ERAvsCorona Action Plan - *Ad hoc* working group of MS: Manufacturing sub-group

Meeting of 08 May 2020, 09:30-10:30

Report

Participants:

- EC: (10)(2e) (chair), (10)(2e) (10)(2e)
- EMA: (10)(2e)
- AT: (10)(2e)
- BE: (10)(2e)
- MT: (10)(2e)
- IT : (10)(2e)
- NO : (10)(2e)
- CH: (10)(2e)
- PT: (10)(2e)
- FR: (10)(2e) (10)(2e))(2e)
- Consilium: (10)(2e)

SANTE introduced the aim of the Manufacturing subgroup, one of the four subgroups set up under the ERAvsCorona Action Plan, which is a joint initiative of DG RTD and SANTE to look at the complete Covid-19 vaccine, treatment and testing pipelines, from research to deployment. The other three subgroups concern Clinical Trials, Testing, and Financing. The subgroups are composed of Member State representatives and Commission services.

The attention of this subgroup is on the **manufacturing capacity** for diagnostics, therapies and vaccines in Europe, and to consider actions how to **scale-it up.** The suggested objectives are:

1. To map and determine the existing manufacturing capacity in EU/EEA/EFTA, both in publicly and privately owned facilities.
2. To determine the required degree of scale-up in manufacturing capacity: what is urgently needed in the short-term and what is also needed in the long-term to maintain adequate manufacturing capacity for resilience and other use after COVID-19.
3. To define the associated investment needs, both for (a) repurposing, upgrading and expanding existing manufacturing facilities, as well as (b) building new facilities.
4. To identify relevant national investment initiatives, the contributions that the current and future EU funding instruments can make, and to explore complementarities among all these.

The Commission deems essential to start mapping the manufacturing capacity in Europe, with **first focus on vaccines.** The Commissions has also started discussions with industry on this. Also important to look for synergies for investments; need to know any relevant national plans and initiatives in this regard. The Commission is working on repurposing the Multi-annual Financing Framework for 2021-2027 and mobilising instruments for Covid-19 response and recovery. For instance, how to use the Emergency Support Instrument and work with the EIB.

It is important to consider that we cannot afford to disrupt the production of other vaccines for other diseases; we need to take this into account in the needs for scaling-up.

Therapeutics can also help to relieve the pressure on the health systems, if a promising medicine shows to have a real impact. The diagnostics will be checked by the Testing sub-group. Both therapeutics and diagnostics can also be included in the mapping if a big demand appears.

The distribution capacity is a significant issue too and worth discussing about it and the related investments in future meetings of the sub-group.

Questions were raised by the Member State participants on the following:

- Shouldn't we consider also the manufacturing possibilities outside Europe?
- What type of vaccine candidates do we have? We need to consider manufacturing capacity per type.
- What about IPR?
- As this is a global challenge, should there be a reference to the WHO initiatives?
- Should EFPIA be present/involved in this exercise?
- Should the mapping also include the capacity for producing the lots for clinical trial phases?

The Commission replied that one can look at manufacturing capacity outside EU/EEA/EFTA but when it comes to national investments and the use of EU programmes, the investments will be directed to facilities in EU/EEA/EFTA countries. We need to make sure that we have enough capacity on European soil to provide the vaccine to Member States and also step-up to global cooperation. There is a list of promising vaccines (and their technologies), compiled by EMA. This will be circulated to the members of the sub-group.

IPR is an issue and it is known that at some point negotiations will have to take place, also on liability and access issues. Member States and the Commission may have a better negotiation position if we have a strong public investment component, use joint procurement mechanisms, introduce regulatory facilitation. We may need to consider public-private partnerships.

Collaboration with the WHO is being taken into consideration. References can be made to the work of WHO and to the other partners coming through the Pledging Conference of 4th May.

Mapping the manufacturing capacity for clinical trials is better left to the Clinical trials sub-group. The Manufacturing sub-group will focus on the capacity for deployment. Mapping exercise needs to begin, starting with the already existing facilities since it is more manageable to scale them up instead of building new facilities. It is also essential to bear in mind that different facilities may be 'tuned' to different types of technology and therefore some technologies and production methods can be ramped up more quickly than others. The diversity of technologies in candidate vaccines may also require different production sites.

Member States were invited to share their views on the involvement of EFPIA or national associations too and how to verify information we may get from the industry. We should be mindful about information on the capacity of individual companies; this cannot be shared, however presenting the aggregate level of capacity should be feasible.

Conclusions & Next steps:

1. Mandate for the Manufacturing sub-group to be agreed by written procedure. Member States to provide comments to the mandate **by Monday 11/5 COB.**
2. Commission and EMA to circulate, on a confidential basis, a preliminary list of candidate vaccines (and their technologies) and the criteria used to select these, **by Friday 8/5 COB**.
3. Member States to send any comments about these promising candidate vaccines and if they are aware of any others **by Wednesday 13/5 COB**
4. Member States to discuss internally about the candidate vaccines and send **by Friday 15/5 COB:**
    - views on how to approach the mapping of existing manufacturing capacity for vaccines
    - information about ongoing or planned national initiatives to invest in or incentivise manufacturing
    - views on how to approach investments
    - what kind of questions to ask to industry
5. Discussion will focus on vaccines for now. 'Game-changer' therapeutics will be added if a manufacturing capacity bottleneck is identified in getting these therapeutics from research to deployment. Distribution capacity will be considered in future meetings too.
6. Other demand/supply mismatches will not be tackled where there is no research dimension.