From: [redacted] (SANTE)
Sent: dimanche 24 janvier 2021 10:58
To: RYS Andrzej Jan (SANTE); [redacted] (GROW); [redacted] (SANTE)
Cc: [redacted] (SANTE); [redacted] (GROW); [redacted] (SANTE)
Subject: BTO on structured dialogue scoping meeting - EFPIA, MfE, EFCG/ CEFIC

Dear Andrzej, [redacted] and colleagues,

Please find below the BTO on the structured dialogue pre-scoping meeting (18 Jan) with industry representatives, EFPIA, Medicines for Europe, EFCG/ CEFIC. Thanks to [redacted] and [redacted] for their input. If you have any questions please let me know.

Best regards,
[redacted]

18 January 2021

Attendees:
External: [redacted] (CEFIC), [redacted] (EFPIA), [redacted] (MfE), [redacted] (MfE), [redacted] (Merck KGaA), [redacted] (Hovione FarmaCiencia SA), [redacted] (EFPIA), [redacted] (Novartis), [redacted] (Fresenius Kabi)

Internal: [redacted]

Note:
Overall, all participants showed support for the structured dialogue initiative and agreed to nominate their representatives. Regarding the six focus areas suggested by the EC, some suggestions were made mainly to clarify and make the themes and topics more explicit. All agreed that these are a good basis for discussion.

The following points were raised:

- Important to have clearly defined definitions e.g. robust, vulnerability, dependency, ability to respond (pace). [EC noted that this will be included in Phase I]
- Industry are (legally) limited in the data that they can collect which impacts resilience. EC / national authorities collecting and assessing data would ensure compliance with antitrust rules.
- Ensuring appropriate participation of those MS who have advanced strategies/ policy already developed such as DE, IT and FR. Public authorities will be central to considering medicinal products considered to be critical for public health.
- Due to the time sensitive nature it may be difficult to secure calendars of the global CEOs. [EC explained that the event will not be public. EC also explained that industry associations do not need to come to the event with a common,

agreed industry position. Participants to the high-level event are strongly encouraged to express themselves freely, engage in interactive discussions with others and share their views to pass on messages they would like others to hear.]

- EC requested that participants who are likely to engage and constructively contribute should be proposed by representative bodies. EC willing to liaise with representatives as proposals are received to ensure diversity based on the pre-defined criteria. Also, welcomed any information in advance in writing.
- Queried if representation should be at global, European or national level. [EC: As the conversation is in the EU context, and considers approaches to EU strategic autonomy, those participants who have an understanding of that should be proposed. There may be opportunity to present in a broader way.]
- Participation of DGs of representative bodies was queried.
- It was proposed that there could be one conversation on 26 February, covering all points at a high level, sharing examples of success by sector. [EC explained that the current plan is to have discussions in smaller breakout groups. This should be seen as an opportunity to connect with public authorities on equal footing and to pass on messages, as well as set the scene for future work.]
- On the operational work, sequencing work executed under each of the 6 focus areas was recommended, as some may inform the approach to others.
- On the six areas, it was again reiterated the need to agree definitions and conduct a knowledge/data gap analysis to inform the basis for policy options. Wording was proposed and it was suggested that each of the six points could be further elaborated for clarity. (see below)
  With regard to order, it was recommended that cost implication should be considered after R&D needs, because that will assume an additional cost. The cost to respond in emergency/ crisis situations to secure supplies should also be considered.
  Regulatory aspect/ hurdles should be considered (chemical part specifically). [EC noted that this would be captured under 2 – drivers and causes of vulnerabilities and dependencies. EC also stressed that as this is not an expert group, it cannot give advice on legislative changes].

The participants committed to:

- Propose participants for the 26 February meeting, by 28 January to allow time to circulate the meeting invitation
- Share written feedback post meeting

EC committed to:

- Expand on the detail provided under the six focus areas
- Share the presentation post meeting

Wording on six focus areas (EFPIA comments in red):

1. Definition of a robust pharmaceutical supply chain;
2. Causes based on data and drivers of vulnerabilities and degrees of dependencies of the supply chains;

3. Identification of the products critical from the public health point of view; (all products/ critical products)
4. Mapping the EU manufacturing capacity;
5. Cost implications of increasing the robustness and capacity to respond/crisis preparedness ~~state and weaknesses identified~~ of the supply chains;
6. Identification of the R&D needs (modernisation of manufacturing processes, green and digital transition).

Under each of six headings divide into knowledge gathering and gap analysis.
Additional points in Phase II to consider policy options and review of impact.