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SCIENCE MEDICINES HEALTH

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EMA plan for emerging health threats

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List of abbreviations

ARs:	Assessment reports
BCP:	Business Continuity Plan
CMD(h):	Coordination Group from Mutual Recognition and Decentralised Procedures – Human
CHMP:	Committee for Medicinal products for Human Use
DG SANTE:	EC DG Health and Food Safety
EC:	European Commission
ECDC:	European Centre for Disease Prevention and Control
EMA:	European Medicines Agency
EFSA:	European Food Safety Authority
ENS:	Early Notification System
EPL:	EMA Product Lead
EU:	European Union
ETF:	EMA Task Force
EWRS:	Early Warning Response System
FDA:	Food and Drug Administration
GMP:	Good Manufacturing Practice
GVP:	Good Pharmacovigilance Practice
HC:	Health Canada
HSC:	Health Security Committee
IDWP:	Infectious Diseases Working Party
IMP:	EU Incident Management Plan
IRN:	Incident Review Network
MS:	EU Member State
OMCL:	Official Medicines Control Laboratory
PDCO:	Paediatric Committee
PIP:	Paediatric investigation plan
PM:	Procedure Manager
PRAC:	Pharmacovigilance Risk Assessment Committee
PSUR(s):	Periodic Safety Update Report(s)
RMP:	Risk management plan
SAG:	Scientific Advisory Group
SAWP:	Scientific Advice Working Party
SL:	Scientific Lead
SOP:	Standard Operating Procedure
VWP:	Vaccine Working Party
US FDA:	United States Food and Drug Administration
WHO:	World Health Organisation
WP(s):	Working Party(ies)

1. Introduction

Planning for, responding to and communicating on serious health threats is foreseen in the [EU Medicines Agency Network Strategy to 2020](#) and is complementary to ongoing [EC initiatives](#) in this area. At EU level, [Decision 1082/2013/EU](#) on serious cross-border threats to health provides the framework to coordinate preparedness and response planning to strengthen capacities for the monitoring, early warning, assessment and response to health emergencies. For the purposes of this document, the term 'emerging health threat' refers to 'cross border health threat' (as per the above Decision) and means *a hazard of biological, chemical, environmental or unknown origin which is likely to spread across national borders of Member States (MS) and which may cause a potential severe risk to public health necessitating a coordinated action at the Union level in order to ensure high level of human health protection*. Public health emergencies of international concern are also included as serious cross-border threats to health by the EU legislation, and in addition international emerging health threats are in principle covered by the plan.

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources for the evaluation, supervision and pharmacovigilance of medicinal products. This document explains the principles upon which the Agency will operate in the event of an emerging health threat to humans, and describes high level process, responsibilities and desired outcomes. It thus relates to human medicinal products; however, in case of need, interactions will take place with the Veterinary Medicines Division of the Agency.

An important role of the Agency is to provide regulatory support to public health decisions taken by MSs, and to streamline coordination of scientific regulatory matters across the EU during an emergency.

The health threat plan is based on the Agency's Pandemic Plan (published in 2006) and on the experience from the 2009 influenza H1N1 pandemic, however it has been redefined in order to be applicable to various acute hazards as per EU legislation (see above) and following experience gained in emergencies such as the Ebola outbreak in Western Africa in 2014-2016. The Agency published in 2011 [lessons learnt](#) from the 2009 H1N1 pandemic. Other documents related to the Agency's [pandemic](#) preparedness are published on the EMA website. In parallel to the current revision of the plan, EMA has implemented improvements to different areas and procedures to reflect the lessons learned (see section 3.4).

