

EU R&I Actions on a Vaccine against COVID-19

Written Contribution of **Belgium** to the discussion between the Member States and the European Commission

0) General comments

- **The vaccine industry constitutes a strategic sector for the European economy.** Europe has a long history of vaccine discovery, development and manufacturing, and benefits from a strong industrial infrastructure.
- While major innovative vaccine manufacturers are global in nature, **many of their operations are based in Europe.** 80% of vaccine doses produced by Vaccines Europe (VE) members are being manufactured in the European region and 86% of these doses are exported for worldwide use. That being said, 80% of the drugs' active ingredients are imported from China and India.
- There is a need of an anticipation of vaccine production phase.
- Need to welcome the new proposals concerning State Aid, to cover RDI, Testing and Upgrading infrastructure, and investment aid projects. The proposals should cover the full development chain, until the production and market launch.
- It is **important to develop shared funding responses between international, EU and MS level.**

1) Are there further national funding intentions on vaccine research and development? How can adequate funding for vaccine development and production in the EU be better coordinated?

Finding a vaccine is a top priority and although duplication of research should be avoided at all times, it is important as well to **allow different parallel options to be developed and tested** to find the best working options and alternatives. It should also be possible to fast switch research focus, based on breakthrough insights that need extra funding. In this vain, it is important to make the most of initiatives funded by past or current EU projects to pool expertise, resources and communities together to increase agility and impact of future actions.

This is a (non-exhaustive) list of Belgian (funding) intentions on vaccine R&D:

- The federal government and the Belgian pharmaceutical industry are cooperating in the context of the so-called **R&D Bioplatfrom**. They have agreed to (i) accelerate the procedures in Belgium to start clinical studies for new vaccines and treatments against COVID-19, and (ii) to scale up the test capacity so that testing of COVID-19 patients can now also be carried out in labs of the pharmaceutical companies. The financing will be performed via a public-private partnership worth 40 million Euro.
- **Vlaams Instituut voor Biotechnologie (VIB)** will reallocate about 1 million Euro of its budgets for its Grand Challenges Programme to COVID-19 projects to test novel interventions in patients after preclinical evidence of the potential; to test

immune status during infection; and to test the potential of suppressing inflammation response.

- [Flanders Vaccine](#) is a non-profit, strategy-driven platform for academic, industrial and public stakeholders that serves as a one-stop-shop for vaccine trials.
- **Lab of Virology, Antiviral Drug & Vaccine Research - Rega Institute (Prof. Dr. Johan Neyts, KU Leuven)**. The team works on the development of a vaccine and on antiviral therapy. In the past weeks, two EU-projects¹ were submitted and selected for funding (SCORE and [EXSCALATE4CoV](#)). They also received funding from the Bill and Melinda Gates Foundation (BMGF) to test candidate drugs against SARS-COV2. With Johnson & Johnson, the lab is involved in Biomedical Advanced Research and Development Authority (BARDA) funding; and is partnering in 3 IMI proposals.
- The **Centre for the Evaluation of Vaccination (Prof. Dr. Pierre Van Damme, University of Antwerp)** has been approached by 4 different companies and bio tech for the conduct of their respective phase 1 SARS-CoV2 vaccine trials in healthy adults. The centre is being prepared to be able to perform such phase 1 trial in social distancing and semi-quarantine conditions, based on previous experience with polio vaccine trials.

Also industry is gearing up in the search for a vaccine. To name a few:

- [GlaxoSmithKline](#)
- [Janssen Pharmaceutica](#) - research on 12 different tracks
- [UCB Biopharma](#)
- [Novasep Belgium](#)
- [PolyPeptide](#)
- [eTheRNA](#)
- [Eurogentec](#) - genomics, proteomics, vaccines, diagnostic
- [Univercells](#) - The continuous miniaturised process technologies developed by Univercells allow the establishment of local plants of medium capacity at a lower cost. These approaches therefore allow for local autonomy (even at the scale of a country or a little more) in the production and distribution of vaccines.
- [Vésale Pharma](#)
- [Xpress Biologics](#)
- [Ziphius Therapeutics](#)

2) How can Europe's future autonomy in vaccine production be ensured, so that vaccines can be produced and distributed according to the EU principles and values of ethics, fairness and solidarity?

- There is a need for **inventories of critical needs** to ensure sufficient starting material, manufacturing equipment, capacity needs, etc. This will have to be done in close collaboration with the pharmaceutical companies.
- We should **continuously interact with all stakeholders** from the earliest stages of development – especially regulatory authorities and recommending bodies to

¹ The other two selected SC1-CORONAVIRUS projects with Belgian participants are RECOVER (University of Antwerp) and EpiPose (University of Antwerp and UHasselt).

ensure that resources are not spent on developing vaccines that are unlikely to be approved and recommended.

