EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2025
EMA/864626/2022 **Rev. 2**
European Medicines Agency
Health Threats Department

EMA health threats plan

Endorsed by	Date
EMA Crisis Preparedness and Response Steering Group	21 February 2025
MSSG consultation	01 April 2025
EMA Executive Board	27 October 2025
Scientific Coordination Board	13 October 2025

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Table of contents

List of abbreviations

AMR:	Antimicrobial resistance
BCP:	Business Continuity Plan
CEPI:	Coalition for Epidemic Preparedness Innovations
CMD(h):	Coordination Group from Mutual Recognition and Decentralised Procedures – Human
CHMP:	Committee for Medicinal products for Human Use
DG SANTE:	EC Directorate General for Health and Food Safety
EC:	European Commission
ECDC:	European Centre for Disease Prevention and Control
EMA:	European Medicines Agency
EFSA:	European Food Safety Authority
EPL:	EMA Product Lead
EU:	European Union
ETF:	EMA Emergency Task Force
EWRS:	Early Warning Response System
GMP:	Good Manufacturing Practice
DG HERA:	EC Directorate General for Health Emergency Preparedness and Response
HC:	Health Canada
HSC:	Health Security Committee
ICMRA:	International Coalition of Medicines Regulatory Authorities
IDWP:	Infectious Diseases Working Party
IHR:	International Health Regulations
IMP:	EU Incident Management Plan
MS:	EU Member State
OMCL:	Official Medicines Control Laboratory
PDCO:	Paediatric Committee
PIP:	Paediatric investigation plan
PHEIC:	Public Health Emergency of International Concern
PRAC:	Pharmacovigilance Risk Assessment Committee
SAG:	Scientific Advisory Group
SL:	Scientific Lead
VWP:	Vaccine Working Party
US FDA:	United States Food and Drug Administration
WHO:	World Health Organisation
WP(s):	Working Party(ies)

1. Introduction

The European Medicines Agency (EMA) is the European Union body responsible for coordinating the existing scientific resources for the evaluation, supervision and pharmacovigilance of medicinal products. An important role of the Agency is to provide regulatory support to public health decisions taken by MSs, and to streamline coordination of and contribute to scientific regulatory matters across the EU during a public health emergency.

Planning for, responding to and communicating on serious health threats is foreseen in the EU Medicines Agencies Network Strategy, which is complementary to EC initiatives in this area. In March 2022, Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 *on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices* came into force. Regulation (EU) 2022/123 sets out specific tasks for the EMA in relation to public health emergencies. The Regulation established the EMA Emergency Task Force (ETF) as advisory and support body separate from, and without prejudice to, the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the medicinal products targeting a public health emergency and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. In November 2022, a new Regulation on serious cross-border threats to health (Regulation (EU) 2022/2371) came into force repealing Decision 1082/2013/EU. It provides the framework to coordinate preparedness and response including planning to strengthen capacities for the monitoring, early warning, assessment and response to health emergencies.

In line with the above legal basis, this document lays out an **incident and crisis preparedness and management plan**, i.e. a set of structures, processes and measures foreseen by EMA to prepare for and respond to incidents and crises in the area of health threats to humans and related medicinal products. Under the One Health approach, an integrated approach with veterinary measures and medical countermeasures should be considered where relevant. Details of the Agency's preparedness activities to address public health threats, including past pandemics, are published on the EMA website.

2. Definitions

Emerging health threat: the term refers to a 'serious cross border threat to health' as specified in Regulation 2022/2371, Article 3(1), and means *a hazard of biological, chemical, environmental or unknown origin, as referred to in Article 2(1)* (of Regulation 2022/2371), *which spreads or entails a significant risk of spreading across the national borders of Member States (MS), and which may necessitate coordination at Union level in order to ensure a high level of human health protection*. In addition, for the scope of this document, nuclear and radiological events are included in the definition. An emerging health threat corresponds to an **incident** in the EMA Crisis preparedness and response Overarching framework (an issue that could have a serious impact on public health and/or could have important policy, political or reputational consequences for the Agency and/ or could lead to a serious interruption of key business activities). Where needed, the EMA scientific lead (see section 5.2) decides whether a threat represents an emerging health threat for the purpose of this document.

Public health emergency: pursuant to Regulation (EU) 2022/123 article 2(a), the term indicates a situation of public health emergency recognised by the Commission in accordance with Article 23 of Regulation (EU) 2022/2371[1]. This also applies to Public health emergencies of international concern (PHEIC) declared by WHO in line with Article 12 and Annex 2 of the International Health Regulations (IHR), which the European Commission has confirmed that it should be treated as Public health emergency within the EU. A public health emergency corresponds to a **Crisis** in the EMA Crisis preparedness and Response Overarching framework (an incident that poses a serious risk to public health or has important policy, political or reputational consequences for the Agency, or leads to serious interruptions of key business activities and requires special measures and/or urgent coordinated action at the EU or Agency-wide level (i.e., foreseen routine measures and processes are not sufficient).

