@minvws.nl]; 5.1.2e To: 5.1.2e 5.1.2e @minvws.nl]; 5. @minvws.nl]; 5.1.2e @minvws.nl]; 5.1.2e 5.1.2e @minvws.nl]; @minvws.nll: 5.1.2e 5.1.2e 0minbuza.nl]; 5.1.2e 5.1.2e 5.1.2e 5.1.2e @minbuza.nl] From: Sent: Tue 2/16/2021 3:31:55 PM RE: ter info: Commissiemededeling ER toelichting 5.1.2e in Horizon PC Subject:

Ha allen.

Received:

Tue 2/16/2021 3:31:56 PM

flash note joint H2020-HE Health meeting 15-2-2021.pdf

In aanvulling op mijn mail van gisteren hierbij nog het flash report. Zoals jullie kunnen lezen, wijkt onderstaande schriftelijke toelichting iets af van de mondelinge toelichting van 5.1.2e Hopelijk biedt dit extra duiding.

Groet, 5.1.2e

5.1.2e (SANTE)

On February 15 the European Commission convened an ad-hoc meeting to discuss the need for urgent new R&I actions to address the increased threat of SARS-CoV-2 variants with the Programme Committee for the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) – Configuration 'Health, demographic change and well-being' and the Shadow Health Configuration of the Horizon Europe Programme Committee. There is a pressing need for preparedness actions now to better understand the impact of the spread of different variants in terms of transmissibility, severity of disease and effectiveness of current vaccines, also to address the development of modified vaccines which are specific for the new variants or adjusted vaccination strategies. These build on important initiatives announced in the 2020 Health Union, the new Health Emergency Response Authority (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Response-Authority) and the Commission's January 2021 Communication on COVID-19 vaccination (https://ec.europa.eu/info/sites/info/files/communication-united-front-beat-covid-19 en.pdf).

In preparation of the European Council of 25-26 February 2021, the European Commission is currently preparing a package of actions that will help the European Union and its partners to detect characterise and adapt to virus variants. Actions would particularly focus on; (1) rapidly detection of variants, (2) swift adaptation of vaccines, (3) Setting up a European Clinical Trials Network, (4) Fast-tracking regulatory approval of updated vaccines and new or repurposed manufacturing infrastructures; and (5) Enable upscaling of production of existing, adapted or novel COVID-19 vaccines. This will require to further mobilize support from the EU's research framework programmes.

After the 3 legislative proposals building an EU Health Union and the announcement of Von der Leyen to set up a HERA, the "policy paper" of next Wednesday will look into the next phases of dealing with the Corona virus. It should be seen as part of the general

push to reinforce preparedness and response in Europe and it will focus on 5 domains:

- 1) New variants of COVID in communities/population. EC will propose to strengthen information on sequencing in Member States. EC will support data platforms for open research data sharing. Focus is research, but additionally EC aims to support pharmaceutical sequencing. DK and FIN are towards 30% of sequencing, but some Member States won't even reach 1%. Through this proposal and the ECDC mechanism the EC is encouraging Member States to carry out additional sequencing, aiming to reach a 5% target for all Member States.
- 2) Deploy quickly PCR tests in Member States EC will propose joint procurement
- 3) Need for a clinical trial network focusing on the adaptation to variants of the virus. EMA will pursue engagements in these networks.
- 4) Advance purchase agreements for the next generation of vaccines. EC wants to set up a dialogue with MS about which vaccines are needed. EC will propose to mobilize funds for advance generation purchase agreements.
- 5) Proposal for a **regulatory framework of new vaccine alterations**. EC will launch research projects in the field of pediatrics clinical trials, an area where more information is needed. Further focus on researching vulnerable groups and taking into account specific aspects, f.e. ethnical aspects.

groet,

5.1.2e