2. Preparedness prior to an emerging health threat

The Agency undertakes the following as part of routine preparedness activities to ensure that it will be in a state of readiness to deal with an emerging health threat:

- Regular interactions with vaccine/antimicrobials experts and the regulatory network via Working Parties/Groups of the CHMP and CMD(h);
- Activities in relation to products in development, such as scientific advice or orphan designation of medical countermeasures;
- Regular interactions with the European Commission, the Health Security Committee ([HSC](#), an advisory group on health security at European level), the European Centre for Disease Control and Prevention ([ECDC](#)) and European Food Safety Authority ([EFSA](#));
- Regular interaction with EU MSs through the Early Warning and Response system set up by the [EC](#) ([EWRS](#)). 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;

- Regular interactions with industry;
- Regular interactions with international partners such as WHO, FDA and Health Canada.

3. The EMA health threat plan

3.1. Scope

The aim of this plan is to provide internal general guidance on EMA activities during a health threat. This and associated documents are drafted based on the experience gathered from what may be viewed as the most likely cause of an emerging health threat, i.e. a biological health threat and in particular a pandemic influenza, and as such incorporates any existing systems/processes which might be utilized during such a crisis. However the overall plan has been redefined in order to be applicable to various acute hazards including threats of chemical, environmental and unknown origin.

The health threat plan is not intended to be triggered by product related issues, which should be handled through the EU Incident Management Plan (IMP) and the operations of the Incident Review Network (IRN) that deal with product specific incidents.

3.2. Main objectives

Overall the aim of the health threat plan is to meet the following key objectives, which however may or may not be all immediately applicable, based on different scenarios (see also sections 3.3 and 4.2):

- Initiate and coordinate scientific and regulatory activities by involving all interested parties within the EMA and the European Medicines Regulatory network (i.e. EMA experts groups, National competent authorities and European Commission), including ECDC and OMCLs as relevant.
- Manage and coordinate the discussions on development, authorisation and surveillance of relevant medicinal products (e.g. vaccines and antivirals for pandemic influenza), which are under the remit of EMA, and post-authorisation follow-up of all relevant EU authorised medicinal products to be used to address the health threat.
- Provide to the European Commission, the National Competent Authorities, Public Health Authorities of the Member States, and ECDC the outcome of the review of dossiers (e.g. pandemic influenza vaccines and influenza antivirals in case of pandemic influenza) and appropriate support on any regulatory aspect as needed (e.g. coordination of compassionate use across the EU).
- Effectively communicate relevant information to healthcare professionals, patients and regulatory partners. Communication to these parties is also foreseen during the review process.
- As required, provide support to international partners, stakeholders involved in the research and development of medicinal products and public health authorities outside of Europe, e.g. WHO.
- All of these activities should be undertaken in line with this plan and associated work instructions (see section 6).

3.3. Triggers and level of activation: health threat vs. health crisis

There are different levels of activation of the health threat plan (see table 1 and the Health Threat Process Map in Annex I), which will translate into a different level of EMA staff involvement in the emergency (refer to the role of different teams in section 4 and especially section 4.2). This will be evaluated by the EMA Executive Director (ED) or the Deputy ED (DED) based on the perceived emergency of the situation in consultation with the therapeutic area concerned.

The Executive Director (ED) or the Deputy ED (DED) will activate levels 2 to 4 of the health threat plan (see table 1) in the following situations:

- [Determination of a Public Health Emergency of International Concern](#) (PHEIC) by the WHO or the European Commission as per art. 12 of [Decision 1082/2013/EU](#).
- [Declaration of a pandemic](#) by the WHO or the European Commission during the period of spread of human influenza caused by a new subtype. This will automatically lead to a level 4 crisis of the EMA health threat plan.

It is also possible that any emerging health threat may need to be followed up by the Agency since its inception when it is still highly uncertain whether it will lead to formal declarations by official bodies. In these situations, defined as level 1 in Table 1, it is not mandatory to have a formal ED/DED decision to activate the plan due to the uncertainty that a threat will ever evolve into a declared emergency.

