to inform EMA of their needs and expectations and discuss opportunities for further engagement.

Introduction

Sandra Gallina, Director General of the European Commission's DG for Health and Food Safety (DG SANTE) explained how the extended mandate of EMA has to be seen in the context of the wider EU legislative framework. It is one of the initiatives introduced by the European Commission (EC) to build

[1] except for the provisions on shortages of critical medical devices (MDs) which will apply as of 2 February 2023. For the purposes of the new Regulation 2022/123, "'medical device' means a medical device as defined in Article 2, point (1), of Regulation (EU) 2017/745 or an in vitro diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746, and includes accessories for such devices within the meaning of Article 2, point (2), of Regulation (EU) 2017/745, and Article 2, point (4), of Regulation (EU) 2017/746, respectively;"

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a European Health Union (EHU), a common EU strategy for crisis management to protect the health of EU citizens. The European Health Union package includes the following:

- Regulation on serious cross-border threats to health, repealing and upgrading Decision 1082/2013/EU
- Extension of EMA's mandate in crisis preparedness
- Extension of the European Centre for Disease Prevention and Control (ECDC)'s mandate; and
- Establishment of a new Health Emergency Preparedness and Response Authority (HERA).

The aim of the EHU package is to move closer to a Union that is ready to face the next health crisis. The package builds on the learnings from the COVID-19 pandemic, strengthening EMA and making it an important pillar in the EU response for mitigating and preventing medicine and medical device shortages and ensuring faster approval and availability of new medicines to address future health threats. The new legislation makes close collaboration between all actors involved with public health emergencies and major events, the Commission (DG SANTE and DG HERA), EMA and ECDC, a key requirement to tackle future public health emergencies and major events.

As part of their introductory remarks, the directors of EMA (Emer Cooke), ECDC (Andrea Ammon) and DG HERA (Wolfgang Philipp) made a clear commitment to collaborate more closely. For this, transparency and communication are essential and will build the trust with stakeholders that is necessary to make the new mandate a success and protect public health in times of crises.

Representatives of all stakeholder groups welcomed the new mandate but raised concerns and challenges that will require particular attention. These include a high administrative burden linked to the need to streamline processes to avoid duplication of data reporting and processes. In fact, interoperability between systems is an important pre-requisite to ensure efficient crisis management.

Participants were asked to identify their expectations for the new mandate. The most frequently highlighted priorities by stakeholders were:

- Collaboration with all stakeholders in the supply chain
- Harmonisation of processes and avoiding duplication
- Increased information about medicines availability.

Workshop Session 1: Monitoring and mitigating shortages of medicines and devices

Co-chairs: Monica Dias (EMA Head of Supply and Availability of Medicines and Devices Workstream), Karl Broich (MSSG Co-chair)

Key messages:

- The new Regulation (EU) 2022/123 for the monitoring and mitigation of shortages of critical medicinal products became applicable on 1 March 2022
- The Agency is currently transitioning from the ad hoc structures and processes put in place at the start of the COVID-19 pandemic to those mandated in the new Regulation
- The Agency is starting preparations to ensure a smooth and efficient delivery of the ESMP in February 2025
- For critical MDs, preparatory work is ongoing to set up the necessary structures and processes by 2 February 2023 (when the provisions on medical devices will become applicable). The Agency is also establishing the necessary collaborations with stakeholders in the field of MDs

- The new mandate provides tools to prevent shortages of medicines and ensure their supply during a health crisis. For the first time, this will extend to monitoring MDs.

Joao Ferreira (EMA Medicines and Medical Devices Shortages) explained how shortages of medicines have been a longstanding problem in the EU and globally, which was exacerbated during the pandemic. Before the pandemic, improving the availability of medicines authorised in the European Union (EU) was already a key priority for the European Medicines Regulatory Network. EMA, in conjunction with Heads of Medicines Agencies (HMA), set up a dedicated taskforce to improve availability issues. With the emergence of COVID-19, countries across the world went into lockdown, shutting down or reducing factory outputs and transport within and across borders. This affected the manufacturing, supply and distribution of medicines, leading to constraints in the global medicines supply chain. Demand also increased for some medicines used in patients with COVID-19, mainly in the hospital intensive care unit (ICU) setting, which contributed to shortages. (2)

As a result, EMA initiated a number of activities to build new networks or extend existing ones to better monitor and coordinate actions on shortages within the network.

