European Health Emergency Preparedness and Response Authority (HERA)[1]

Non-paper by the Netherlands

1. Introduction

The COVID-19 pandemic has laid bare the existing vulnerabilities and the pressing need to secure European health care supplies, in particular for vaccines, medicinal products, medical technology, protective equipment and chemical precursors. During this pandemic outbreak, it became clear that a transparent, coordinated approach, both in preparedness and response to cross border health threats, is preferable and more beneficial than individual actions by Member States.[2] In addition, the importance of upholding the fundamental principles of the European Union (EU), such as the functioning of the internal market in times of crisis also became evident. For the Netherlands, the overarching aim of the EU Health Union and of a future authority should be to reassure and build trust among Member States, so that coordinated cooperation can become the pathway to achieve better results for European citizens.

A comprehensive EU framework for cross-border health threats currently exists[3]. However, it does not take into account the ensuing large-scale shortages of medicines, vaccines or medical devices. A future authority, as a part of the proposals for an EU Health Union, should enable the EU and its Member States to respond flexibly to cross-border health threats by rapidly deploying the most advanced medical countermeasures in the event of a cross-border health emergency. In doing so, it could operate in the realm of monitoring (upcoming) shortages together with the European Medicines Agency (EMA). The new mandate of EMA is still under negotiation. Jointly, these agencies should safeguard a proper EU response to the shortcomings identified.

In this document, the Netherlands further defines its priorities for a future establishment of this authority.

2. In short

a) The Netherlands recognizes the potential added-value of a future authority and the opportunities it could generate; it believes that the mandate and structure of the authority should be built upon the outcome of an in depth cross-sectoral evaluation of the shortcomings at EU level of the response to the COVID-19 pandemic. Lessons learned are to be taken into account when developing an authority that should be fit to cater for medical countermeasures for new and still unknown cross-border health threats.

b) The Netherlands stresses the need for a thorough and full-fledged Impact Assessment, which analyses all policy options, among which the "baseline option". This Impact Assessment should elicit the gap that a future authority is expected to fill. Furthermore, it should identify potential synergies between the new authority and existing agencies, bodies and mechanisms, both in public health and civil protection.

c) Valuable lessons to help shape the future authority could be drawn from the recently started bio-defence preparedness plan ("HERA-incubator"). Yet, the range and nature of the future, permanent authority with a focus on future cross-border health threats, is fundamentally different from aggregating the joint activities performed under the bio-defence preparedness plan, addressing the COVID-19 pandemic.

[1] The Netherlands reserves its position till its assessment of the final proposal once published. In addition, any budgetary consequences stemming from the establishment of such an authority shall be taken into account.
[2] This position is in line with the non-paper "Future of Crisis Management in EU context" of The Netherlands, Sweden and Romania (20 October 2020).
[3] Decision 1082/2013/EU, mandate ECDC, mandate EMA.

d) The Netherlands expects the future authority's mission to be that of enabling the EU and its Member States to make the required medical countermeasures rapidly available in the event of a serious cross-border health threat.

e) The Netherlands envisages an authority with a coordinating role that boosts the EU's crisis preparedness to cross-border health threats. An authority that stimulates innovation under the necessary conditions to uphold public interests, strengthens and promotes already existing activities in that field. This demands a compact, efficient, flexible and effective authority with an unambiguous mandate. This mandate should be clearly distinguishable from those of other actors in public health and civil protection.

f) The future authority should build its activities on existing and future EU-wide horizon-scanning programmes for vaccines, medicinal products and medical technology, such as the International Horizon Scanning Initiative (IHSI). The horizon-scanning intelligence gathered can cater to the information needs of various other initiatives, such as the Health Technology Assessment (HTA) collaboration.

g) The activities of the future authority should result in a strengthened supply chain for medicinal products (including vaccines) and medical devices, thus yielding benefits not only for critical products, but also to the resilience of the overall supply chain. In this context, intra EU export restrictions should be avoided and free movement should be guaranteed, also in times of crises, thus strengthening a proper functioning of the Single Market.

3. In greater detail

Policy principle

The Netherlands envisages the future authority's mission to be that of enabling the EU and its Member States to make available and in a rapid manner, the most required medical countermeasures in the event of a serious cross-border health threat.

The Netherlands recognizes that, in order to achieve that, the main strength of the future authority resides in the non-crisis periods and is to be based on the five pillars: knowledge generation, development, production, deployment and use.

