The Hague, 29-03-2021

Comments from the Netherlands on Chapter III en V of the Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (COM(2020)725)

With this proposal the Commission aims to provide a clear framework for the activities to be deployed by the EMA in preparation for and during public health emergencies and other major events. The Covid-19 pandemic showed that the Union's ability to respond in a coordinated, quick and efficient manner to cross-border health threats in order to ensure the functioning of national health care systems is insufficient. Individually and independently, Member States are unable to guarantee the availability of (certain) medicinal products and medical devices. The Netherlands therefore generally supports a reinforced role of the EMA in crisis preparedness. We however have several comments in regards the proposals put forward in **Chapter III en V** of the draft regulation.

1. General comments

The proposal officially establishes EMA's ad hoc pandemic Task Force as the Emergency Task Force (ETF). However, it has not been evaluated **whether this is indeed the most efficient and effective solution** to the problems encountered during the pandemic or whether other solutions might be more adequate. This needs further consideration. Also, the **additional costs** that an extra body within the EMA would bring need to be clarified and fully justified.

We also wish to support the written **comments from Austria** concerning the ETF that were tabled for the CWP of 23 March 2021. More specifically:

- The proposal foresees a **limited representation of Member States** in the ETF. This diminishes the national competence of the Member States and, as such, leads to a lack of trust in decision-making, transparency and consensus.
- The **proposal foresees several tasks for the ETF that currently lie with EMA's SAWP and CHMP**. The proposal does not make it evident why these fully functioning, established structures would need the support of a separate body. Instead, the setting up of such separate body leads to inefficiency, additional costs and the risk of controversial and inconsistent outcomes.
- The ETF **does not solve the issue of Member States' workload**, since the scientific expertise for the ETF needs to come from the Member States. The same assessors that support the SAWP and CHMP members will also support the ETF members.

In addition to Austria's comments, we would like to add that more clarity is needed **on the type of advice and recommendations** that the ETF should provide and **whether EMA's scientific committees and working parties as well as Member States should adhere to ETF's conclusions** or are allowed to amend or deviate from them.

For all reasons above, we are currently not convinced that the ETF should become an established separate body within the EMA. Unless shown otherwise through a proper evaluation of EMA's ad hoc pandemic Task Force, **ETF's foreseen tasks should be integrated into the mandates of EMA's existing scientific committees and working parties**.

2. Detailed comments on Chapter III

Please find below our detailed comments per article, where relevant.

Article 14 Emergency Task Force

1. The Emergency Task Force is hereby established as part of the Agency. It shall be convened during public health emergencies, either in person or remotely. The Agency shall provide its secretariat.

The scope of ETF's activities during 'public health emergencies' should be clarified as to avoid its mandate extends beyond what is necessary to support EMA's foreseen responsibilities in crisis preparedness and response.

2. During public health emergencies, the Emergency Task Force shall undertake the following tasks:

(a) providing scientific advice and reviewing the available scientific data on medicinal products with the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions;

The Netherlands supports the added possibility of requesting data from developers. The current system is for a large part based on what is provided to the EMA. Proactive data gathering could further crisis preparedness and scientific evaluation. However, more clarity is needed on the type of data that can be requested. Clarification is also required on a possible duplication of responsibilities with the SAWP and whether the advice given is non-binding to the receiving party as is currently the case with scientific advice.

(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15;

(c) providing scientific support to facilitate clinical trials to be conducted in the Union for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency. Such support shall include advice to sponsors of similar or linked planned clinical trials on the establishment, in their place, of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with Articles 2(14) and 72 of Regulation (EU) 536/2014;

Again, a possible duplication with EMA's existing scientific committees and working parties should be avoided.

(d) contributing to the work of the scientific committees, working parties and scientific advisory groups of the Agency;

It is unclear from the proposal under which circumstances and in what fashion the ETF would be contributing to the work of EMA's existing structures. As stated before, clarity is needed on the division of competences and responsibilities between the ETF and above mentioned existing structures.