Therefore the Head of Office of the relevant therapeutic area (e.g. Anti-infectives and Vaccines for health threats of a biologic nature) is to be considered the Scientific Lead (SL) and focal point of contact for any emerging health threat until a status of declared emergency is confirmed. The Scientific Lead should always be contacted at the start of the health threat plan activities (see section 4.2). This represents the minimum level of activation of the plan (level 1, see table 1). As the health threat emerges, the EMA scientific Committees and EU experts' network will be informed and an EMA Task Force (ETF, see section 4.4) will be activated as indicated in table 1. The ETF and the Committees will discuss the products development plans and regulatory actions.

The maximum level of activation of the plan represents a status of health crisis (level 4, see table 1), and this occurs when the Business Continuity Plan (BCP) is activated, either due to relocation of staff to a remote location or due to internal transfer of staff to deal with a crisis situation. Upon confirmation of a health threat or a crisis, the Crisis Coordination Officer (CCO, see section 4.2) will take over the overall coordinating responsibility and the SL will continue to lead the scientific activities.

Table 1 presents a schematic overview of likely examples of health threat scenarios and consequent levels of health threat plan activation.

Table 1. Different levels of activation of the Health Threat Plan and associated scenarios

Emergency level	Teams involved*	Staff/Experts	Activities
Health Threat			
Level 1 (outbreaks reported)	Scientific Lead Ad hoc EMA Task Force (ETF)	Head of therapeutic area office CHMP chair plus relevant CHMP/WPs experts	Activities are scientific & product-related, SL takes the lead, Responsive Team informed
Level 2	Responsive team	SL, CCO, Head of Office	Activities are as for

Emergency level	Teams involved*	Staff/Experts	Activities
<i>PHEIC declared</i>	ETF	of Media and Public Relations, Head of EMA International Operational staff as needed Chairs of CHMP/PRAC/PDCO/WPs plus other relevant experts	level 1 plus media alerts and increased liaison with other (non)EU Institutions
Level 3 <i>PHEIC declared</i> (Higher impact on the EU public health and comms)	Strategic team Responsive team ETF plus SAGs	ED/DED as above, additional staff involved for support operational staff as needed Chairs of CHMP/PRAC/PDCO/WPs plus other relevant experts SAGs experts	Activities are as for level 2 but more intense with ongoing procedures for medicinal products
Crisis			
Level 4 <i>PHEIC or Pandemic declared</i> (Public health in the EU severely impacted)	Strategic and Responsive teams BCP activated ETF plus SAGs	All of the above plus additional support staff and reallocation of additional resources as needed chairs of CHMP/PRAC/PDCO/WPs plus (co)-Rapporteurs and assessors SAG experts	Activities may involve a significant number of staff Potential need to authorise medicines fast

ABBREVIATIONS: SL (Scientific Lead); CCO (Crisis Coordination Officer); Comms (Communications); EU (European Union); BCP (Business Continuity Plan)

NOTES: *for a definition of the different teams see section 4; PHEIC (Public Health Emergencies of International Concern)

3.3.1. BCP activities during a health crisis

An ongoing reassessment of the need to activate the BCP is being run as the health threats activities are initiated at or reach level 3 of the plan. If based on that a crisis is confirmed and in any case if a pandemic is declared (level 4), the ED or DED will activate the BCP. The BCP Gold Group Directorate

will be activated in the first instance a crisis is confirmed in order to make way for any immediate, Agency-wide strategic decisions. The BCP Gold Group Directorate is defined in the Agency's BCP and was created in order to speed up the decision-making process in specific non-scientific areas in the event of a BC situation. The BCP Gold Group Directorate is a subset of the Gold Group and comprises the ED, the DED and the Head of Communications.

In the case of a health crisis, BCP Groups are involved in non-scientific activities; therefore the Health Threats Plan will run in parallel to BCP activities and will continue to oversee the scientific, regulatory and communication activities of the health crisis.

BCP activities as currently established remain valid and are not described in this plan.

