National COVID-19 Vaccination Strategy

Strategy for the continued delivery and evaluation of vaccination against SARS-CoV-2 in Germany (updated)

Version 2

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Bundesministerium für Gesundheit

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Contents

Background, current status and outlook

Widespread vaccination with the vaccines that have already been developed against COVID-19 and the continued development of further safe and effective vaccines are key factors in ending the current pandemic and in controlling SARS-CoV-2 infection rates in the longer term. Vaccination enables immunity to be achieved in broad sections of the population. The aim is to counter the spread of the virus, reduce the potential health-related consequences of infection and prevent the health system from being overrun. However, developing and introducing new vaccines in pandemic conditions is challenging.

This is the backdrop against which the Federal Ministry of Health (BMG), together with the Robert Koch Institute (RKI), the Paul Ehrlich Institute (PEI), and the Federal Centre for Health Education (BZgA), presented the "National COVID-19 Vaccination Strategy: Strategy to Introduce and Evaluate a Vaccine against SARS-CoV-2 in Germany" on 6 November 2020. That document sets out the key components of the national COVID-19 vaccination strategy and describes the systems to ensure vaccination of the German population according to uniform standards along with timely evaluation of the vaccines following their widespread application.

More than 280 different COVID-19 vaccine candidates, some on the basis of novel vaccine platforms, are currently under development worldwide (as of 8 June 2021). **The first four vaccines have received central EU approval since December 2020.** On 31 May 2021, approval for the BioNTech vaccine (Comirnaty®) was extended to include adolescents from age 12. Moderna has likewise applied for approval for its vaccine to be extended to adolescents from age 12. The European Medicines Agency (EMA) is currently considering that application. Other promising vaccine candidates are expected to be approved this year. The objective is to provide safe and effective vaccines as soon as possible and in sufficient quantities. The Federal Government is thus actively engaged in vaccine procurement and in the expansion of production capacity to be able to provide reliable vaccines in sufficient quantities.

Vaccination in vaccination centres and with mobile vaccination teams began on 27 December 2020. The basic aim is to make vaccines available to the entire population once approved. However, the supply of vaccines has been limited from the outset. As a result, the Standing Committee on Vaccination (Ständige Impfkommission – STIKO) initially called in its vaccination recommendations for the **prioritisation of specific groups of persons who need to be vaccinated first. This was made law in the Coronavirus Vaccination Ordinance** (Coronavirus-Impfverordnung – CoronaImpfV). **The prioritisation was lifted on 7 June 2021 under the revised Ordinance of 1 June 2021.**

Over 67 million vaccine doses have already been administered in Germany. More than 42 million people have been vaccinated at least once (51.2%) and over 26 million (31.6%) are already fully vaccinated. Over half of the German population have thus already been vaccinated at least once and almost a third are already fully vaccinated (as of 22 June 2021).

The target is to be able to offer vaccination to the entire population by the end of summer 2021. In April, in view of the progress made in the vaccination campaign, some of Germany's 16 Länder went over to offering vaccinations to persons in prioritisation group 3 (moderately high priority) and started allowing people to make appointments. All Länder had taken this step by the end of May 2021. On 17 May 2021, the German Health Ministers Conference (GMK) decided to cease prioritising from 7 June 2021 and to open the vaccination campaign to all those willing to be vaccinated. This was enacted into law in the Coronavirus Vaccination Ordinance of 1 June 2021 (Bundesanzeiger Amtlicher Teil [Official Section of the Federal Gazette] of 2 June 2021). Because of the quantities of vaccines expected to be delivered, it should be emphasised that it will not be possible to vaccinate all those willing to be vaccinated in the course of June. As has been announced, the vaccination campaign will have to continue in this form until the end of summer 2021.

This (updated) National COVID-19 Vaccination Strategy constitutes a revision of the National Vaccination Strategy of 6 November 2020, taking into account the current status as described above. In particular, deprioritisation from 7 June 2021 has taken the vaccination strategy into a new phase. Primarily in view of the initial target group prioritisation, the ongoing limited number of vaccine doses and in some cases certain product characteristics (such as storage and transport conditions and supply in multi-dose vials), it continues to make sense to conduct vaccinations in central vaccination centres and using mobile teams, and this remains a central component of the National Vaccination Strategy. Organisationally speaking, vaccination has been placed on a far broader basis since April 2021. Since 6 April 2021, statutory health insurance (SHI)-accredited medical practices have been included in the vaccination campaign. This was initially limited to general medical practices but was subsequently extended to include specialist medical practices and from 7 June 2021 also private medical practices. Likewise commencing 7 June 2021, vaccinations can now be obtained in the workplace, where they are provided by workplace occupational physicians or occupational medicine service providers. These steps are included in the newly inserted Phase II of vaccination under the updated National Vaccination Strategy, the previous Phase I having been subdivided for the purpose. The long-term goal is a transition to routine vaccination, meaning Phase III of the National Vaccination Strategy (previously Phase II in the strategy as of 6 November 2020).