(e) providing scientific recommendations with regard to the use of any medicinal product, which may have the potential to address public health emergencies, in accordance with Article 16;

This task lies within the current mandate of the CHMP. It has not been made evident that a new structure is needed to support or take over part of the responsibilities of the CHMP. It is further unclear whether the CHMP and Member States should adhere to ETF's scientific recommendations or whether they can amend or deviate from it. EMA's scientific committees should under all circumstances be able to independently evaluate applications based on available data and provide independent scientific recommendations. Similarly, Member States should have the opportunity to fully execute their national competences.

(f) cooperating with Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations on scientific and technical issues relating to the public health emergency and to medicinal products which may have the potential to address public health emergencies, as necessary.

3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014.21 External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency.

4. The composition of the Emergency Task Force shall be approved by the Management Board of the Agency. The Executive Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all meetings.

5. The Chair may invite representatives of Member States, members of scientific committees of the Agency and working parties, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers of medicinal products, clinical trial sponsors, representatives of clinical trial networks, and interest groups representing patients and healthcare professionals to attend its meetings.

If established as a separate body, the ETF should consist of representatives from all Member States in order to ensure adequate expertise is made available and to safeguard trust in and overall support for the decision-making as well as consistent implementation within the EU. It is understood that the proposal aims to allow for some flexibility in the composition of the ETF to accommodate the needs relevant under specific circumstances. However, it is considered unacceptable that membership is based on an invitation from the chair, especially in light of the fact that the current proposal foresees tasks of major importance in regards the review and recommendations on the use of medicinal products. Instead, Member States should designate the relevant experts, especially when dealing with tasks that touch upon national competences. Also, it is not evident to have the ETF be chaired by the EMA. Chairs should be appointed by and from the Member States in a similar fashion as with the scientific committees.

6. The Emergency Task Force shall establish its rules of procedure including rules on the adoption of recommendations. The rules of procedure shall enter into force after receiving a favourable opinion from the Commission and the Management Board of the Agency.

In line with the rules of procedure of EMA's existing scientific committees, those of the ETF should also lay down the procedures for appointing and replacing its chair as well as a clear description of the activities and responsibilities of the ETF.

7. The Emergency Task Force shall perform its tasks as a 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 concerned medicinal products and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products. The Emergency Task Force shall take account of any scientific opinion issued by those committees in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.

"*The Emergency Task Force shall perform its tasks as a body separate from, and without prejudice to the tasks of the scientific committees…*". The same applies to EMA's existing scientific bodies and working parties; they should be able to perform their duties independently from the ETF and be able to amend or deviate from its recommendations whenever their independent evaluation of available data supports such amendment/deviation.

8. Article 63 of Regulation (EC) No 726/2004 shall apply to the Emergency Task Force as regards transparency and the independence of its members.

9. The Agency shall publish information about the medicinal products that the Emergency Task Force considers may have the potential to address public health emergencies and any updates on its web-portal.

Article 15 Advice on clinical trials

1. During a public health emergency, the Emergency Task Force shall review clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers of medicinal products as part of an accelerated scientific advice process.

2. Where a developer engages in an accelerated scientific advice process, the Emergency Task force shall provide such advice free of charge at the latest 20 days following the submission to the Agency of a complete set of requested information and data by the developer. The advice shall be endorsed by the Committee for Medicinal Products for Human Use.

3. The Emergency Task Force shall establish procedures for the request and submission of the set of information and data required, including information on the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted.

It is unclear how the activities of the ETF in requesting and submitting data align with the authorisation of clinical trials.

4. The Emergency Task Force shall involve representatives of the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted in the preparation of the scientific advice.

Scientific advice is to be given before an application is made. It should therefore be clarified what the foreseen purpose is of giving advice in relation to already submitted trials.

5. When authorising a clinical trial application for which scientific advice has been given, Member States shall take that advice duly into account.

6. Where a developer is the recipient of scientific advice, the developer shall subsequently submit the data resulting from clinical trials to the Agency following a request made pursuant to Article 16.

