

## Vaccination strategy

After approval of vaccines by EMA, the Federal Institute for Vaccines and Biomedicines (Paul-Ehrlich-Institute) will release the respective batches for distribution at national level. The Institute is also in charge to admit clinical trials during vaccine development by national producers. All COVID-19 vaccines are procured centrally by the Federal Ministry of Health to then be deployed to the 16 Federal States ('Länder'). Point of delivery at States level are 'delivery centres' capable to store large quantities of vaccine at ultra-low-temperature conditions (-70°C +/- 10°C).

The transport from the manufacturer to our distribution hub and from the distribution hub to the distribution hubs of the Federal Sates follows the European guideline for Good Distribution Practices and the regulations for Good Transportation Practices. The maintenance of the cold chain is a main topic during transport and storage. The temperature and transport conditions are

recorded following these guidelines. Most vaccines will be deployed by using specialised logistics providers and with support by the Armed Forces. In case of some national producers the vaccines will be deployed directly using a proprietary logistics chain with regard to the cold chain. Once the vaccines are handed over, the single States are in charge to carry out the vaccination campaign. For centralised vaccination, the Federal States are responsible for organising and setting up the vaccination centres. They will set up and operate them with the support of general practitioners, in particular the Federal State-level SHI-accredited physicians associations (Kassenärztliche Vereinigungen) and, where appropriate, medical staff from hospitals or other institutions.

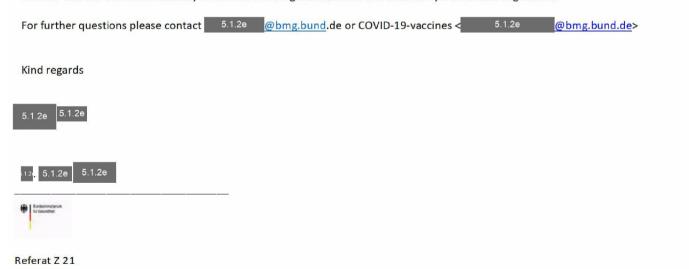
After arrival at the country boarder the vehicles are guided by Federal Police to the national hub to ensure safe transport. After arrival of Vaccine A at the national distribution hub, safe and temperature controlled storage is necessary to ensure that vaccine A reach those to be vaccinated in all 16 5.1.2a states undamaged and intact.

For the vaccination of prioritised groups, especially in retirement homes, mobile teams of the vaccination centres are available. After arrival at the national distribution hub, Vaccine A is stored until delivery to the Federal States in ultra-low temperature freezers (UTC). The transport to the Federal States is temperature controlled again using dry ice. In the distribution hubs of the Federal States the vaccine is stored again in UTC freezers and the vaccination centres are provided with vaccine A in dry ice for additional use. For the vaccination the vaccine is thawing in a refrigerator and used within five days. In 5.1.2a vaccine doses will be distributed to the central locations designated by the Federal Sates proportionate to the population of the respective state. The vaccination centers are also protected and the access is controlled. To minimise waste and to ensure well organised vaccination different software tools are used. A time scheduling program allows a strict planning of vaccination and the strict coordination of the campaign. To reduce waste, additionally not all vaccine doses are misplaned and only 80% of the patients are invited for vaccination.

The vaccinations will be monitored real-time by a digital system that is developed by the Robert Koch Institute and allows to assess vaccination coverage and also backtracking of vaccinations in case unexpected side-effects are reported.

When the vaccine is introduced, active surveillance of the safety and efficacy of the vaccine product is absolutely essential. Routine pharmacovigilance is based on established real-time monitoring of possible side effects or vaccination-related complications. In the short term, a cohort study using a smartphone app will prospectively track the frequency and severity of adverse effects and of the infection in vaccinated adults over a period of one year. In the longer term, the hospital-based case-control study to investigate the efficacy of vaccination in hospitalised patients (vaccinated and unvaccinated) will also investigate the severity of the clinical course of the infection and look for possible indications that could suggest a worsening of the infection following vaccination.

At a first stage vaccinations are offered to prioritised groups in vaccination centres and by mobile teams e.g. in nursing homes. The vaccination centres allow to reach out for prioritised groups in a first place and to handle vaccines at the requested ultra-low temperature as required. At a second stage when more vaccines will be licensed and available including vaccines that can be stored at standard conditions, vaccination activities will transfer to the regular supply system (decentralised via pharmacies, GPs and company doctors). Prioritised groups include older people (beyond an age of 80), health care and nursing professionals working in places where COVID-19 patients are treated and staff working in structures essential for public welfare. The prioritisation is based on an ethical guideline developed jointly by the 'Standing Commission on Vaccine and Vaccinations - STIKO', the 'National Ethical Council' and the 'National Academy of Science'. The legal framework was defined by a dedicated regulation.



Bilaterale Gesundheitspolitik

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-----Ursprüngliche Nachricht-----

Von: 5.1.2e 1.2e 5.1.2e 5.1.2e @rivm.nl]
Gesendet: Dienstag, 29. Dezember 2020 14:00

An: Z21 BMG < 5.1.26 @bmg.bund.de>

Betreff: FW: contactperson on logistics Covid-19 campaign - urgent question

Wichtigkeit: Hoch

I have asked the same question to: I 5.1.2e Is there a logistics expert available before the yearend?

From: 5.1.2e 5.1.2e 5.1.2e

Sent: dinsdag 29 december 2020 13:42

To: 5.1.2e @bmg.bund.de' < 5.1.2e @bmg.bund.de>

Subject: contactperson on logistics Covid-19 campaign

Importance: High

Dear 5.1.2e

Our Ministry of Health has shared your name and email address with me to be used in my quest for the right person to contact.

With great interest we are looking at the news about the vaccination campaign in effort between the federal government and the Bundesländer. Here in the Netherlands the campaign is a joint effort between the RIVM / Ministry of Health and regional partners like the youth health organizations and general practitioners. The role of my department is, amongst others, the supply and delivery of the vaccines. We are organizing vaccination centers to start with. And we are working on plans for mobile teams. Therefore, we are very interested in how you have organized your mobile teams and probably repack of the Pfizer vaccine in smaller quantities.

have a name and contact details for me? Maybe you are the right person? In that case I would love to have a telephone call with you. I am available daily from 9:00 until 22:00 for this important issue.
Hoping to hear from you soon,
Kind regards,
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