



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Public health
Health Security

DG level Meeting on Health Security

24 October 2022 12:00-16:00

Brussels

AB / 2.C, Albert Borchette

Chair:

Sandra Gallina, Director General

European Commission Directorate-General for Health and Food Safety

Meeting participants:

- Physical attendees: AT; BE; CY; DE; EL; ES; FR; HR; HU; LT; NL; NO; PL; PT; SE; SK; IS; DG SANTE
- Virtual attendees: BG; CZ; DK; FI; IT; LV; MT; RO

Key messages:

DG SANTE organised a meeting with Member States/EEA countries at Director General level in order to discuss health security and the implementation of the Regulation on serious cross-border threats to health (CBHT) repealing Decision 1082/2013/EU (adopted on 24 October 2022).

The meeting had two specific agenda points: (1) Updates on the new Regulation on serious cross-border threats to health and repealing Decision No 1082/2013; and (2) Initial thoughts about the Union prevention, preparedness and response plan. Overall, the meeting served to reinforce the previous discussion of the Health Security Committee (HSC) held in early October 2022.

A follow up meeting, in order to discuss in more depth Article 5 (the Union prevention, preparedness and response plan) of the Regulation on serious cross-border threats to health, will be arranged as soon as this regulation is formally adopted and published..

1. Updates on the new Regulation on serious cross-border threats to health and repealing Decision No 1082/2013

DG SANTE informed the representatives of Member States/EEA countries about the adoption of the last and underpinning piece of the European Health Union legislative package and about the implications of the new legislation for the Member States/EEA countries. The new CBHT Regulation addresses the weaknesses exposed by the COVID-19 pandemic and supports a strengthened EU health security framework, as well as strengthening preparedness, reinforcing surveillance and improving data reporting. The new CBHT Regulation is divided into several chapters:

- Chapter I (Art 1-4) on **general provisions**: new elements: a network of EU reference laboratories, a network for substances of human origin, an advisory committee for recognition of public health emergency at Union level; and definitions: oneHealth, Health in all policies, medical countermeasures, medical devices, health system capacity.
- Chapter II (Art. 5-12) addresses **prevention, preparedness and response planning**: the Union prevention, preparedness and response plan, reporting on and assessments of preparedness and response planning, public health and cross-sector stress tests and exercises, training and knowledge exchange activities for healthcare and public health staff, and reinforced joint procurement.
- Chapter III (Articles 13-17) addresses **epidemiological surveillance and new networks**: high performing epidemiological surveillance system at the EU level, access of ECDC to health data for research and epidemiological aspects, reporting requirements, creation of an EU reference laboratories network, creation of a network supporting the use of substances of human origin. Here, DG SANTE, in collaboration with ECDC, will organise a specific meeting with the Member States/EEA countries to discuss the current notifiable disease list, to discuss which diseases should be added/removed.
- Chapter IV (Art. 18-22) addresses **early warning and response (EWRS)**: notifications including on urgent need or shortage of medical countermeasures (enhanced Early Warning and Response System (EWRS): forming bridges to connect different alert systems (food, environment, chemical, etc), enhanced risk assessment framework (additional agencies to contribute to risk assessments).

DG SANTE emphasised that the implementation of these articles also depends on the willingness of other networks to share threats and collaborate.

- Chapter V (Art. 23-25) addresses **public health emergency at Union level**: declaration of an EU emergency situation, recommendations on response measures by ECDC, adoption of opinions and guidance, including on specific response measures by the HSC (for example, the first HSC agreement on a document (Ebola) took place on 5 October 2022 during the HSC Plenary meeting).
- Chapter VI (Art. 26-35) on **final provisions**: the first evaluation of the implementation of the new CBHT regulation will be carried out by 31 December 2024 as well as the additional assessments highlighted in Article 33.

DG SANTE emphasised the importance to collaborate on the implementation of the new CBHT Regulation noting that the HSC will have a key role in the set-up of the structure and implementation of the new CBHT regulation. The representatives of Member States/EEA countries were invited to share their views about the forthcoming implementation of the Regulation and, in particular, where to set priorities.