Potential public health emergency: an emerging health threat (incident) that is considered to be at high risk of developing into a public health emergency. This term corresponds to '**potential crisis'** in the EMA Crisis preparedness and Response Overarching framework. Where needed, the EMA scientific lead (see section 5.2) decides whether an emerging health threat represents a potential public health threat for the purpose of this document.

[1] Article 12(1) of Decision No 1082/2013/EU has been replaced by Article 23 of Regulation (EU) 2022/2371.

One Health: a multi-sectoral approach that recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions (article 3 of Regulation (EU) 2022/2371).

Relevant medicinal products: a medicine that targets the respective emerging health threat or (potential) public health emergency, e.g. a vaccine or an antiviral against pandemic influenza or COVID-19.

Relevant medical device: a medical device used for delivery or administration of a relevant medicinal product (as defined above) or otherwise relevant in the context of use of such products; this includes in vitro diagnostics.

Relevant clinical trials and observational studies: a clinical trial or observational study which investigates a medicine that targets the respective emerging health threat or (potential) public health emergency, e.g. a trial or study investigating a vaccine or an antiviral against pandemic influenza or COVID-19.

Experts: assessors belonging to the EU Medicines Regulatory Network or external subject matter experts (e.g. scientists or academics), who possess adequate expertise on relevant medicines such as vaccines, antimicrobials, or medicines against chemical or nuclear incidents.

3. Scope

The aim of this document is to provide general guidance to EMA staff and experts to define the necessary activities of the Agency in preparation for and in response to emerging health threats and (potential) public health emergencies and to enhance coordination and efficiency of implementation. Animal health threats are excluded from the scope, except to the extent that they may pose a threat to human health. The plan builds on the experience accumulated with various biological health threats and pandemics over the years (avian influenza outbreaks, Ebola and ZIKA PHEICs and A/(H1N1)pdm09, and COVID-19 pandemics). Therefore, this set of instructions is adapted for a bio-threat, in particular a respiratory virus with pandemic potential, since this may be viewed as the most likely cause of a future potential public health threat. Notwithstanding, the principles and overall structure of the plan are deemed applicable to different acute hazards including biological, chemical, nuclear, radiological, environmental and of unknown origin.

This document should be read in conjunction with the EMA Overarching Crisis Preparedness and Response Framework. Other types of emergencies or issues not specified in this document, occurring either independently or in the context of a public health threat, are handled through different frameworks as described in the EMA Overarching Crisis Preparedness and Response Framework. For example, during a public health emergency it may become necessary to activate the Business Continuity Management Plan (BCMP) as a consequence of absenteeism, due to the public health measures put in place or of the increased workload to handle the crisis. In such case, the activities under the Health Threats Plan will run in parallel to business continuity activities under the BCMP. Management of shortages of medicines and medical devices is conducted in parallel, as needed, through activities foreseen in Chapters II and IV of Regulation (EU) 2022/123. Similarly, incidents related to quality, safety or efficacy of medicines are being addressed through the Incident Management Plan, which may be activated in parallel to the Health Threats Plan, if required.

The coordination of measures taken under different plans is ensured through measures described in EMA Overarching Crisis Preparedness and Response Framework, mainly taken at the level of the EMA Crisis Preparedness and Response Steering Group.

In case of a complex crisis situation, the EMA Crisis Preparedness and Response Steering Group may decide to adjust the structures and processes to ensure sufficiently agile decision making and execution of required actions.

4. Main objectives

The overarching objective of the plan is to facilitate and accelerate the development, authorisation, access and close monitoring of medicines targeting an emerging health threat or a potential or ongoing public health emergency. To achieve this, some or all of the following key objectives should be met. All the objectives listed are relevant not only whilst handling an emergency, but

also in preparation for an emergency, or at the onset of an incident or a crisis. However, some of the objectives become critical during a public health emergency:

- Manage and coordinate the discussions on scientific, regulatory and technical issues regarding the development, authorisation and surveillance / post-authorisation follow-up of relevant medicinal products.
- Initiate and coordinate required scientific and regulatory activities involving all relevant parties within the EMA and the European Medicines Regulatory network (i.e. EMA experts groups, National competent authorities and European Commission), involving ECDC and OMCLs as relevant.
- Provide input as needed to the European Commission, including HERA, to the ECDC, the National Competent Authorities and Public Health Authorities of the Member States, including through the Health Security Committee (HSC), the Health Crisis Board and various EU governance bodies, related to the outcomes of the review of dossiers or of information on relevant medicinal products.
- Provide appropriate support on any regulatory aspect pertaining to use of relevant investigational medicines (e.g. through scientific opinions to support national decisions on emergency use or compassionate use authorisation); provide information or recommendations to stakeholders regarding relevant medicinal products).
- Effectively communicate relevant information to stakeholders, including patients, healthcare professionals and industry, including already during the review process of relevant medicinal products.
- Provide support to and engage with international regulatory partners, stakeholders involved in research and development of relevant medicinal products and public health authorities outside of Europe, e.g. CEPI, ICMRA and WHO.

All of these activities should be undertaken in line with this plan and associated roles and responsibilities (see section 6).

5. Activities under the Plan

To facilitate the description of the activities foreseen in the plan, the following four types of situations are identified (see also definitions in section 2):

1. preparedness
2. emerging health threat,
3. potential public health emergency,
4. public health emergency.

A health threat generally emerges as an incident (e.g. a localised virus outbreak or episodic zoonotic spillover) characterised by an often unpredictable potential to evolve into a public health emergency (e.g. MERS). The pattern and rapidity of this evolution depends primarily on the nature of the threat or pathogen, for example its ability to mutate and/or spread among people and to cause severe disease and death, but it also depends on the extent and rapidity of the public health measures taken at the onset. In some cases, it may be possible to anticipate if the emerging health threat is potentially likely or highly likely to evolve rapidly into a public health emergency. This could be the case for example for the H5N1 avian influenza virus outbreaks or the Ebola outbreaks. A heightened status of alert and cross-agency coordination/cooperation should be considered for emerging health threats that represent potential crises.

Since the mandate of the EMA includes also preparedness activities for future and unknown health threats (article 15 of Regulation (EU) 2022/123), and since some or all of the four types of situations described above may co-exist due to different threats happening at the same time, the health threat plan does not require a specific trigger to become operational but it has a continually active status of operation. The plan represents an armamentarium of activities that are run in parallel as applicable, with the necessary adaptations depending on the situation.

5.1. Preparedness

The Agency undertakes the following as part of preparedness activities to ensure that EMA will be in a position to deal with an emerging health threat and to prevent (emerging) health threats to materialise as much as possible, with focus on identified high priority threats:

- Monitoring carried out by the Agency in accordance with Article 4(1) of Regulation (EU) 2022/123 and information from relevant entities, such as ECDC, EC and WHO regarding emerging threats or pathogens and their epidemiological situation. Through the ETF: monitoring outbreaks and epidemics, which have the potential to become public health emergencies; gathering information on relevant medicines under development; advancing regulatory science, providing guidance and optimising regulatory processes for health threats.
- Scientific and regulatory activities in relation to relevant medicinal products in development, such as scientific advice, paediatric investigational plans or orphan designations, and post-authorisation activities; scientific and regulatory support to relevant investigational clinical trials and observational studies (and related networks).
- Any other necessary interactions between the ETF, the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), CHMP and its Working Parties/Groups, as well as CMD(h).
- Regular or ad hoc interactions with the European Commission (DG SANTE, the Health Emergency Preparedness and Response Authority (HERA), Civil Protection and Humanitarian Aid Operations (DG ECHO) and DG for Research and Innovation (DG RTD)), the Health Security Committee (HSC, a working group on health security at European level), the European Centre for Disease Control and Prevention (ECDC), the European Environment Agency (EEA), the European Chemicals Agency (ECHA), and the European Food Safety Authority (EFSA).
- Regular interaction with EU MSs, the Commission and the ECDC including through the Early Warning and Response system. EWRS is the informatics tool designed by the European Commission and the Member States allowing the notification and the information sharing of health measures planned or undertaken against serious cross border health threats. More information on the activities of EMA linked to EWRS are described in the relevant document.
- Regular interactions with stakeholders, including industry.
- Regular interactions with international partners such as WHO, FDA and Health Canada, including though ICMRA.

Preparedness activities are handled by several departments within the Agency, based on established roles and responsibilities. The activities related to the work of the ETF, including monitoring of health threats, are led by the Department of Public Health Threats together with the relevant therapeutic area and are coordinated through the Therapeutic Response Group (the TRG, which is a discussion and coordination group described in section 6.3) in collaboration with relevant offices and departments in the Human and Veterinary Medicines Divisions and with the EMA Crisis Response Manager and Lead.