Preparation

The Netherlands stresses that the process to establish a future authority should start with a thorough evaluation of the response to the COVID-19 pandemic, including the shortcomings of that response. The Netherlands also stresses the need for a full-fledged Impact Assessment, which analyses all policy options among which "the baseline option". It is of paramount importance that this assessment includes a mapping of crisis prevention and response activities and the roles therein of the existing EU bodies[4], their current mandates and the proposed enforcement thereof. This mapping should also take into account other regulatory bodies[5], programmes[6] and instruments[7] in all relevant fields. This would elicit the gap that a future authority is to fill, identify potential synergies and help the European Commission to plan, together with Member States, the opportunities to be seized.

The Netherlands supports the EC efforts to bring together activities to further control the COVID-19 pandemic within the current bio-defence preparedness plan ("HERA-incubator"). However, the Netherlands re-iterates that the nature of a future permanent authority, which is expected to prepare and strengthen response to all future cross-border health threats, is fundamentally different from aggregating joint activities addressing an already known cross-border health threat. Nevertheless,

[4] Such as European Centre for Disease Prevention and Control (ECDC) and the EMA.
[5] Such as Notified Bodies and expert panels for medical devices.
[6] Such as Horizon Europe and EU4Health.
[7] Such as the Union Civil Protection Mechanism, including EU Emergency Support Instrument (ESI) and RescEU.

the Netherlands recognizes that valuable lessons to help shape the future authority could be drawn from the experience with the bio-defence preparedness plan.

Role of a future authority

The Netherlands notes that the EU is currently confronted with vulnerabilities in the sector of vaccines, medicinal products, medical technology, protective equipment and chemical precursors. This should be addressed at EU level. A future authority could offer an opportunity to tackle this and enhance the security of supply in the area of public health. Within the broad European public health landscape[8], the establishment of a future authority is perceived by the Netherlands as an opportunity to fulfill a coordinating role in enhancing the open strategic autonomy[9] for medical products and medical technology with the purpose of ensuring their security of supply for patients and health care professionals.

In the Netherlands' view, a future authority should develop clear criteria and flexible mechanisms to assess cross-border health threats, shortages, unmet medical needs and capabilities identifying priorities and corresponding medical countermeasures for the Union. These criteria and mechanisms should be established in close collaboration with all relevant EU bodies, the Member States and the private sector, whilst respecting the division of competences.

The aim of the future authority is to bring the essential public and private entities together, based on an EU-wide risk assessment, to stimulate and coordinate new developments (e.g. in the field of antimicrobial resistance (AMR)) and, when necessary, to make proposals for the (re-)allocation of funds.

The future authority as a stepwise approach

Based on its mission, a potentially formidable task awaits the future authority. To keep this manageable, the Netherlands advocates adopting a stepwise approach. The result should be a compact, efficient, flexible and effective authority. Any allocation of additional tasks should be preceded by an independent evaluation at specific milestones, involving the Member States.

After its establishment, the future authority should build a track record and establish its position, focusing on high-rated risks to public health. This should be based on risk assessment and horizon scanning methodologies.

Bearing in mind the above-mentioned role, the Netherlands considers that the future authority should focus on the following tasks:

- Map risks and vulnerabilities in supply chains, establishing new and/or maintaining existing EU stockpiles, in order to increase supply-chain robustness and promote greater open strategic autonomy for medical products. To strengthen EU's response capacity, the future authority should monitor the market and act when (risks of) serious shortages arise affecting multiple Member States. This knowledge is to be coupled with incentives to promote innovation under the necessary conditions to uphold public interests, as well as advanced research and development of new countermeasures. Furthermore, the future authority should support Member States by sharing information on the medical countermeasures developed.
- Coordinate EU-wide risk assessments for emerging or unknown cross-border health threats based on the available epidemic intelligence knowledge at the relevant EU bodies, including the ECDC and the Union Civil Protection Knowledge Network, aimed at identifying medical countermeasures. Further, cooperation will be sought with the World Health Organization (WHO).
- Combine efforts between IHSI and the future authority into a comprehensive EU approach to horizon-scanning for pharmaceuticals and medical technology. This would cater to information

[8] This landscape includes Member States, the EP, the EC, industry, academia, research institutes, health authorities, partnerships and civil society.
[9] The Netherlands defines open strategic autonomy of the Union as its capacity as a global player, in cooperation with international partners, to safeguard its public interests based on its own insights and decisions and being resilient in an interconnected world.

needs of both EU initiatives and all Member States: not only to assist the future authority, but also to support the future EU HTA collaboration, as well as Member States in their national policiy and reimbursement decisions on medical devices and medicinal products.