Table 1. EMA activities to better monitor and coordinate actions on shortages within the network at the beginning of the COVID-19 pandemic (2)

1	Set-up of ***EU Executive Steering Group on shortages of medicines caused by major events*** to provide strategic leadership for urgent and coordinated actions to prevent and mitigate supply disruptions within the EU during the pandemic (3)
2	Regular meetings with industry associations
3	Introduction of regulatory flexibility for pharmaceutical companies to prevent/mitigate shortages
4	Launch of i-SPOC (industry Single Point of Contact) system, a sub-network of contact points from marketing authorisation holders to report supply issues for critical medicines
5	Establishment of an enhanced fast-track monitoring system to help prevent and mitigate supply issues with critical medicines used to treat COVID-19 patients. The system focused on medicines used in COVID-19 patients in intensive care units (ICUs) that were in high demand early in the pandemic. It allowed regulators to detect and monitor common issues, spot patterns in medicine supply, anticipate future supply disruptions and identify EU/EEA-wide measures to address disruption issues
6	Set-up of a common framework for Member States to forecast demand data in the EU/EEA, to improve the forecasting for medicines used in ICUs, and to see how to better match the estimated demand with the available supply
7	Use of EU SPOC network, which was set up in the context of the EMA/HMA taskforce on availability of authorised medicines for human and veterinary use, to share information between Member States, EMA and the EC on critical medicine shortages.

The COVID-19 pandemic demonstrated that coordinated EU level action benefits all Member States. However, it also showed a gap in the system, where the Agency needed to be reinforced and equipped with a stronger mandate to better protect EU citizens and address cross-border health threats.

The new legislation formalises processes that EMA had put in place for the COVID-19 pandemic (and even before), making them more robust. In the area of shortages EMA is nowtasked with the monitoring of events, including medicine shortages which might lead to a crisis situation. There are also new obligations for industry and Member States to report shortages of critical medicines and MDs during a crisis. In order to do this, the following groups were established:

- The Executive Steering Group on Shortages and Safety of Medicinal Products (the 'Medicine Shortages Steering Group – MSSG') to coordinate major events or public health emergencies, including urgent actions in relation to the supply of medicines. The MSSG is an executive group composed of representatives from the EC, EMA and Member States. It is multidisciplinary and includes observers from patients and healthcare professional representatives. Representatives of marketing authorisation holders, wholesale distributors and other relevant actors in the pharmaceutical supply chain may also be invited to the meetings of the MSSG, either as observers or to provide expert advice. The MSSG will provide recommendations to EC, Member States and marketing authorisation holders on measures to prevent or mitigate medicine shortages. The MSSG also has a role to evaluate information on the quality, safety and efficacy of medicines affected by a public health emergency or major event, and to make necessary recommendations.
- The SPOC Working Party (SPOC WP), which consists of nominated experts on shortages from National Competent Authorities (NCAs) to support the MSSG activities. The Working Party formalises the EU SPOC network that was set up in 2016 and was key, during the pandemic, to monitor supply issues of critical medicines in EU/EEA countries. The role of the working party has been extended to the monitoring of events, including medicine shortages, which might lead to a crisis situation. Upon request, it will also provide advice to the MSSG on any issues related to shortages of medicines.
- The current i-SPOC network will be extended as needed in a public health emergency or major event to report on shortages of critical medicines. Reporting, which was voluntary during the pandemic, will now become mandatory for marketing authorisation holders of critical medicines. In addition, there will be a legal requirement to provide data on active manufacturing sites, marketing status, sales and market share and available stocks. Reporting of prevention and mitigation plans, forecasts of demand, plus supply capacity, will also become mandatory.

In terms of governance, the MSSG will link to DG HERA, Health Security Committee and ECDC to coordinate EU wide actions. It will also link to the ETF for support on medicines which have the potential to treat or prevent a public health emergency.

One of the first key tasks for the MSSG includes the development of a working methodology for establishing a list of main therapeutic groups (MTGs) of medicines to be monitored during a public health emergency, as well as lists of critical medicines to respond to public health emergencies or major events.

EMA will set up, by early 2025, a centralised EU IT platform to report, monitor and manage medicine shortages (ESMP). Pharmaceutical companies and Member States should use this platform to report information on shortages, supply and demand of critical medicines during crisis situations, and potential supply issues that can lead to such crises.

The mandate also gives EMA new responsibilities in the field of MDs, enabling it to monitor the supply of critical MDs (during public health emergencies only). The legal provisions will become applicable on 2 February 2023. Member States' and Economic Operators' networks will be set up for medical devices,

mirroring the network in place for medicines, with the necessary adaptations to the medical device sector. In this context, a steering group to coordinate EU actions to mitigate supply issues with medicines and medical devices, the Executive Steering Group on Shortages of Medical Devices, will be set up.

