Briefing for Premier Rutte on SARS-CoV-2 vaccine

EU cooperation

30/03/2020

Context:

- Based on the key attributes of Janssen's technology platforms and our established Vaccines developmental and manufacturing capabilities in the Netherlands, Janssen is well positioned to respond to the COVID outbreak, through making a SARS—CoV-2 vaccine available in large volumes in the 2021 timeframe.
- To allow for speedy development and early approval of the vaccine, it will be important to ensure regulatory requirements which are globally aligned and are adapted to the emergency situation. Several areas of attention are worth mentioning:

1. Regulatory environment

- The outcome of the recent workshop of International coalition of Regulatory Authorities (ICMRA) related to COVID-19 vaccine development has been very encouraging. We hope that this initiative is the start of an intensified partnership between the regulatory agencies, especially FDA, EMEA, WHO and that this will result in harmonized, pragmatic, requirements.
- 5.1.2e is already engaged in a direct dialogue with the European Medicines Agency (EMA) based in Amsterdam.
    - The Paul Ehrlich Institute (PEI) in Germany has long-standing in-depth vaccine/biologicals experience and it would be important if they can be appointed as rapporteur for scientific/regulatory discussions during this development process. The Belgian or Dutch agency would certainly have the expertise needed as co-rapporteur countries.
    - The EU should immediately put in place adapted regulatory framework to mimic the 'Emergency Use Authorization' process in the US which allows to roll out large scale vaccination based on a limited data package. Based on current discussions with FDA's Center for Biologics Evaluation and Research (CBER), such an authorization could be granted, if phase I and IIa are successful, as early as summer 2021. Potentially even earlier under certain scenarios.
    - As to clinical trials in Europe, there are several national regulations that might impact overall fill/finish capacity (biocontainment requirement for the filling at BSL2). In addition, country specific Genetically Modified Organisms (GMO) regulations create potential extra delays in study start. Clarity on the acceptability of multidose presentations would also significantly address the filling capacity gap.

4. Free flow of goods/critical employees

Manufacturing vaccines is a complex process, which involves a large series of raw material, sourced throughout the world. In addition, as a global company we are seeking the fastest path to reach the population in need for the vaccine across the globe. Therefore, it is critical that borders remain open within EU and with rest of the world for the free flow of materials and critical employees related to the development of the vaccine.