FR emphasised the importance of a collaborative approach and look forward to the implementation of the CHBT Regulation together with the Commission, Council, Parliament, EU Agencies and the Member States. FR highlighted several key elements for implementation, including taking into account different Member States' capacities, aligning epidemiological surveillance, and the early warning and response, as well as noting that a Joint Action on the implementation of the Regulation may prove useful. Moreover, the strengthening of national preparedness plans, risk assessments, and training of healthcare and public health staff could benefit from a collaborative approach. Strong Member State engagement is essential regarding reporting and the evaluation mechanism of national plans – this could be achieved through the HSC. FR also highlighted the importance to build on the existing instruments (such as the EU Health security network, as example the SHARP Joint Action) to support the implementation of the new CBTH Regulation. The work to strengthen the EU health Security framework should also be articulated within the broader pan-European network context and should strengthen its relationship with WHO institutions, including WHO Lyon office (IHR - health security), the WHO academy (training), the WHO hub in Berlin (epidemiological intelligence), as well as with the International Health Regulation architecture. Here, it should be flexible and not duplicate mechanisms such as the WHO's Joint External Evaluation and Universal Health Preparedness Review tools. FR also highlighted the successful EU collaboration at global level regarding the EU Digital COVID Certificate, noting that such collaborations can be expanded going forward.

DG SANTE thanked FR for the contribution and agreed that collaboration is key for successful implementation.

PT supported FR's comments and also emphasised the need to ensure medical stockpiles, data interoperability and human workforce to cope with new demands for public health surveillance and risk assessment/ management/ communication/ artificial intelligence, etc. PT also mentioned that the timeline for the Union prevention, preparedness and response plan is ambitious and may be difficult to manage within one year and highlighted that cross - border collaboration is important and neighbouring countries especially should share information on measures and mechanisms being implemented.

DG SANTE agreed with the comments of PT and the need to ensure that systems allow for information sharing across countries as well as clear contact points.

IT noted that a common approach in the early stages in the COVID pandemic was challenging and that this should be addressed in order to ensure better preparedness and response in case of future pandemics. In terms of pandemic threats, IT noted that plans exist at national level but that that information sharing of these plans should improve as, for example, during the COVID-19 pandemic, it was difficult to receive information on what other Member States were implementing. Here, IT noted that the work done on the Advanced Purchase Agreements and Joint Procurements is an example of a good cooperative response. IT concluded by highlighting the importance of linking public health with other networks (e.g. vets, food sector) and emphasised the importance of avoiding duplication – also between HERA and ECDC on data collection and surveillance.

DG SANTE thanked IT and agreed that avoiding duplication is essential. The focus should be on implementing legally based systems covered in the cross border health threats regulation and ECDC regulation as a sustainable solution, supporting the member states to have the necessary capacity to implement at national level.

SE supported the comments of FR and emphasised the importance of taking into account the pan-EU and WHO level; the Pandemic Agreement must fit within the EU level. SE welcomed the new CBHT Regulation and synergies with other stakeholders. In SE, the regions are responsible for the preparation plans. The Union prevention, preparedness and response plan should complement and not overtake national plans, that it should provide added value and be complementary to national legislation. The Union plan should ensure clear access to financial and other supporting mechanisms, as listed in Article 5, when required. The Union Plan should safeguard national health security as well as consider threats that may emanate from outside the Union. Member States and Union agencies should maintain discretion and information security during the development process of this Union plan. The Union plan should be based on evidence-based actions and take into consideration different Member State contexts, in agreement with national legislations, and taking into account proportionality and children rights. SE perceives the proposed timeline as manageable.

DG SANTE agrees with the importance of discretion as mentioned by SE. Drafts of the documents could be sent through the secured system CIRCABC in order to ensure security.

HR emphasised that the Union prevention preparedness plan is the key element to enable and ensure early and effective monitoring of serious cross-border health threats. HR pointed out three main elements to focus on: timely exchange of information, determination of elements to support Joint Procurements of countermeasures and digitalisation of the system to allow faster communication. The elements of the Union plan for prevention, preparedness and response should be determined as soon as possible as will help to define national plans. HR emphasised the importance of training programmes for healthcare and public health professionals and the exchange of best practices. It remains unclear, however, how the national plans will be taken into account in the first drafts of the Union plan.

DE highlighted the importance of avoiding duplication and overlap between the different activities at EU and national level as well as the importance of identifying how to best utilise the links between different EU institutions, national authorities, and creating synergies. Other priorities are the establishment of the Union Health Task Force and the digitalisation of the surveillance systems, which will require work and collaboration, particularly on the technical level. DE also highlighted the EU's work at a global level as another important point.

DG SANTE underlined that the Union plan's development will necessitate collaboration between the Commission, Member States/EEA countries and Union agencies and bodies. To this end, it is important to put a clear list of needs together, clarify responsibilities and also consider clear and aligned communication roles.

NO called for a strong EU crisis preparedness and response system, noting that close collaboration between the Member States, as well as with the EU is highly important. With the new CBHT regulation, the new HERA and a stronger EU Civil Protection Mechanism, the EU will be better prepared. NO also highlighted the importance of infrastructure and cyber security.

IS highlighted that it is important to strengthen the crisis preparedness framework now with the lessons learned from the COVID-19 pandemic and underlined appreciation that the Joint Procurement process has been opened to EFTA states. IS noted that a new national legislative proposal on epidemics is expected to be adopted by the end of 2022 and highlighted the importance to coordinate the efforts of the national and the Union plan.