3.4. Post health threat/crisis review

Following closure of the health threat or of the crisis it is important to take the opportunity to learn from the experience, i.e. to conduct a "lessons learned" exercise. This should cover aspects of the health threat or of the crisis that were not handled well and may need to be changed, but should also describe what was done well and does not need to be changed. A forum to discuss these matters and identify ways of improving the emerging health threat plan is to be established. The activities linked to the lessons learned exercise should be led by the Responsive team. Further guidance on how to conduct the post incident review can be found in the Overarching Business Continuity Management Plan (BCMP).

As mentioned, in addition to the revision of the Agency health threat plan, the following points represent some of the implemented improvements to different areas and procedures to reflect the lessons learned from the 2009 pandemic:

1. Revision of the regulatory framework and scientific guidance for pandemic vaccines (follow links to the [quality](#), [regulatory](#) and [clinical](#) module of the new influenza guideline);
2. In light of recent improvements to the [GVP Modules](#), the core RMP for pandemic vaccines was not considered relevant. The general requirements for RMPs are described in the Guideline on good pharmacovigilance practices: Module V – Risk management systems ([EMA/838713/2011](#)) and Guidance on format of the risk-management plan in the European Union – in integrated format ([EMA/PRAC/613102/2015](#) Rev.2). Specific aspects of pharmacovigilance planning for vaccines are described in the Guideline on good pharmacovigilance practices (GVP) - Product- or Population-Specific Considerations I: Vaccines for prophylaxis against infectious diseases ([EMA/488220/2012](#));
3. Revision of the [labelling provisions](#) for pandemic vaccines;
4. Increased co-operation with stakeholders e.g. with EC, ECDC, MS competent and public health authorities, public, health care professionals, international stakeholders.

4. Roles and Responsibilities

The following EMA designated teams and expert groups from the Committees and relevant Working Parties will deal with the health threat/crisis:

4.1. Health threats Strategic team

The Strategic Team is composed of the Executive Director (ED) and the Deputy ED (DED). The Strategic Team is involved from the onset of the health threat/crisis (levels 3 and 4) but it has no role

in day-to-day activities. The Strategic team gives consideration to the major scientific, regulatory and communication aspects. Other aspects of their role will be covered in the BCP, if activated.

The Health Threats strategic team is to be assisted by the CCO, the Scientific Lead, or the Responsive team, and as needed also by the operational staff (technical support) taking into account the level of the emergency as depicted in section 3.3.

In case of level 4 emergencies (crisis) when a rapid response is required, the ED together with the DED might have to take executive decisions in the interest of EU public health with the support of the Responsive team.

4.2. Health threats Responsive team

The Responsive team is composed of the following functions: the Scientific Lead (Head of Office of the relevant therapeutic area, see section 3.3) the Crisis Coordination Officer (CCO), a representative of the International Affairs Team and the Head of Office of Media and Public Relations.

In very early phases of any emerging threat, e.g. before formal declarations are released by official bodies, the Scientific Lead should be the initial point of contact for interaction with external stakeholders and coordination within the network and (s)he may be the only person involved in dealing with the emerging health threat as a level 1 activation of the health threat plan (see table 1). For these cases, the Scientific Lead ensures that other members of the Responsive team are kept informed in a timely manner by circulating a brief summary of the situation by email or a high level status report. The SL will work in close liaison with the Committees of the EMA (CHMP, PRAC, PDCO as needed) and in particular with the experts of the EU network represented in the ETF (see section 4.4).

In case of emergency levels 2 to 4, the Responsive team will be regularly involved in the management of the activities related to the health threat. Within the Responsive team, scientific activities are coordinated by the Scientific Lead whereas the CCO takes the overall lead coordinating role. Thus (s)he should be kept informed of all international, institutional and scientific developments relating to the emerging health threat, as (s)he keeps a high level status report of the activities. The Scientific Lead maintains oversight of the scientific support activities throughout the emergency including scientific interaction with stakeholders and partners. Specific expertise from other offices will be identified and involved as required.

The EU Institutional Liaison Team will be involved in the activities of the Responsive team as needed based on the extent of cooperation and interaction with EU institutions.