5.2. Emerging health threat

Any identified emerging health threat will be followed up by the Agency since its onset, regardless of whether it will lead or not to formal emergency declarations by official bodies (see section 5.3). The amount and type of activities to be conducted beyond preparedness are based on the scientific evaluation of (re)emerging or ongoing outbreaks. The Head of Department of Public Health Threats (AF-HT) is responsible for such decision, and (s)he is thus nominated as the Scientific Lead for the activities related to the (emerging) health threat.

The Scientific Lead (SL) represents the focal point of contact within EMA for any emerging health threat and until a status of public health emergency is confirmed. The SL is also responsible to identify and flag potential crises to the EMA Crisis Preparedness and Response Steering Group to ensure the Agency's preparedness. The SL shall work in close collaboration and consultation with the heads of relevant therapeutic area offices (e.g. Office of vaccines and therapies for infectious diseases (H-TA-INF) in case of biological health threats, or Offices of Oncology [H-TA-ONC], Advanced therapies and haematology [H-TA-ATH] and Pharmaceutical Quality Office [H-QS-QUA] for a radiological or nuclear event). For biological health threats, this work is carried out by the SL with the support of the Therapeutic Response Group (TRG, see section 6.3), which includes relevant

members of the AF-HT Department, the H-TA-INF Office and the Regulatory Affairs Office (H-QA-REG). See section 6.3 for more details on how this group operates.

As the health threat evolves, the EMA ETF (see section 6.5) will be kept informed by the Scientific Lead of the main activities conducted in accordance with table 1, as considered relevant. The scientific lead is normally also the EMA co-chair of the ETF. The SL will also keep informed the EMA scientific Committees and EU experts' network at regular intervals as relevant. The ETF will discuss product development plans and regulatory pre- or post-authorisation activities to support the decisions of the Committees.

As per Article 20 of Regulation (EU) 2022/2371, EMA may be requested to conduct or contribute to a risk assessment on an emerging or developing serious cross-border threat to health. The process for coordination and preparation of such risk assessment is outlined in the relevant document.

5.3. Potential public health emergency

If an emerging health threat has been identified as a potential crisis, it continues to be addressed as described in section 5.2. , but in addition is also monitored by EMA Crisis Preparedness and Response Steering Group, who can also decide on additional non-routine actions that may be warranted and may provide strategic guidance on incident response based on the principles described in the EMA Overarching Crisis Preparedness and Response Framework.

5.4. Public health emergency

Based upon specific criteria, the European Commission (EC) is responsible for the legal recognition of a public health emergency in the EU. This may take place as follows:

- Determination of a public health emergency in the EU through a Commission Decision as per Art. 23 of Regulation 2022/2371.
- Confirmation that the declaration of Public Health Emergency of International Concern declared by WHO should be regarded as a public health emergency in the EU.

Once a public health emergency is recognised, and as necessary during the time leading to it, the EMA Crisis Response Lead (see section 6.2) will take over the overall coordinating responsibility within the EMA, and (s)he should be kept informed of all international, institutional and scientific developments relating to the emerging health threat and the (potential) public health emergency. The SL will continue to lead the scientific activities as co-chair of the ETF.

It is expected that the frequency of the ETF and TRG meetings will intensify to cope with the increased number of activities and procedures (scientific advice, meetings with manufacturers, regulatory applications, discussions with stakeholders). Based on past experiences, the ETF may need to meet up to 3 times per week and the TRG weekly. The decision to pool additional resources to the crisis response activities or to create new groups will be evaluated by the EMA Crisis Preparedness and Response Steering Group.

The scientific activities are centred at the level of the ETF, which will provide rapid support to the scientific Committees and will assess the need to publish statements or scientific positions as per its mandate. Generally, support to the ETF is provided by the AF-HT, but other offices can be heavily involved, especially H-TA-INF and H-QS-QUA, as well as other therapeutic areas depending on the nature of the emergency (e.g. H-TA-IMM during COVID-19, and H-EG-PME for aspects related to paediatric development plans). Special crisis rules apply during public health emergency to regulatory procedures and communication to stakeholders and the public, developed based on past experience, best practices and applicable legal provisions. These are outlined in Annex 1.

5.5. Post emergency review

Following closure of the public health emergency it is important to conduct a "lessons learned" exercise. This should describe what was done well and does not need to be changed and also cover aspects that were not handled well and may need to be

changed or improved. The Crisis Preparedness and Response Steering Group serves as the central forum to discuss these matters and identify ways of improving the emerging health threat plan. The activities linked to the lessons learned exercise are coordinated by the EMA Crisis Response Lead with involvement of the Therapeutic Response Group.