These enhanced structures are expected to prevent some of the situations observed at the beginning of the pandemic, such as export restrictions and other national protective measures, which can seriously impact the solidarity principle and functioning of the internal single market.

The new mandate provides tools to prevent shortages of medicines and ensures supply in emergencies, and, for the first time, will extend monitoring to devices in emergencies.

Panel expert Tour de Table

João Ferreira (EMA Medicines and Medical Devices Shortages), Hilmar Hamann (EMA Head of Information Management Division), Sylvain Giraud (EC Head of Unit SANTE B4 - Medical products: quality, safety, innovation), Thierry Sirdey (ANSM Division for medical devices, cosmetics and in vitro diagnostic devices Director), Darren Scully (HPRA Medicine Shortages and Borderline Classification Manager), Marco Farinelli (EFPIA representative), Adrian van den Hoven (Medicines for Europe Director General) and Jesus Rueda (MedTech Europe Director of Strategies, Special Projects & International Affairs) contributed to the discussion.

During the discussion concerns were raised by industry stakeholders that the new processes may lead to a duplication of efforts between EU-wide and national shortage reporting in crisis situations as well as outside crisis situations. Processes should be streamlined as much as possible with existing sources of data (e.g. EMVS, SPOR, IRIS, IDMP) and reused while avoiding overlapping data-entry requirements from other existing systems.

There are high expectations from all stakeholders for the implementation of ESMP, which will be a key tool to monitor medicines supply and prevent shortages and to move from "reporting" shortages to "avoiding" them. ESMP is expected to become a one-stop reference point for all stakeholders and will be key to establishing a "two-way communication" channel between industry users and regulatory authorities to mitigate/prevent shortages.

Session 2: Addressing public health emergencies through the Emergency Task Force (ETF)

Co-chairs: Marco Cavaleri (EMA Head of Biological Health Threats and Vaccines Strategy and ETF Co-Chair), Bruno Sepodes (CHMP Vice-Chair and ETF Co-Chair

Key messages:

- ETF is legally established, with new tools to facilitate and accelerate approval of medicines in emergencies, building on experiences during COVID-19
- Importance of preparedness: ETF will be key to lead and coordinate activities for future emergencies
- ETF has important links to Clinical Trial Regulation to support clinical trials sponsors and facilitate large multinational studies with higher quality results
- Mandate provides for improved collaboration and coordination across stakeholders and EU Agencies, DG HERA, clinical trials groups (CTCG, CTAG) and ECDC
- Better preparedness and response to emergencies guarantee protection of public health in the EU and globally.

Manuela Mura (EMA Biological Health Threats and Vaccines Strategy) explained how the new mandate legally established the ETF as a support body advising on medicines for public health emergencies which is independent from the scientific committees of the Agency. Outside public health emergencies, the ETF also has an important preparedness role to enable proactive decision making and allow better preparation of the EU for the next crisis.

So far, crisis-related regulatory activities were led by a dedicated expert group, the EMA Pandemic Task Force, which has been operating since 2009 and led the Agency's crisis response in the context of H1N1v, Ebola and Zika as defined by EMA's Health Threat Plan (3) and Decision 1082/2013/EU on cross-border health threats (3). During the pandemic the taskforce's activities were broadened to better address COVID-19 specificities. It became a forum of discussion on the rolling data assessment and ensured a thorough and timely assessment of COVID-19 treatments and vaccines.

Building on the experiences gained during COVID-19, the activities of the taskforce have not only been formalised but also strengthened. The process for scientific advice has been streamlined, and with the new mandate rapid scientific advice will become the norm for clinical trials of medicines with a potential to address a public health emergency. Rapid scientific advice will be free of charge and according to a 20-day timetable.

During the pandemic, the taskforce was an important forum providing recommendations to reduce the use of medicines without sufficient evidence and to increase safe and harmonised use of medicines across the EU. Examples are the reviews on the use of ivermectin (4) and hydroxychloroquine (5) for COVID-19 infection. Under the new ETF these types of reviews will be systematically carried out. ETF will also improve access to medicines in public health emergencies by systematically screening evidence on medicines in the pipeline to prepare for potential marketing authorisation applications. As it did during the pandemic, ETF will also continue to provide recommendations or position statements on scientific or public health matters related to the emergency. In terms of clinical trial conduct, experience during the COVID-19 pandemic revealed fragmentation of investigations and disparity in requirements and timelines at the national level. ETF will have a role in coordinating the provision of scientific advice to sponsors and in facilitating larger multinational clinical trials, providing scientific support to sponsors on establishing joint clinical trials and sponsor agreements together with national regulators and other bodies responsible for clinical trial authorisation. The goal of these activities is that they will further facilitate clinical research and the generation of timely and robust evidence on the quality, safety and efficacy of medicinal products.