During the health threat/crisis at levels 3 and 4 and depending on the need identified, additional staff members may attend meetings held by the Responsive team or may provide scientific/regulatory support to facilitate the team's operations; such additional staff may more likely include the Heads of Service/Office of: Quality, Regulatory Affairs, Paediatric medicines and Scientific Advice. Other ad hoc members can be directly or indirectly involved at any time in the activities of the Responsive team depending on the nature of the health threat.

The main role of the responsive team is to ensure that the health threat/crisis plan is followed and that the operational activities during the health threat/crisis are conducted, e.g. stakeholder liaison, implementing communication strategy, workload management, representing the Agency at external and internal meetings as relevant. The Responsive team reports to the Strategic team as needed.

Once operational responsibilities and relative resources are assigned at the beginning of a health threat/crisis, the Responsive team in principle meets if issues cannot be resolved within one operational entity or if interdisciplinary discussion is needed.

4.3. Operational staff involved in health threats activities

At the onset of a health threat (level 1), the need to involve operational entities is evaluated by the SL on a case by case basis. Depending on the need, colleagues may be involved based on specific needs, e.g. scientific administrators from the Anti-infectives and Vaccines, Biostatistics and Methodology Support, or Quality Offices.

From level 2 of the health threat plan, key operational staff involved besides the CCO include a scientific coordination officer (SCO, e.g. an Anti-infectives and Vaccines Office representative in case of a biological threat), a regulatory coordination officer (RCO) and a procedure coordination officer (PCO). They work in close collaborations with the Responsive team by implementing their decisions and ensuring information flows to EPL/PM/other product team members, Committees and Working Parties, i.e. undertaking EMA crisis activities. The main roles of the coordinators are summarised in table 2, but could be readjusted based on the need.

Table 2. Activities by the Coordination Officers

Crisis Coordination Officer	Scientific Coordination officer	Procedure Coordination officer
Organises meetings chaired by the strategic team, the responsive team and operational staff	Organises Committees expert group meetings e.g. EMA task force SAGs meetings	Organises daily interactions with internal and external stakeholders such as industry and Rapporteurs for evaluation activities
Coordinates adequate Agency input / drafting of briefings	Drafts content of briefings (scientific outcomes, minutes, review of CHMP ARs)	Manages all evaluation procedures (rolling reviews and standard)
Coordinates crisis communications to stakeholders together with S-Division	Ensures adequate information flow through experts groups and relevant WPs, if needed in addition to the ETF	Ensures adequate information flow through committees
Maps requests for Agency representation at relevant external meetings, and at international*/EC & ECDC level	Ensures periodic briefing of MLT (Scientific issues)	
Tracks resources needs for the crisis to make sure these are addressed by management	Ensures adequate review of disease progression and internal dissemination of information using information from ECDC/WHO etc.	

*International activities handled by EMA international Office

Other staff members to be regularly involved in operational support may include scientific administrators from the Quality, Paediatric medicines, Communications and Scientific Advice Offices.

In addition, depending on the nature of the health threat/crisis, *ad hoc* staff can also be involved/consulted: scientific administrators from Manufacturing and Quality Compliance, Clinical & Non-Clinical Compliance, Monitoring & Incident Management, Patients & Healthcare Professionals,

Biostatistics and Methodology Support, Clinical Pharmacology and Non-clinical Support, Orphan medicines, Labelling review and standards Offices and the Legal department.

If a crisis is confirmed (level 4), a greater number of staff may need to be involved based on expertise specific to the particular health crisis, including EMA Product Leads (EPLs), Project Managers (PMs) and additional scientific administrators from Specialised Scientific Disciplines. The additional staff will provide further resources to help with necessary product team related activities and ensure that adequate feedback is channelled to the SCO and PCO for coordination.