Lessons learned exercises can also be conducted outside crisis situations, for example for emerging health threats or potential crises, in which case it is led by the Scientific Lead and his/her team.

6. Roles and Responsibilities

The following EMA designated entities, including specific teams and expert groups will be the main contributors to the therapeutic response during preparedness, incidents and crisis situations.

6.1. Executive Steering Group on Shortages and Safety of Medicinal Products

(Gold level – strategic, EMRN-wide)

Regulation (EU) 2022/123 introduced a reinforced role for EMA in crisis preparedness and management for medicinal products and medical devices. One of the objectives of the Regulation is to monitor and mitigate potential and actual shortages of medicinal products considered critical in order to address a given public health emergency or other major event(s), which may have a serious impact on public health. For this purpose, an executive steering group, the EMA MSSG, which is formed by representatives of EU MSs, EC and EMA, is tasked to ensure a robust response to major events and/or public health emergencies, and to coordinate urgent actions within the Union in relation to the supply of medicinal products or issues related to the quality, safety and efficacy of medicinal products. As the most senior group in the EU Medicines regulatory Network for crisis response, the group also agrees on actions required for EMRN-wide response to the crisis, e.g. in relation to a network-wide business continuity measures or coordination of application of crisis-appropriate available regulatory flexibilities (e.g. based on approaches to regulatory flexibility described in MSSG Toolkit on recommendations on tackling shortages of medicinal products).

The crisis phase of the work of the MSSG will be triggered by the recognition of a public health emergency or the recognition of a major event (see Regulation (EU) 2022/123 for definition of major event). Details of the MSSG activities are reflected in the MSSG Rules of Procedure.

In preparation for and during major events and/or public health emergencies, and as needed also during potential crises, the MSSG is kept up to date by the SL about the therapeutic response against the health threat, including the activities of the ETF. The MSSG may in turn consult on specific matters with the EMA scientific Committees, their working parties, other expert groups including the ETF and/or the CMDh.

Following the recognition of a public health emergency or major event, the MSSG will consider information on the quality, safety and efficacy of medicinal products in the context of said emergency or major event and discuss the need of urgent and coordinated action at Union level.

6.2. EMA Crisis Preparedness and Response Steering Group

(Gold level - strategic, EMA internal)

The EMA Crisis Preparedness and Response Steering Group is composed of the Executive Director (ED), the Deputy ED (DED), relevant EMA senior management and selected staff members depending on the nature and stage of the crisis. It is chaired by the EMA Crisis Manager and supported by the EMA Crisis Response Lead.

The group is convened whenever an incident is being escalated to a potential crisis or to a crisis and thereafter meets regularly at a frequency agreed by the group or as indicated by the EMA Crisis Manager, until the incident is no longer considered as (potential) crisis and post-crisis lessons learned, if applicable, have been finalised.

In context of a crisis, the group provides a strategic steer on evolving scientific, regulatory and communication challenges related to the emergency, performs monitoring of the EMA and EMRN response to crises, ensures adaptation of the business continuity plan as needed and oversees the review and reporting of lessons learned from crisis events. The EMA Crisis Preparedness and Response Steering Group is assisted by the EMA Crisis Response Lead, the Scientific Lead, or members of the TRG, and as needed also by other operational staff depending on the situation and the need. Other aspects of their role are covered in the Overarching Crisis Preparedness and Response Framework.

6.3. Therapeutic Response Group

(Silver level – tactical, EMA internal)

The Therapeutic Response Group (TRG) is composed of the following core functions: the Scientific Lead and relevant staff members of the Public Health Threats Department (AF-HT), the EMA Crisis Response Lead and the Head and relevant staff member(s) of the relevant Therapeutic Area Office, generally H-TA-INF, and of the Regulatory Affairs Office (H-QA-REG). It is led by the SL (AF-HT Head of Department) with the support of the Head of Office from the relevant Therapeutic Area. The TRG composition above mentioned is specific for a biological health threat, therefore it may require adaptation depending on the nature of the crisis, e.g. different therapeutic areas or veterinary medicines functions may need to be involved on a case-by-case basis. The TRG reports to the Crisis Preparedness and Response Steering Group during a (potential) public health emergency, and to the SL or Head of AF-HT during preparedness and emerging health threats.

The TRG has the role to manage preparedness, emerging health threats and to address tactical aspects of therapeutic response to public health emergencies under the lead of the SL.

