To: [redacted]
Cc: [redacted]
From: [redacted]
Sent: Sun 3/21/2021 5:45:01 PM
Subject: FW: Follow up on our meeting and future topics
Received: Sun 3/21/2021 5:45:01 PM

Ha [redacted] ben jij op de hoogte van onderstaande workshop?

Groet
[redacted]

Van: [redacted]
Verzonden: donderdag 18 maart 2021 11:37
Aan: [redacted]
Onderwerp: FW: Follow up on our meeting and future topics

Van: [redacted]
Verzonden: donderdag 18 maart 2021 11:35
Aan: [redacted]
Onderwerp: FW: Follow up on our meeting and future topics

Van: [redacted]
Verzonden: donderdag 18 maart 2021 10:57
Aan: [redacted]
CC: [redacted]
Onderwerp: Follow up on our meeting and future topics

Dear [redacted]

Thank you for your comments and suggestions on the following items, that we have very carefully assessed. I would like to get back to you on each of them.

Concerning the **radioisotopes and Pallas reactor project**, on 9 February relevant Commission services and the European Investment Bank met with representatives of the Dutch Ministry for Health to follow up on the meeting of 29 January. The meeting was an excellent opportunity to be updated about the Pallas Reactor project and to share and discuss potential EU financing opportunities to support the project. I welcome the research potential of the Pallas project, as well as its potential impact on isotopes supply in the EU. I would regret that, in case no public funding opportunities will be found, you will be obliged to renounce to the project. I hope that the discussions to find potential EU support will continue, and I would be glad to be updated about any new development, as I understand that you will take a decision very soon.

The **Pharmaceutical Strategy for Europe** foresees specific actions with deadlines for each one. A major flagship is the revision of the general pharmaceutical legislation (Regulation (EC) No 726/2004 and Directive 2001/83/EC) by 2022. On 22 February 2021, the Pharmaceutical Committee adopted a work programme based on priority topics that will inform this revision and will guide policy discussions among EU and national actors, including with stakeholders where necessary.

The intention of the Commission has never been to limit the discussion on unmet medical needs only to the areas of rare and paediatric diseases. We have initiated the discussion during the Pharmaceutical Committee meeting of December 2020 in order to collect the information necessary for the impact assessment of the revision of the two concerned legislations which had already started.
The topic of unmet medical needs for the general population, and its link with access and affordability of medicines, will be one of the main pillars of the work with Member States on the pharmaceutical strategy. This has been discussed during the Pharmaceutical Committee meeting of 22 February 2021.

The Commission is planning to discuss unmet needs in the Pharmaceutical Committee. A first opportunity will be a workshop of the Committee (tentative date 26 March), open to pricing/reimbursement & Health technology Assessment experts and HTA bodies. The workshop will also cover the system of incentives in the general legislation which links to the question of unmet needs. Indeed striking a balance between incentives for innovation and access to affordable medicines is key. We invite the Dutch authorities to actively participate to this meeting.

I would like to take the opportunity to recall that the Strategy also foresees that the Commission will propose to revise the pharmaceutical legislation addressing aspects that impede the competitive functioning of the markets and to take account of market effects impacting on affordability. A first workshop on this issue with experts from the pricing, reimbursement authorities and public payers has already taken place. The outcomes of this workshop were presented on 12 March at the meeting of national competent authorities on pricing and reimbursement, organised by the Portuguese Presidency.

As regards the other aspect you raise concerning the **unused medicines**, the Commission Communication on a strategic approach to pharmaceuticals in the environment (COM (2019) 128) sets actions across the whole life-cycle of pharmaceuticals including the ones related to the unused medicines. To implement some of those actions, the Commission set up a Working Group focused on pharmaceuticals in the environment under the Pharmaceutical Committee. This concerns also the actions on the collection schemes for the unused medicines, their assessment and consider how their availability and functioning could be improved. The Netherlands is a member of our Working Group and in that forum we could further discuss this topic at technical level.
The Pharmaceutical Strategy proposes actions to address the environmentally sustainable medicines. It published a progress report of the actions set in the EU Strategic approach to pharmaceuticals in the environment, it builds on those actions as well as sets further actions to address the environmental challenges of pharmaceuticals. We are currently working on the implementation of the strategy. As announced in the Pharmaceutical Committee, we will also organise a thematic Workshop on pharmaceuticals in the environment to discuss further with the Member States these issues. We look forward to further discussing with the experts representing your country at the technical level also during that event. An invitation to that event will follow.

The **European Health Union** proposal was prepared during the ongoing crisis, addressing the lessons learned from the early stages of the pandemic. Due to the urgency of the matter, the package is not accompanied by a formal impact assessment. However, the proposal is based on an assessment of data collected in the first months of the COVID-19 pandemic and exchanges held with public and private stakeholders in the framework of the COVID-19 pandemic on issues encountered and possible ways of addressing them. Moreover, the proposal also draws on the recommendations contained in the joint opinion 'Improving pandemics preparedness and management' by the Group of Chief Scientific Advisors, the European Group on Ethics in Science and New Technologies, and the Special Advisor to the President of the European Commission on the response to COVID-19. With regards to medical devices, the proposal takes into account the impact assessment carried out in preparation for the adoption of Regulations (EU) 2017/745 on medical devices and 2017/746 on in vitro diagnostic medical devices."

We appreciate your acknowledgement of the **Joint Procurement Agreement** as a relevant tool for cross-border health threats. As you know, this instrument has been designed as a preparedness tool. After having used it extensively to respond to an emergency situation, we can indeed see some areas for improvement. Thus, your suggestion of the in-depth analysis of practical implications, especially for use in medicinal products, is very pertinent. While we have been looking into lessons learned on our side, we would appreciate to receive more insights from you on this matter.

Kind regards,

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European Commission

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+32 5.1.2e

5.1.2e @ec.europa.eu