It is foreseen that in a crisis such as influenza pandemic at least two members of staff from each of the following Offices should be dedicated to the crisis: Quality, Anti-infectives and Vaccines and Regulatory Affairs. At least 4 persons should be mobilised from the relevant Office of the E-PM Department. At least 2 staff members should be mobilised from each of the following Offices based on need: Paediatric medicines, Manufacturing & QC, Clinical & non-clinical compliance, Monitoring & Incident Management, Patients & healthcare professionals, Communications, Labelling review and standards, Data Collection and Management, Legal department. In other types of health threat scenarios, this should be decided on a case by case basis.

4.4. Experts groups

Specific expert groups such as the EMA Task Force (ETF) and the Scientific Advisory Groups (SAGs) are convened to assist the CHMP, PRAC and PDCO or take part on behalf of the CHMP in early scientific discussions and products reviews as needed. Under direction and supervision of the CHMP, the ETF may be mandated to:

- provide advice to manufacturers on developing medicinal products, e.g. vaccines/ antimicrobials, against the emerging health threat;
- contribute to product-related assessment and post-authorisation surveillance activities;
- prepare specific positions / input into Q&As;
- interact with stakeholders;
- maintain European and International cooperation.

At the beginning of every health threat there may be no need to involve the whole ETF, hence an ad hoc subgroup of the ETF should be defined based on the actual need (the *ad hoc* ETF). If there is a need to act rapidly in the face of a growing emergency, the 3 chairs of the Committees for human medicinal products expected to be mainly involved with the health threat (CHMP, PRAC, PDCO), with the support of the chairs of the relevant therapeutic area WPs (e.g. VWP or IDWP for a biological health threat) and the Scientific Lead, will discuss as needed with the ED/DED.

The Scientific Coordination Board, which brings together the chairs of all the EMA scientific Committees, is also available as a platform for discussion and can be considered to facilitate regulatory decisions in times of emergency.

One of the main activities of the (*ad hoc*) ETF is to provide product-specific scientific advice to manufacturers on behalf of the CHMP. At Level 1 of emergency, initial interactions with sponsors will likely occur in an informal setting, i.e. teleconferences with the SL/*ad hoc* ETF. At subsequent levels of emergency, and as products approach clinical development phases, formal scientific advice procedures will have to be carried out by the ETF. In case of need to provide responses swiftly, the Rapid "Scientific Advice" procedure shall be used, which may include discussion of the advice with other regulatory authorities where applicable.

SAGs will retain their role of external expert advisory group to the ETF and the CHMP on specific questions, as per SAG mandate in non-emergency situation. Full mandates and objectives of SAGs and ETF or *ad hoc* ETF in the context of a health threat plan are not included in this document.

5. Operational aspects

The following sections provide high level recommendations to be followed in key areas of health threat/crisis related activities, as identified based on the lessons learned from past health threats/crisis such as the 2009 influenza pandemic.

5.1. Facilitation on regulatory input into clinical trials

From a regulatory perspective there is the need to facilitate clinical trials design in the context of an emerging health threat by agreeing up front to key principles. Clinical trial design may differ substantially depending on the health threat and type of product. The possibility of informal early interaction/consultation with EMA and ETF, and structured procedures such as a rapid scientific advice (SAWP/CHMP) may be offered to both manufacturers of medicinal products and academic/investigators conducting clinical research. Ongoing stakeholders' discussions and projects will be taken into account when defining this strategy further. Incentives for development such as rapid orphan designation have been also used in previous emergency situations and may be taken into account as appropriate.

5.2. Procedural aspects

In the context of an emerging health threat caused by e.g. a biological hazard, detailed procedures have been set up:

- for rapid scientific advice of products in development;
- for fast-track approval of medicines, e.g. vaccines and antimicrobials for prophylaxis and treatment of an emerging health threat, via the centralised procedure;
- for post-authorisation follow-up of centrally authorised products, e.g. emerging data on safety and efficacy;
- to react to any safety signals arising from the use of non-centrally authorised products, e.g. from the use of bulk active substance of centrally authorised antimicrobials.