The TRG remains active throughout preparedness to coordinate relevant activities and advances in scientific regulatory paths and approaches for future emergencies. Furthermore, the group has an important role in discussing emerging health threats to initiate and coordinate relevant activities in a timely manner. The SL is responsible for cascading down to the TRG the strategic orientation obtained at the gold level (especially in case of (potential) public health emergencies) and for reaching tactical and operational decisions with the support of the relevant TA Head of Office. During preparedness and to handle emerging health threats, the need to involve operational entities outside of the TRG core members is evaluated by the SL on a case-by-case basis. The Workstream of Supply and Availability of Medicines and Devices (TRS-SAM) are kept informed if a considerable impact on supply or demand of medicines in the EU is anticipated.

During a potential public health emergency, the TRG remains the centre of scientific activities coordination under the Scientific Lead. The SL maintains the oversight of the scientific support activities throughout the duration of a public health emergency including on scientific interactions with stakeholders and partners. During (potential) public health emergencies, specific expertise from other offices shall be identified and involved as required based on need or on the nature of the emergency, e.g. the Pharmaceutical Quality Office, Inspections Office, Paediatric medicines and Scientific Advice, Pharmacovigilance Office and EMA International Affairs. The additional staff members may need to attend the TRG meetings or may provide scientific/regulatory support to facilitate the group's operations. The EU Institutional Liaison Team (part of Institutional and Policy Department) will be involved in the activities of the TRG as needed based on the extent of cooperation and interaction with EU institutions.

The SL and the members of the TRG will work in close liaison with the experts of the EU network represented in the ETF and with the Committees of the EMA (CHMP, PRAC, PDCO as needed), as well as their working parties and groups.

In case of a complex crisis situation the Crisis Preparedness and Response Steering Group may decide to amend the composition and naming of the TRG (e.g. if several tactical groups have to be established separately for public health response and other aspects of the crisis, or in case several crisis of a different nature hit at the same time, e.g. biological and nuclear threats).

6.4. Overview of EMA staff member responsibilities

The table below summarises some of the key responsibilities under the Health Threat Plan across all situations.

Table 1. Summary of activities by the relevant EMA entity

EMA Crisis Response Lead	AF-HT Head/Department	Therapeutic area Head/Office
Organises meetings of the Crisis Preparedness and Response Steering Group	Monitors (re)emerging health threats Organises TRG and ETF meetings Organises interactions on relevant medicines with internal and external stakeholders such as industry outside of specific pre/post-authorisation procedures	Organises authorisation and procedure-related interactions with internal and external stakeholders such as industry, SAGs and Rapporteurs for evaluation activities
Coordinates adequate Agency input / drafting of briefings and summaries of outcomes from the meeting of Crisis Preparedness and Response Steering Group	Drafts content of briefings (scientific outcomes, ETF minutes, TRG minutes, ETF statements) Ensures adequate information flow through experts' groups and relevant WPs, if needed in addition to the ETF	Manages all authorisation procedures (rolling reviews and standard) Ensures adequate information flow through committees
Coordinates crisis response activities (e.g. response to requests from EU bodies) that require involvement of several EMA functions*	Ensures periodic briefing of Steering Group and other governance and scientific bodies (e.g. MSSG, CHMP)	Ensures periodic briefing of MLT (Product specific scientific issues)
Coordinates dissemination of information to relevant groups and functions*	Ensures adequate review of health threat progression and internal dissemination of situation and scientific updates using information from ECDC/EC/WHO etc. Act as key spokesperson for external communication	

*Unless already performed by involved function(s)

6.5. Expert groups

The key expert group dealing with public health emergencies, emerging health threats as well as preparedness is the EMA Emergency Task Force (ETF) established by article 15 of Regulation (EU) 2022/123. As per Regulation (EU) 2022/123 and in line with its Rules of Procedures, the ETF is mandated to:

- provide scientific advice to developers of medicinal products, e.g. vaccines/ antimicrobials, against the emerging health threat;
- provide scientific support to the EMA scientific committees on product-related assessment and post-authorisation surveillance activities for relevant medicines;
- provide scientific support to facilitate relevant clinical trials conduct in collaboration with other groups such as the Clinical Trials Coordination Group (CTCG) and the Clinical Trials Advisory Group (CTAG), EU MSs authorities and other EU governance bodies;
- review available evidence and prepare specific positions / input and recommendations with regard to the use of medicinal products which have the potential to address public health emergencies (including jointly with ECDC);

- liaise with expert panels on relevant medical devices as necessary. The expert panels should flag to ETF for discussion any topic that falls under its remit.

A full list of activities of the ETF is included in the Rules of the Procedure. The remit of the ETF is limited to specific pathogens and health threats, which are listed in the Annex of its working plan.