The advice given should be non-binding for the receiving party (Member State, developer) as is currently the case for scientific advice given by the SAWP. In that regard, it should be further clarified what is meant by 'Member States shall take that advice duly into account'.

7. Without prejudice to the provisions of this Article, the scientific advice shall otherwise be provided to those developers in accordance with the procedures established pursuant to Article 57 of Regulation EC (No) 726/2004.

Article 15 seems to create a duplication of activities between the ETF and SAWP. It is unclear how the activities described in this article would contribute to the work of the SAWP and in which situation ETF instead of SAWP is foreseen to take the lead in assessing clinical trial protocols and providing scientific advice.

Article 16 Review of medicinal products and recommendations on their use

1. Following the recognition of a public health emergency, the Emergency Task Force shall undertake a review of the available scientific data on medicinal products, which may have the

potential to be used to address the public health emergency. The review shall be regularly updated during the public health emergency.

2. In preparation of the review, the Emergency Task Force may request information and data from marketing authorisation holders and from developers and engage with them in preliminary discussions. The Emergency Task Force may also, where available, make use of observational studies of health data generated outside of clinical studies taking into account their reliability.

3. Based on a request from one or more Member States, or the Commission, the Emergency Task Force shall provide recommendations to the Committee for Medicinal Products for Human Use for an opinion in accordance with paragraph 4 on the following:

(a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004;

(b) the use and distribution of an unauthorised medicinal product in accordance with Article 5(2) of Directive 2001/83/EC.

The Netherlands supports the possibility to request data from not only marketing authorisation holders, but also developers to engage in preliminary discussions. The current system is for a large part based on what is provided to the EMA. Proactive data gathering could further crisis preparedness and scientific evaluation.

However, all above mentioned tasks currently fall within the mandate of the CHMP. It is not evident that a separate body is required to fulfil these tasks for the purpose of health crises preparedness and management. Also, even though the above mentioned tasks are to be seen within the context of compassionate use and the distribution of unauthorised products, the recommendation of the ETF may likely impact the scientific evaluation of any subsequent application for a marketing authorisation. In its currently proposed form with limited representation from the Member States this seems undesirable and may impact on the trust in decision-making. Also, as stated before, EMA's scientific committees should be able to independently assess the data provided.

4. Following receipt of the recommendation, the Committee for Medicinal Products for Human Use shall adopt an opinion on the conditions for use, the conditions for distribution and the patients targeted. The opinion shall be updated where necessary.

5. Member States shall take account of the opinions referred to in paragraph 4. Where Member States make use of such an opinion, Article 5(3) and (4) of Directive 2001/83/EC shall apply.

It is unclear whether the CHMP should adopt the recommendations of the ETF or is allowed to deviate from them. It is similarly unclear whether the Member States are obliged to adhere to the opinion following from an ETF recommendation and whether this could infringe on the agreed division of competences. The Netherlands wishes to stress that the CHMP and Member States should under all circumstances have the full right and opportunity to amend or deviate from any recommendation given by the ETF.

6. In the preparation of its recommendations provided pursuant to paragraphs 3, the Emergency Task Force may consult the concerned Member State and request it to provide any information and data, which informed the Member State's decision to make the medicinal product available for compassionate use. Following such a request, the Member State shall provide all of the requested information.

7. The Agency shall publish the opinions adopted pursuant to paragraph 4 including any updates on its web-portal.

Article 17 Communication on the Emergency Task Force

The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force.

The Netherlands generally supports transparency around decision-making. However, if indeed EMA's scientific committees as well as the Member States can amend or deviate from recommendations given by the ETF, consideration should be given to how these recommendations are published as to not create confusion with the reader and to avoid the image of inconsistency and discord within the EMA itself.