The work of the ETF will be facilitated by real-world evidence gathered through Data Analysis and Real World Interrogation Network (DARWIN EU®) which will provide the necessary data on the use, safety and efficacy of medicines. It will support the ETF to address specific questions by carrying out high-quality, non-interventional studies, including developing scientific protocols, interrogating relevant data sources and interpreting and reporting study results.

A new vaccines monitoring platform (a network set up by EMA and ECDC to coordinate and oversee EU funded studies) will coordinate independent monitoring studies on use, and provide necessary data on effectiveness and safety of vaccines.

The composition for the ETF is multidisciplinary, based on expertise. The composition can be adapted after the declaration of an emergency or during an emergency to better focus on the specificities of the crisis. At the end of a crisis, emergency-specific membership will be revised to adapt to preparatory measures. If a new emergency occurs whilst one is ongoing, new or ad-hoc members may be included depending on the nature of the new threat.

The new ETF has become operational and took over from the current EMA pandemic taskforce after its formal establishment in mid-April.

ETF will have links with the MSSG and the medical device panels. It will also coordinate activities with relevant EU bodies, including DG HERA, ECDC as well as international bodies, in order to improve preparedness, global harmonisation of regulatory decisions and support for developers.

Outside of a public health emergency, ETF will lead regulatory activities during outbreaks of emerging pathogens that could become serious threats, provide scientific advice on, and develop strategy and requirements for medicines with potential to address future emergencies and maintain an overview of medicines in development for future emergencies, and up-to-date information on potential bioterrorism agents.

An important aspect is transparency, and the increased requirements on transparency that were applied during COVID-19 will continue for any public health emergency.

In conclusion, ETF will become a permanent structure with an important preparedness role. Collaboration and cooperation with stakeholders and the network are key for the new ETF to carry out its mission to protect EU citizens during public health emergencies.

Panel expert Tour de Table

Manuela Mura (EMA Biological Health Threats and Vaccines Strategy), Aleksandra Dacić-Pilčević (EMA Head of Customer Advocacy and Delivery), Florian Schmidt (EC Deputy Head of Unit SANTE B5 - Medicines: policy, authorisation and monitoring), Lucia Pastore Celentano (ECDC Head of Programme, Vaccine-Preventable Diseases), Martin Huber (PRAC member), Mair Powell (VWP Chair and IDWP member) and Ann Marie Janson Lang (CTAG and CTCG member) contributed to the discussion which provided more details on the scope of ETF responsibilities.

Session 3: Coordinating expert panels on high-risk medical devices and in vitro diagnostics

Co-chairs: Alexis Nolte (EMA Head of Human Medicines Devices), Anna-Eva Ampelas (EC Head of Unit SANTE B6 - Medical devices and HTA)

Key messages:

- From 1 March 2022, EMA provides the secretariat for the 'EU Expert Panels' that support and advise on the scientific assessment of certain MDs to ensure their safety. Until then, the secretariat had been run by the European Commission's Joint Research Centre (JRC) which had established relevant tools, databases and guidance documents and provided training to experts concerning the legal mandate of consultations and their practical aspects.
- EU Expert Panels were set up by JRC and SANTE as an outcome of the new Medical Devices Regulation (MDR) to improve safety and performance of MDs and IVDs and provide a mechanism of scrutiny for stakeholders as well as transparency for patients and healthcare professionals.
- Under the new mandate, expert panel activities are under the coordination of EMA and implementation is done taking a step-wise approach.
- EMA is ideally positioned to manage EU expert panels due to its experience coordinating scientific Committees and scientific evaluations.
  - EMA's new mandate **strengthens the preparedness for public health emergencies and provides further resilience** for the availability of medical devices through its advisory role on critical medical devices.
  - EMA's coordination of the expert panels will lead to a **more integrated and synergistic approach** to the management of the scientific panels for MDs that will help improve public health protection for the entire Union.

During this session, Silvy da Rocha Dias (EMA Committees and Quality Assurance) explained that articles 106 and 48(6) of the MDR (Regulation (EU) 2017/745) (6) and IVDR (Regulation (EU) 2017/746) (7), respectively, require the EC to create expert panels. The expert panels play an important role in supporting the scientific assessment and advice in the field of MDs and IVDs.