In addition, the EMA working parties have a prominent role in specific areas, such as the Biologics Working Party (BWP) and the Quality Working Party (QWP) for quality issues related to medicines targeting a health threat. The Non-clinical Working Party (NcWP), the VWP, the IDWP and the Methodology Working Party (MWP) may closely interact with the ETF to support the provision of scientific guidance or scientific advice for developers. These interactions are not dependent on the type of emergency and are established by the Rules of Procedure of each group mentioned.

Other operational expert groups under the clinical domain such as the Scientific Advisory Groups (SAGs) may be convened to further assist the ETF, CHMP, PRAC and PDCO. The role of SAGs as external expert advisory groups to the CHMP on specific questions shall apply to both emergency and preparedness situations. More operational details are reflected in the Role and mandate of the Scientific Advisory group.

6.6. Overview of roles and activities under the plan

Table 2 below presents a schematic overview of the extent of activities envisaged in the EMA health threat plan during preparedness, emerging health threats and (potential) public health emergencies.

Table 2. Situation and associated activities

Situation	Groups involved*	Activities
PREPAREDNESS	SL, TRG and ETF	Scanning of information from various sources and entities on (re)emerging pathogens and other threats under the ETF remit; support to product development; development of regulatory paths and networks to prepare for future incidents and crises horizon scanning for medicines in development Additional activities may be agreed ad hoc (e.g. on communication, engagement with partners and stakeholders), depending on the needs identified
EMERGING HEALTH THREAT *Incident or outbreaks reported.* *Risk to evolve into a crisis (i.e. potential crisis)* *Possible high public health impact outside EU* (e.g. AMR, MERS-, ZIKA-, Ebola- or H5N1-like scenario)	SL and TRG ETF Crisis preparedness and response steering Group (for potential crises only)	Outbreak monitoring and identification of medicines in development or authorised that could tackle the emerging threat ETF activities on the specific pathogens or threats start or are intensified Crisis Preparedness and response steering group and MSSG kept informed by SL as required Additional activities may be agreed ad hoc (e.g. on communication, engagement with partners and stakeholders), depending on the needs identified Activities of ETF such as recommendation for use of certain medicinal products could occur even before there is a EU or WHO declared emergency, when the situation is rapidly deteriorating and requires rapid public health interventions

Situation	Groups involved*	Activities
PUBLIC HEALTH EMERGENCY Moderate/high impact on the EU public health (e.g. H1N1v/Monkeypox (2022)-like scenario). Public health in the EU severely impacted (e.g. COVID-19-like scenario)	Crisis Preparedness and Response Steering Group TRG, AF-HT and Therapeutic Areas Offices Additional staff depending on need and the nature of the emergency EMA ETF, scientific committees, relevant working parties and SAGs MSSG**	Rolling reviews and other exceptional measures to support accelerated authorisation of medicines, rapid scientific advice and PIP decisions Frequent ETF meetings and, if needed, ad hoc Committee meetings. Intensive review of all available information by the ETF, possible ETF recommendations (see Annex 1) Relevant interactions between ETF and MSSG including on monitoring of critical medicines and shortages by MSSG Agency activities reprioritised to focus on the crisis, BCP may be activated Additional activities agreed at the Crisis Preparedness and Response Steering Group, e.g. on communication, engagement with partners and stakeholders

NOTES: *for more information on the different groups see section 6

**The ETF will liaise with the MSSG on matters related to quality, safety and efficacy of critical medicines, which includes contributing to the review of the list of critical medicines in accordance with Article 6(3) of the Regulation (EU) 2022/123.

7. Procedural and regulatory adjustments during crisis

During public health emergencies, the Agency can implement faster timelines and exceptional accelerated procedures for rapid approval of medicines targeting the emergency, in full respect of legislative requirements including the standards of quality, safety and efficacy of medicines.

Specific procedures have been set up to accelerate assessment and authorisation of medicines during public health, which are only applicable during a public health emergency:

- for rapid scientific advice of products in development including on clinical trial protocols as specified by Regulation EU 2022/123;
- for fast-track approval of medicines via the centralised procedure, including rolling review of medicines targeting a public health emergency;
- for post-authorisation follow-up of centrally authorised products, e.g. review of emerging data on safety and efficacy;
- flexible and rapid case-by-case approval of Paediatric investigational Plans (PIPs) and compliance checks.

See Annex 1 for more details.

Regulatory and GMP flexibilities may be considered as required for the response to public health emergencies. Such measures can be agreed by the MSSG and may be based on approaches to regulatory flexibility described in MSSG Toolkit on recommendations on tackling shortages of medicinal products.

7.1. Pharmacovigilance during public health emergencies

Pharmacovigilance activities for medicinal products addressing a public health emergency should build on tools and processes already in place in the well-established pharmacovigilance system of the EU Regulatory Network, while also considering the specific circumstances imposed by the given public health emergency.