- Stimulate R&D and manufacturing of medicinal products as countermeasures, with AMR as a priority. The Netherlands favours tackling AMR based on a one-health approach, through strong international collaborative efforts, which in turn yields robust collaborative actions. Policy advice and/or coordination activities already exist in abundance. A future authority could provide an opportunity to pilot innovative approaches to EU Research and Development and public procurement for antimicrobials and their alternatives, aiming to provide pull incentives for novel antimicrobials. It could also promote investment and coordinate research, data technology, development, manufacturing, deployment and use for novel antibiotics. These activities coincide with the two flagship initiatives from the Commission's Pharmaceutical Strategy, a synergy that can and should be leveraged.

- Create a "menu" of procurement options. First, it is key for all procurement instruments, including the Joint Procurement Initiative (JPI) to be thoroughly assessed as to their effectiveness, both to outcomes to ensure availability of medical products for Member States as well as to ensure affordable prices by effective execution of bargaining power. Second, a future authority could define various procurement options tailored to various threat levels. In compliance with the proposed Regulation on serious cross-border health threats, a future authority could thereby act as a single point of contact for EU procurement options. This includes both existing and newly developed instruments, including the JPI, the Emergency Support Instrument (ESI) and the RescEU medical reserve and distribution mechanism, insofar as these would fall under the future authority's mandate.

Form and position of the future authority

The future authority should be a coordinator, brokering information and networking for the anticipation, generation and dissemination of knowledge, as well as being equipped to cooperate with the private sector to stimulate production of appropriate medical countermeasures in the event of an emerging cross-border health threat.

As a new EU coordinating entity, the future authority must be defined and positioned among existing EU bodies and at the interface of public and private domains. This demands a compact, efficient, flexible and effective authority with an unambiguous mandate, one that is clearly distinguishable from those of other actors in public health and civil protection.

The future authority should monitor the market of medical devices and medicinal products and act when (risks of) serious shortages affecting multiple Member States arise. While strengthening the supply chain for critical medicinal products (including vaccines) and medical devices in preparation for future crises, the future authority's activities could also improve the supply chain for other medicinal products and medical devices.

Governance

With a view to building confidence in strong collaboration and cooperation, the future authority should foster Member State participation. This could be achieved by setting up a governance structure which could consist of:

- A group of Member State representatives which is regularly consulted, also in non-crises episodes, about the state of play of crisis preparedness (i.e. potential risks identification, assessment of production capacity and supply of essential medical products). This group should be involved in decision making on budgetary issues related to production capacity investments or joint purchase of medical products during crises.

- An expert advisory committee consisting of a wide range of experts from academia and industry.[10] When necessary and depending on the subjects to be discussed, the expert advisory

[10] In order to prevent any conflict of interest of one of its members, the expert advisory committee is subject to the horizontal rules on the creation and operation of Commission expert groups (C(2016)3301 and C(2016)3300).

committee can invite additional external experts. In doing so, the full knowledge and innovation chain is covered, including close-to-market innovations. The expert advisory committee is consulted by and formulates (non-binding) recommendations to the future authority and the group of Member State representatives. It cannot take any decisions, nor drive the agenda of the authority.

The future authority should conduct regular, independent evaluations on its functioning at specific milestones, involving the Member States, on the functioning of the future authority.

Innovation and relationship with Horizon Europe

The Netherlands supports collaboration between the future authority and Horizon Europe with the aim to ensure that the knowledge gained through Horizon Europe is being optimally used to the benefit of society. With regard to the interplay with Horizon Europe, it is key for the future authority to have solely an advisory role. Budgetary decisions on Horizon Europe, as well as its objectives, remain subject to comitology. However, the future authority should provide input to the European Commission for the Horizon Europe Work Programmes. In doing so, Horizon Europe could finance long-term EU research and innovation projects and partnerships in the field of the future authority's mission.[11] Taking stock of the lessons learned from the bio-defence preparedness plan, at times of crisis, an ad-hoc emergency Horizon Work Programme could be adopted.[12] In addition, the Netherlands favours sufficient budget for cross-border health crisis-related calls for research and innovation activities under Horizon Europe.

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[11] F.e. collaboration between the future authority and the Horizon Europe pandemic preparedness partnership should be encouraged.

[12] F.e. VACCELERATE, a clinical research network for the coordination and conduct of COVID-19 vaccine trials, was funded both under the regular Horizon 2020 Work Programme, as well as under the bio-defence preparedness plan (by mobilizing additional funds from Horizon 2020).