To: 5.1.2e @minvws.nl[5.1.2e @minvws.nl]; 5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e)[5.1.2e @minvws.nl]; 5.1.2e @minezk.nl[5.1.2e @minezk.nl]; 5.1.2e (5.1.2e)[5.1.2e @minvws.nl]
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From: 5.1.2e
Sent: Tue 4/7/2020 7:38:51 PM
Subject: uit conclusies SANTE management board 7/4 - svp vertrouwelijk behandelen
Received: Tue 4/7/2020 7:39:05 PM

B1.a. Update on corona virus:

Validation of testing
3 work strands: (1) project group on test performance with JRC and ECDC compile existing assessment of performance of tests. This work will be delivered at the end of this week (12/04) and is intended to serve as input into the ministerial discussion on 15/04; (2) the establishment of a European coordination Centre on Epidemiological testing and Control (under the EURL model); and (3) guidance on validation of testing equipment – which has been added to the Commission agenda for adoption next Wednesday. On the latter, there is a need to clarify what its scope should be. Guidance on validation would be difficult but we could explain the regulatrory framework and facilitate the certification process, similar to what was done on medical devices. SANTE will start drafting (2-3 pages) and JRC will provide link with data they are collecting.

Clearing house for medical equipment:
First meeting of clearing house – 5 product clusters have been created. Each cluster is composed from colleagues of SANTE GROW, TRADE, COMP, JRC, SG. SG is leading the clearing house. The role of the clearing house is to obtain an overview of needs of MS, to determine which instrument should be followed (JP, ESI, rescEU) and to clarify process. In SANTE, 5.1.2e is the main contact point with the support of 5.1.2e (F4) for PPE, 5.1.2e 5.1.2e (F4) for ventilators, 5.1.2e for medical devices (F5 5.1.2e 5.1.2e for test materials, kits and reagents (B6, 5.1.2e , 5.1.2e for medicinal products and vaccines (B1, 5.1.2e) and 5.1.2e 5.1.2e 01) for horizontal tasks.

Health weekly Ministerial meetings:
Yesterday's meeting covered the cross-border healthcare guidelines for COVID-19. Next week there will be informal Health Council organised by presidency on 15 April. The objective will be to prepare for a coordinated exit strategy. Discussion on mobile apps will also take place. In addition, guidance on optimal use of pharma to be presented as AOB on 15 April. The next Ministerial VC organised by SANTE will be on 20 April.

Exit strategy:
The Exit strategy will establish principles governing the progressive lifting of confinement measures, based on 2 criteria: epidemiological (i.e. stage of the outbreak) and saturation of hospitals. The principle of a coordinated relaxation of the measures will also be mentioned. It will need to be gradual as we are far from having a vaccine or reaching herd immunity.

The exit strategy will need to be accompanied by a testing strategy. The Expert panel advised to be cautious with wording and to present a deescalation strategy, given that the virus will be present in the future. Two countries already announced softening of contained measures: Austria will reopening shops after Easter, and Denmark is considering reopening schools.

The ECDC will publish tomorrow a new risk assessment and guidelines on testing and masks. The latter will put up additional pressure on demand for masks.

Pledging conference:
President VDL is very keen to show European leadership and to partner up with countries who also have global vision. The pledging conference will take place sometime between are end of April and mid May. It should focus on quickly addressing global needs: research, strengthening healthcare capacity in countries with weaker health systems, fair access to therapeutics.

Apps and tracing:
Guidelines prepared by CNECT, JUST and SANTE will be adopted tomorrow.

Cross border – medical teams are increasingly dispatched to other countries.

Clinical trials guidelines – The industry is calling for help to facilitate the conduct of clinical trials as it is very difficult for patients to go to hospital for normal visits. Guidelines have been prepared by SANTE, EMA, and heads of medicine agencies but they will be reviewed to provide further flexibilities, which would however require that Member States take owndership and apply the flexibilities. The guidelines wil therefore be sent to MS for comments an if needed can be presented to health ministers under AOB on 20 April (to be included in the Commissioner's speaking points).

Vaccines – work with RTD is ongoing to develop vaccine strategy. RTD is working on a strategy for vaccine development, focusing on research perspective. In parallel colleagues in B5 have been working on regulatory aspects. When looking at accelerating procedures to authorise a vaccine, lone needs to reflect on potential risks, such as liability issues. Furthermore, even an effective and safe vaccine might not solve problem if there is insufficient production capacity in EU and lack of solidarity globally.

ESI – Initial ideas in SANTE are to focus on purchase of essential medical supplies, protective equipment, testing, therapeutics and vaccines. It is important to have clear ideas of where ESI could help us overcoming regulatory bottelnecks. The Art 122 TFEU legal basis allows a lot of flexibility. Council has put forward a proposal which would give us the right to apply a lot of exceptions for the joint public procurement and to purchase at Commission level. The Clearing house is put inside this ESI task force.

Guidelines on rational use / supply of ICU medicines: Guidelines on the rational use of medicines will be published tomorrow 11 am and include recommendations to lift export bans and restrictions, avoid national stockpiling, fight misinformation, monitor stocks, ensure manufacturing capacity through fiscal incentives/state aid, etc..At same time, the College will adopt a DG COMP-led Communication on relaxation of competition rules which will help us to bring companies together and increase production of scarce medicines. DG COMP envisions that companies holding marketing authorisation for products at risk of/ in shortage will be contacted and asked to provide confidentially the state of their stock and production capacity (organised by associations). In parallel to that, models will define what demand is (work with C3). Industry will try to match supply and demand and make possible suggestions to ensure this matchmaking.