ES highlighted the importance to take the COVID-19 lessons learned into account. One of the major lessons is the need for coordinated answers to international threats to provide common answers to the EU population.

DG SANTE agreed with ES on the need for better coordination among the Member States/EEA countries as well as with the EU institutions.

NL supported the intervention of FR on a collaborative approach, on ownership by Member States, to build on existing work, and to link work to the pan-EU level. The Union prevention, preparedness and response plan should give more clarity on how to achieve synergies, efficiencies, complementarity, and interoperability – not only within the EU, but also within the WHO framework. With regards to the new role of the HSC, continuous and strengthened dialogue between the HSC is important, also with the relevant Council bodies (IPCR) to ensure good follow-up on the work of the HSC at both national and EU level. Within the HSC, there is also a need for long-term strategic discussions at senior level. Duplication of work with HERA should be avoided, in particular when it comes to Article 7, 8, 13 and 14 of the new CBHT regulation. NL mentioned that the implementation and reporting cycle of prevention, preparedness and response plans at national level remains unclear and welcomes clarifications on this.

DG SANTE agreed with the NL to further discuss the operationalisation of the implementation and reporting cycle at national level and agreed that other groups, such as those at the Council level need to also be taken into consideration in the wider EU health security framework.

2. Thoughts about Union prevention, preparedness and response plan

DG SANTE introduced Article 5 of the Regulation on serious cross-border threats to health describing the Union prevention, preparedness and response plan. The Union prevention, preparedness and response plan responds to a lesson learned from COVID-19: the need to improve crisis management at the EU level, to strengthen close collaboration and coordination between Member States/EEA countries and the institutions of the European Union, including also other stakeholders, such as the civil society. This is a responsibility of the Commission and is novel when compared to Decision 1082/2013/EU. The Commission will also ensure that the plan is functional, has resources to ensure its operationalisation

and that it remains updated. To this end, the Commission will also facilitate stress tests, simulation exercise and inaction and after-action reviews. In turn, as per Article 6 (**National prevention, preparedness and response plans**), Member States are tasked to coordinate with the Commission in order to seek coherence with the Union plan.

The Union prevention, preparedness and response plan shall include provisions on joint arrangements for governance, capacities and resources for: cooperation between Commission, the Council, the Member States, the HSC and relevant Union agencies or bodies; services and support potentially available under the Union Civil Protection Mechanism and capacities under rescEU; cooperation with WHO for cross-border threats to health; secure exchange of information between Commission, Member States, the HSC and relevant Union agencies or bodies; epidemiological surveillance and monitoring; early warning and risk assessment; risk and crisis communication; health preparedness and response and multi-sectoral collaboration; overview of the production capacities for relevant critical medical countermeasures in the Union; emergency research and innovation; management of the plan; and support to Member States for monitoring impact on provision and continuity of healthcare services.

DG SANTE will develop the Union prevention, preparedness and response plan amongst concerned services as well as Union agencies and bodies. Sharing of the plan with the technical level Preparedness Working Group of the HSC would be expected in the second half of 2023 and its presentation to the HSC senior level working group by the end of 2023. Synchronisation of the timeline of the Union response plan with the timelines of the other elements of the preparedness framework of the Regulation: e.g. reporting cycle one year after adoption of the Regulation and every three years thereafter will be sought.

The representatives of Member States/EEA countries were invited to share any specific expectations or national requirements for the Union prevention, preparedness and response plan and on the feasibility of the proposed timeline.

FR highlighted that alignment within the EU body (ECHO, HERA, GROW, etc.) is essential concerning research, industrial support, production, availability and stockpiling of medical countermeasures. The Union preparedness plan will become an important element of the EU health security framework, which is intended to complement and promote effective synergies between the Member States and the Commission and other Union bodies. The new CBHT regulation indicates several aspects that the Union plan will cover but it is important to prioritise which aspects can be covered in short-term and to continue to build the Union plan over time. In terms of priorities, the Union plan needs to focus on issues of interoperability between Member States and issues that will be of added EU value: digital health technology, data sharing, surveillance, epidemiological intelligence, cross-border collaboration, one health approach, AMR Joint Action, reflection of regulatory aspects of Joint Procurement for countermeasures. FR considered the proposed timeline ambitious but feasible and that the Union plan be complementary to national plans and focus on cross-border health threats and interoperability. FR highlighted that the Union plan should be a living document, updated continuously and that overlaps between the Union plan, EU preparedness reporting, and HERA's preparedness report on medical countermeasures should be avoided.

DG SANTE agreed with FR on the importance to avoid overlaps on the three mentioned documents.