Article 18 IT tools and data

To prepare for and support the work of the Emergency Task Force during public health emergencies, the Agency shall:

(a) develop and maintain electronic tools for the submission of information and data, including electronic health data generated outside the scope of clinical studies;

The Commission should ensure the EMA has the funds, capacity and expertise available to effectively and efficiently develop and maintain the required digital infrastructure to support the work of the ETF. Without a proper functioning digital infrastructure both EMA and Member States will be unable to fully execute the tasks foreseen under this regulation. Involvement of the Member States in developing the required tools seems evident as to ensure these tools are compatible with national digital infrastructures.

(b) coordinate independent vaccine effectiveness and safety monitoring studies using relevant data held by public authorities. Such coordination shall be conducted jointly with the European Centre for Disease Prevention and Control and notably through a new vaccine monitoring platform;

Strengthening EMA – ECDC cooperation and joint coordination is supported. However, clarification is needed on their shared activities to ensure no duplication of activities exist. This need for clarification also extends to the Health Emergency preparedness and Response Authority (HERA). With the HERA proposal awaited and with a lack of details in the current EMA and ECDC proposal, it is unclear whether EMA, ECDC and HERA's responsibilities in crisis preparedness and management will indeed be fully attuned and mutually compatible without any overlap or gaps.

(c) as part of its regulatory tasks, make use of digital infrastructures or tools, to facilitate the rapid access to or analysis of available electronic health data generated outside the scope of clinical studies, and the exchange of such data between Member States, the Agency, and other Union bodies;

(d) provide access to the Emergency Task Force to external sources of electronic health data including, health data generated outside the scope of clinical studies, to which the Agency has access.

It is unclear what type of data 'electronic health data generated outside the scope of clinical studies' and 'relevant data held by public authorities' refers to, what the purpose of collecting such data would be and who should be responsible for providing it. It is important that this new regulation fully respects the GDPR rules as well as Regulation (EU) 2018/1725 on the processing of personal data by Union bodies. It should also be considered that the provision of certain data needs the consent of the owner or person concerned. For instance, an individual participating in a clinical trial has consented to using their personal data for the purpose of the study, but not for other purposes.

It should further be taken into account that certain data cannot be readily provided by Member States, either due to lack of required IT systems or to legislative hurdles. It is also preferred that any health data to be obtained by the EMA should be provided by the national competent authorities in order to maintain a clear and manageable medicine network and to have oversight of all data provided.

3. Detailed comments on Chapter V

Please find below our comments on Chapter V, where relevant:

Article 29 Cooperation between Steering Groups

1. The Agency shall ensure cooperation between the Medicines and Medical Devices Steering Groups in relation to measures to address major events and public health emergencies.

2. Members of the Medicines and Medical Devices Steering Groups and their working parties may attend each other's meetings and working parties and, where appropriate, cooperate on monitoring exercises, reporting and opinions.

3. In agreement with the Chairs, joint meetings of the Medicines and Medical Devices Steering Groups may be held.

At this stage, the Netherlands has no comments on Article 29.

Article 30 Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:

(a) personal data in accordance with Article 32;

It is unclear which article 32 is referenced here.

(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights;

(c) the effective implementation of this Regulation.

2. All parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition in the meaning of Article 101 TFEU.

3. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission and the Agency shall not be disclosed without the prior agreement of the authority from which that information originates.

4. Paragraphs 1, 2, and 3 shall not affect the rights and obligations of the Commission, the Agency, Member States and other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

5. The Commission, the Agency, and Member States may exchange commercially confidential information and, where necessary to protect public health, personal data, with regulatory

authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 30 only takes note of the appropriate protection of commercially confidential information and personal data but omits the topic of competition. For example, the collection of supply data from all pharmaceutical companies and wholesalers in the EU is not permitted under competition law. The Commission should therefore carefully examine whether the different proposals in the draft regulation violate competition rules.

Further, Article 30 should be reassessed in terms of compliance with GDPR rules and Regulation (EU) 2018/1725 on the processing of personal data by Union bodies (please see also our comment on Article 18 regarding the provision of health data). Finally, more clarity is needed on the purpose of and rules for exchange of commercially confidential information with regulatory authorities of third countries.

Article 31 Entry into Force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

The Netherlands has no comments on Article 31.