- To ensure **fairness, ethics and solidarity**, a task force or an advisory body to the policy/decision makers should be established at European level composed of experts from academia and/or industry which will cover all aspects (biotechnological, medical, manufacture, companies) of vaccine development.
- Another important aspect to ensure fairness, ethics and solidarity is that the **information and data coming from the different countries should be reliable and trustworthy**. European data from the various countries are providing reasonably good insights for (i) daily adaptations in specific policies for each country (each having their specific national health services) and for (ii) later follow-up studies, future policies for better prevention programs. However, different countries handle different intervention strategies to combat the pandemic. As the virus is not aware of borders, national strategies affect neighbouring regions and hence the whole community. There is an urgent need for the EU to ensure unified recommended strategies based on scientific information, at least in cases of pandemics that affect the whole territory.
- We should better connect and coordinate vaccine research while also focusing on research for **diseases of low-income countries** and pandemic preparedness to better anticipate and prepare for future health threats, which is one of the greatest challenges of our time.
- We have an urgent need for increased **Biosafety Level-3 (BSL-3) capacity** and access to these BSL-3 facilities to work with SARS-COV2.
- We have an urgent need for **European GMP facilities** to ensure European production capacity.
- We should learn from **previous initiatives** on what is working and what is needed.
- We support the EOSC platform in general and the **opening and sharing of FAIR data** between scientists (open science), and the establishment of a European COVID-19 Data Platform to help store, share, and analyse research data linked to the COVID-19 pandemic.
- There should be an **EU-wide awareness raising campaign on the importance of vaccines** (also relayed at national, regional and local levels), in order to regain citizens' trust in knowledge-based health interventions. Well-informed citizens are more willing to follow the health advices and are key to prevent future pandemics.

3) What are your views on the pledge from President of the European Commission, Ursula von der Leyen and the President of the European Council, Charles Michel? What would be the best way to implement this in a coordinated way (e.g. CEPI, EDCTP....)?

- An **EU coordinated action** to develop and deploy a vaccine and antivirals against COVID-19 is highly supported. There is an urgent need for new, additional and alternative **research platforms and coordination of activities**.
- As the knowledge concerning SARS-COVID2 is still limited, **fundamental research** and support of antimicrobial (antiviral, antibacterial, antiparasitic) vaccine developments is needed.

- We encourage the EU to **build on existing expertise and rely on established experts and research institutes and infrastructures**, where previously already considerable investments have been done for vaccine developments and testing and development of antivirals. Extra **seed money** should go to universities that come with good projects, to non-profit organizations e.g. national epidemiology centres and to dedicated manufacturing companies for vaccines where a willingness exists to interact with academic experts in joint approaches.
- It is important to develop **shared funding responses between international, EU and MS level**. The implementation of a **special taskforce at the EU level** (that are representative of the health innovation ecosystem) would be a good way to coordinate efforts. It could be composed of CEPI, EDCTP or Gavi representatives together with national/regional representatives of innovative ecosystem that are already supporting researchers and companies in this field.
- **Innovative ways of funding** - such as crowdsourcing and an international online pledging event (cf. statement by President von der Leyen and President Michel) - may be considered as well, but it should be clear how funds will be used.
- Also develop **synergies with the European Investment Bank (EIB) and European Investment Fund (EIF)** for innovative risk-sharing solutions.
- The [Council Recommendation of 7 December 2018](#) on the strengthened cooperation against vaccine-preventable diseases also offers relevant recommendations to create a coordinated EU action against epidemics and how to prevent them.

ADDITIONAL INFORMATION

Relevant Belgian therapeutic solutions:

- The **Health Institute of the University of Mons** has launched a study on the bioavailability of the hydrochloroquine which is currently administered to patients, in collaboration with a local hospital.
- A research group at the **Life Sciences Institute at UCLouvain (David Alsteens)** is studying the binding of the coronavirus to its receptor on infected cells. As they have recently done with rotavirus, they are trying to synthesize peptides capable of blocking the interaction of the receptor with the virus and thus the infection. This could lead to a drug that cures the disease, much like an antibiotic for bacteria.
- **Rega Institute, UZLeuven and KULeuven** started an observational study: CONTAGIOUS trial (COvid-19 Advanced Genetic and Immunologic Sampling), to study the host immune response in severe and extreme severely affected COVID-19 patients as compared to healthy controls (sc multi omics).
- At the **UZGhent**, Prof. **Bart Lambrecht** started a clinical study (SARPAC) on the use of [Leukine®](#) (granulocyte macrophage-colony stimulating factor or GM-CSF) to reduce the impact of the coronavirus on lungs. Prof. **Bart Lambrecht** is also preparing for a study to compare the impact of treating severe cases of COVID-19 patients on ICU (intubated, respiratory crisis) with anti IL6 antibodies as compared to anti-IL6-receptor antibodies.
- At the VIB, the lab of **Xavier Saelens** has refocused its RSV research to Corona therapy based on VHH nanobodies.

- **VIB together with LifeTime partners** is developing an EU-wide standardised protocol to test Corona patient samples through single cell technologies.

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