BE welcomed the timely discussion on the implementation of the CHBT regulation and noted interest to participate in the preparedness working group. Transparency and trust among the Member States is key

to cooperate and implement the new CBHT regulation. It is important to lay out priorities, accountabilities, and responsibilities, both on national and EU level.

AT noted that it is evaluating lessons learned from the COVID-19 pandemic so to improve their national prevention, preparedness and response plan. AT considers the EU proposed timetable ambitious, but reasonable. AT stressed the need for a broader, more unified perspective in crisis management: different preparedness plans and alert systems should be aligned. To respond faster and more efficiently, improved collaboration mechanisms, alignment of preparedness plans and alert systems are essential and generic preparedness (flexible and pathogen independent) should also be considered. Integrating the lessons learned from the COVID-19 pandemic is crucial. Incorporating generic preparedness requires intersectional and cross-border collaborative approaches; preparedness must be flexible, scalable and pathogen-independent, as well as independent of pandemic causes. It is important to create more resilient crisis management across countries and sectors.

SK welcomed the coordinated approach to the Union's prevention, preparedness and response plan but that some practical and technical questions related to the strengthening of the EWRS, the Union stress test and national preparedness plans remain. SK stressed the need for clear communication with the other Member States and DG SANTE. The proposed deadline is acceptable, however, improvements of existing structures at national level should be discussed in parallel. SK asked if national preparedness plans shall be prepared simultaneously with the Union plan and stressed that national specifications, such as differences between healthcare systems should be taken into account when preparing the Union plan. SK's current priority is the national coordination of health stakeholders and actors for the preparation of the national and Union preparedness plan.

DG SANTE noted that national plans and timelines is a national prerogative.

NO noted great potential and enhanced EU cooperation in developing scenarios and risk analysis and that it is important to learn from each other and raise the overall level of preparedness and crisis response. NO encouraged involvement of all EU/EEA Member States in the process of developing the Union plan, including the reporting of national plans with transparency being highly important. NO is currently finalizing a white paper on national health preparedness and national plans will be updated accordingly. NO emphasised the need for stronger EU cooperation and that the Union plan can contribute to create rules and responsibilities at EU level – both for preparedness and crisis.

EL welcomed the new CBHT regulation and stressed the need for uniform reporting templates.

DG SANTE recognised the importance of the point raised by EL.

HU highlighted the importance of good and effective collaboration at all levels – between EU agencies, Commission and Member States. The Union plan's proposed timeline is perceived as ambitious by HU.

CY agrees with the previous points raised by other countries. CY emphasised that it is a small country with respective healthcare capacity and that the diversity of capacities must be reflected in the Union plan. The timetable proposed by the EU is considered ambitious by CY.

ES stressed that the Union plan should help avoid duplication and create a strong EU reference, also with the view to the ongoing discussions at international level. The timetable proposed by the EU is considered ambitious but feasible.

LT strongly supports the new CBHT regulation and preparedness plan and highlighted the need to strengthen prevention, preparedness, coordination and response systems at national level. LT also highlighted the importance of a one health approach, sectorial collaboration, joint procurement, logistics, Union and Member State level cooperation and competences, RescEU, and stockpiling aspects. LT called for coordination at cross border regional scale within the Union plan, such as the Baltic and Nordic coordination structures. LT supports the proposed timeline.

PT mentioned that the Union plan should serve as technical guidance, reflecting the work of EU agencies, including mechanisms of surveillance and to think beyond EU borders.

SE highlighted the importance of managing cross-border health threats noting that during the COVID-19 pandemic, borders were closed, leaving medicines, personal protective equipment and medical personnel stuck at borders. It is important to look for ways to prevent this from happening in the future.

DG SANTE responded that it would indeed be important to include mobility elements, such as the green lanes, in the Union plan to secure the supply of medicines, personal protective equipment and medical personnel. In addition, DG SANTE raised the topic of including the humanitarian part (access to the most vulnerable during the pandemic, e.g. homeless, migrants) – in the Union plan and highlighted that this could be addressed in forthcoming meetings during the development of the plan.

DG SANTE also noted that the increased budget of the Multiannual Financial Framework, which can support the implementation of related activities. Financial support could be considered from the EU4Health and Horizon2020 programs as well as the Recovery and Resilience Facility. It is important, however, that Member States/EEA countries consider the aspect of co-financing in these activities.

The chair closed the meeting by highlighting the importance of how to construct these systems together in a harmonised, collaborative and complementary manner and to prioritise the elements that need to be put in place first. As such, a follow up meeting to further discuss the Union prevention, preparedness and response plan will be organised for December 2022.

Participants were also reminded to participate in the COVID-19 Lessons Learned event to be held in Luxembourg on 22-23 November.