5.3. Paediatric aspects

Some aspects related to paediatric activities in times of an emergency have been considered and the recommendations for handling them are summarised below:

- The PDCO Chairperson or a nominated alternative participating in the ETF should allow information flow between this group and the PDCO;
- An EMA/PDCO "mini-team" of 2-3 PDCO members and at least one EMA Paediatric coordinator, with relevant experience, should be set up to draft general guidance on paediatric requirements, when necessary, and manage possible PIP applications;
- Given the variety of potential health threats, a standard PIP approach is not considered feasible for most instances. Instead a flexible, informal and rapid case-by-case approach will be taken, in full respect of legislative requirements.

- PDCO opinions on relevant PIPs should be adopted via written procedure, faster than normal procedural timelines if necessary and appropriate.
- Applicants are strongly advised to consider the paediatric requirements early in development, and to contact the EMA Paediatric Medicines Office as soon as possible (paediatrics@ema.europa.eu), to prevent any possible delay in the marketing authorisation.

5.4. Pharmacovigilance aspects

Pharmacovigilance activities in the situation of an emerging health threat should be enhanced, and a number of tools and processes which could be used in these situations are in place. The main elements to be considered are summarised below:

- Activities related to signal management should be enhanced and/or accelerated during emergency or mass use of new products or during mass use of previously authorised products. For authorised products, requirements for signal detection are reflected in the legislation, Guideline on good pharmacovigilance practices (GVP) and relevant EMA SOPs. The validation and subsequent assessment of signals should be performed by the Signal and Incident Management Service P-PE-SIM in collaboration with Member States and the PRAC. A number of pharmacovigilance tools and resources which could be used in an emerging health threat situation exist. These could be targeted to medicinal products in the scope of the specific situation, and timelines could be shortened accordingly.
- Emerging Safety Issues (ESIs) are safety issues considered by a Marketing Authorisation Holder (MAH) to require urgent attention by the competent authority because of the potential major impact on the risk-benefit balance of the medicinal product and/or on patients' or public health, and the potential need for prompt regulatory action and communication to patients and healthcare professionals. When the MAH in the EU becomes aware of an ESI from any source, they should notify it in writing to the competent authority(ies) of MSs where the medicinal product is authorised and to the Agency. The process is currently in place, and additional resources could be allocated in case of increased use of this route.
- The rapid exchange of information on pharmacovigilance issues between the EMA, MSs and the European Commission can take place through the European Pharmacovigilance Issues Tracking Tool (EPITT). The EPITT communication channels which are in place are the Rapid Alerts (RAs) and the Non Urgent Information (NUIs). Currently resources are allocated according to current amount of EPITT notifications. Should these notifications increase, as in the situation of a crisis, it might be necessary to strengthen EPITT operation by allocating additional resources as needed.

Details concerning safety data and PSURs submissions and assessment in the context of a health threat are not included in this document.

5.5. Communication with the network, stakeholders, international partners and the public

The EMA crisis communication plan describes the Agency communication to the general public (e.g. EMA press releases, conferences, interviews) in the event of any crisis, and coordination of such communication with partners and stakeholders to ensure coherent and consistent messages to the public. The crisis communication plan includes elements specific to emerging health threats. Aspects related to the communication with partners with the pharmaceutical industry and other stakeholders,

such as the Early Notification System (ENS), are also reflected in the same document (not reflected here).

Interactions with international regulators, e.g. US FDA and HC, and public health authorities, such as WHO, are going to be expected. Discussion on specific scientific and regulatory topics will take place as necessary in accordance with the framework described above and in compliance with the confidentiality agreements in place.

In addition, the International Coalition of Medicines Regulatory Agencies (ICMRA) has developed a framework for the involvement of Health Regulatory Authorities (HRA) in the management of global health crisis in a coordinated and consistent manner, by addressing the roles and responsibilities of HRA in this process, as well as by identifying the possibilities for international collaboration and cooperation. The EMA International Affairs Team will ensure adequate coordination of activities with ICMRA.

6. Annex I

EMA health threat process map ([EMA/643755/2016](#))