The Pharmacovigilance Plan of the EU Regulatory Network for COVID-19 Vaccines can serve as a model for similar cases of a public health emergency.

7.2. GMP Inspections

During public health emergencies, national and international restrictions may affect and/or prevent the conduct of certain required on-site GMP inspections and therefore EMA will confer with the supervisory authority to establish the information needed to verify the GMP compliance of manufacturers. It may be possible to implement the following measures in lieu of on-site inspection to verify compliance to approve the MAA:

- Desktop assessment making use of GMP compliance information provided by international regulatory authorities.
- Distant assessment of the manufacturing facility.
- Hybrid inspection in conjunction with a local inspectorate.

Based on these methods of verification, the supervisory authority may issue a GMP Certificate to cover the manufacture of the relevant medicinal product to finalise the assessment within the accelerated timetable. On-site inspections by an EEA authority should be conducted as early as possible according to risk-based inspection planning, taking into account any restrictions. See also Guidance related to GMP/GDP and PMF distant assessments.

7.3. GCP inspections

During crisis situations, on-site inspections may not be possible due to multiple factors such as difficulties and restrictions related to travelling between and within the borders of countries (including travel warnings / restrictions, border controls, transportation difficulties), restrictions to accessing facilities justified by health hazards and local authorities' recommendations / orders, as well as additional health and/or safety risks for inspectors and inspectees.

Information on inspection history and GCP compliance will be shared among international regulatory authorities and will be taken into account when deciding on the need for inspections.

To enable the continuity of GCP inspections requested by the Committee for Medicinal Products for Human Use (CHMP), the following document provides guidance on conducting GCP inspections remotely during crisis situations: Guidance on remote GCP inspections during public health threats emergencies and crisis situations.

8. Communication, stakeholder and public engagement

The Agency maintains communication and engagement with its stakeholders (including patients, consumers and healthcare professionals) through established platforms (PCWP[2], HCPWP[3]), during preparedness and health emergencies. Representatives from patients, consumers and HCP organisations are standing members of the ETF.

A detailed description of how EMA communicates during a crisis is included in EMA's crisis communication plan.

EMA's transparency measures for medicines addressing a public health emergency are described under the 'Transparency during public health emergencies' section on EMA's website. They apply to EMA's activities in relation to the development, evaluation and supervision of medicinal products addressing a public health emergency. In many cases, the measures mirror standard procedures already in place for all medicines. However, due to the high public interest, timelines are often shortened and expected additional information is made available for medicines that address or have the potential to address a public health emergency.

[2] Patients and Consumers Working Party (PCWP)
[3] Healthcare Professionals Working Party (HCPWP)

9. Interactions with partners

9.1. European Union and its Member States bodies

Based on article 7 of the ECDC extended mandate (Regulation (EU) 2022/2370), EMA can request to the ECDC a scientific opinion on matters falling within its mission.

Based on article 11 of said regulation, the EMA can request the ECDC to make available epidemiological forecasts in situations of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States. EMA may for instance request such forecasts when they are necessary for ETF or MSSG activities.

EMA and the ECDC coordinate independent, post-marketing monitoring studies of the effectiveness and safety of vaccines through the vaccine monitoring platform[4]. These activities support the work of the ETF during public health emergencies.

Interactions with other stakeholders include but are not limited to: the European Commission[5] (in particular Health Emergency Preparedness and Response Authority (HERA) and DG Sante), HSC, ECDC, National Immunisation Technical Advisory Groups (NITAGs), CTCG, CTAG.

When the Agency publishes on its web portal information regarding medicinal products that the ETF considers having the potential to address public health emergencies, the Agency informs Member States and the HSC, as appropriate, of any such publication without undue delay and, in any case, prior to such publication[6].

European Commission (DG SANTE and DG HERA) and ECDC attend meetings of the ETF, as appropriate. EMA cooperates with DG HERA on horizon scanning of relevant medicines.

9.2. International partners

Interactions with international regulators, e.g. US FDA and HC, and public health authorities, such as WHO, occur on a regular basis during preparedness and are intensified during emergencies.

The International Coalition of Medicines Regulatory Agencies (ICMRA) has a key role to involve Health Regulatory Authorities in the management of global health crisis in a coordinated and consistent manner, by identifying the possibilities for international collaboration and cooperation, including on harmonisation of regulatory requirements.

10. Annex 1

Acceleration of regulatory procedures

[4] As per Article 5(a) of Regulation EU 2022/2370 and Article 20(b) of Regulation EU 2022/123
[5] https://health.ec.europa.eu/index_en
[6] As per Article 15(9) of Regulation EU 2022/123