The MDR and IVDR introduced a risk-based classification system which determines the obligations for manufacturers in order to be able to market MDs and IVDs. For high risk devices stricter requirements apply than for other lower risk medical devices. This concerns conformity assessments and monitoring procedures to ensure full compliance and traceability of MDs and IVDs, aimed at improving the safety on the market and avoiding safety issues (for example the breast PIP implant scandal).

The MDR enhanced the role of EUDAMED (European Database on Medical Devices) by outlining a range of actions including submissions and notifications in the context of expert panel consultations. EUDAMED is a database for the life cycle monitoring of medical devices which aims to enhance overall transparency in the certification process of medical devices, improving coordination between the different Member States in the EU, and to provide more visibility and traceability to patients and healthcare professionals.

The MDR and IVDR also introduced the provision for scientific, technical and clinical opinions and advice from expert panels:

- for MDs classified as class IIb or III according to Article 51 of the MDR in the framework of the clinical evaluation consultation procedure stipulated in Article 54 of the MDR; or
- for IVDs classified as class D pursuant to Article 47 of the IVDR in the framework of the expert consultation procedure outlined in Article 48(6) of the IVDR.

Importantly, the advice by the panels will be used by notified bodies involved in the conformity assessment of these devices and aims to ensure that conformity assessments of high-risk devices are based on sufficient clinical evidence and that these devices are indeed both safe and performant.

On 1 March, the coordination of the Secretariat of the Commission's expert panels on MDs and IVDs has been handed over from JRC to EMA. EMA is ideally placed to manage EU expert panels due to its experience coordinating scientific Committees for pharmaceuticals and scientific evaluations across the EU. EMA's coordination of the expert panels will lead to a more integrated and synergistic approach to the management of the scientific panels for medical devices that will help improve public health protection for the entire Union.

During the first year of the operation of the panels about 25 dossiers on high-risk devices and in-vitro diagnostics have been processed by the expert panels. This has led to 3 scientific opinions on the clinical evaluation consultation procedure and 15 views on the performance evaluation consultation procedure assessments performed by notified bodies and manufacturers.

In addition to providing opinions on the notified bodies' assessments, the panels will carry out additional advisory roles in the longer term, such as contributing to the development of common specifications for clinical evaluation of device categories, providing guidance on international standards, and contributing to the identification of concerns and emerging issues on safety and performance of medical devices.

The panels are an important tool in supporting harmonisation and standardisation of device specifications. They will:

- Provide **greater transparency** for patients and healthcare professionals on the clinical assessment done by the notified bodies.

- reinforce **the supervisory role** of the competent authorities regarding the use of these medical devices and provide, where applicable, an independent scientific opinion as a basis for the mechanism of scrutiny of high risk devices.
- Help with **developing common specifications and other relevant documents,** which will support manufacturers to standardise the quality and performance of their devices and play a relevant role in crisis preparedness during public health emergencies eg. SARS-Cov-2 IVDs (detection or quantification of SARS-CoV-2 nucleic acid and antibodies).

Panel expert Tour de Table

Round Table: Silvy da Rocha Dias (EMA Committees and Quality Assurance), Aleksandra Dacić-Pilčević (EMA Head of Customer Advocacy and Delivery), Claudius Griesinger (EC Project Leader, Medical Technology Coordinator JRC), Niall MacAleen (Director of Medical Devices, HPRA), Rob Nelissen (Orthopaedics, Traumatology, Rehabilitation, Rheumatology Expert Panel Chair), Olga Polydorou (Screening Expert Panel Chair), Matthias Niedrig (IVD Expert Panel Vice Chair) and Oliver Bisazza (MedTech Europe Director General of Industrial Policies) contributed to the discussion which provided more details on the scope of responsibilities of the panels and highlighted the importance of panels expertise, the need for the opinions to reflect the requirements of the regulation. In addition, the panels discussed the possibility of provisions to support the certification of certain niche products.

Summary and take-home messages

During this workshop, the new framework of EMA's extended mandate was presented and the impact on stakeholders discussed.

Stakeholders welcomed the new mandate as a step forward in crisis preparedness and management, with activities that arose in response to the COVID-19 pandemic now fully established in the Agency's emergency response process.

In order to ensure good, rapid and effective crisis preparedness and management, the importance of good data, for clinical trials and for shortage management, was highlighted. All stakeholders agreed that cooperation and continuous engagement are key to establishing successful crisis preparedness and management. For industry stakeholders this engagement will be in the context of the newly set up industry stakeholder group.

Both EMA and stakeholders highlighted the need for continuous engagement and transparency for the new extended mandate operations.

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