In light of the pandemic situation, the use of novel vaccine platform technologies, high public expectations and multiple vaccines with different product properties being used simultaneously, close communication and scientific support are needed to ensure safe and successful implementation of the COVID-19 vaccination strategy.

Like its predecessor, this (updated) National Vaccination Strategy sets out the key components of the COVID-19 vaccination campaign and describes the systems ensuring vaccination of the German population according to uniform standards along with timely evaluation of the vaccines following their widespread application.

The strategy also includes a number of additional instruments. For example, the digital vaccination certificate has been introduced and provides a new, additional means of verifying vaccination status towards third parties. Instead of showing their vaccination date, vaccine and name in analogue, printed form, users can now conveniently store this information on their smartphones. The rollout of the digital vaccination certificate will continue step by step during June 2021.

Looking ahead, it is also necessary to consider the question of any booster vaccinations that may be necessary and also that of second generation vaccinations (adapted to mutations). This will depend on research into the duration of immunity and on the further path of the pandemic.

Table 1 gives an overview of the components and stakeholders in the National Vaccination Strategy.

Table 1: Overview – Vaccination strategy components and stakeholders

Components	Stakeholders
Vaccine development	Federal Ministry of Education and Research (BMBF), universities, non-university research institutions, pharmaceutical companies
Vaccine approval	Paul Ehrlich Institute (PEI), European Medicines Agency (EMA) and European Commission, pharmaceutical companies
Vaccine recommendations and prioritisation	Standing Committee on Vaccination (STIKO), RKI, Leopoldina (National Academy of Sciences), German Ethics Council
Production and procurement	European Commission, EU member states, BMBF, Federal Ministry for Economic Affairs and Energy (BMWi) Vaccine Production Task Force, BMG, pharmaceutical companies, chemical industry, process engineering industry
Distribution, storage and logistics	BMG, Federal Ministry of Defence (BMVg)/German Armed Forces, Länder governments, logistics companies, pharmaceutical wholesalers, (hospital) pharmacies
Organisation and implementation of vaccination activities	Länder, Public Health Service (ÖGD), National Association of Statutory Health Insurance Physicians (NASHIP – German: Kassenärztliche Bundesvereinigung, or KBV), regional Associations of Statutory Health Insurance Physicians (ASHIPs – German: Kassenärztliche Vereinigungen, or KVen), workplace occupational physicians and occupational medicine service providers providing vaccination in workplaces, medical personnel
Financing	Federal Government, Länder, statutory health insurance (SHI) funds, private health insurance (PHI) funds

Table 2: Overview – Vaccination strategy components and stakeholders (continued)

Components	Stakeholders
Communication, specialist training and public information	BZgA, RKI, PEI, BMG, Länder, Academy of Public Health Services, specialist associations
Vaccination rate monitoring	RKI
Surveillance of vaccine efficacy and vaccine safety in broad application	RKI, PEI, EMA, pharmaceutical companies
International coordination and cooperation	Federal Government, EU, WHO, science forums
Process evaluation	BMG

1. Overview: COVID-19 vaccines and vaccine development

Vaccine development takes place in various phases, from the exploratory and pre-clinical phase with trials on laboratory animals, to clinical phases 1, 2 and 3 with trials on humans, to marketing authorisation.

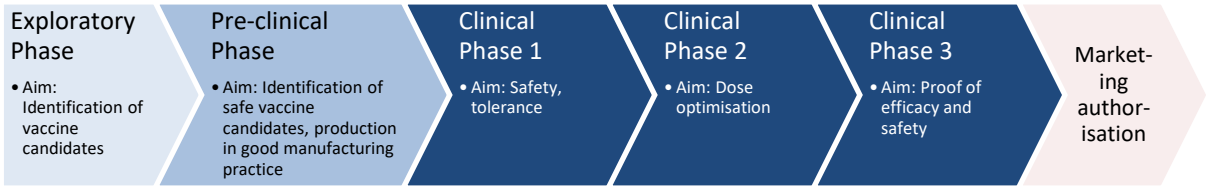

Figure 1: Overview of the phases of vaccine development

After producing a potential vaccine candidate in the research laboratory, initial **animal and cell culture experiments** are conducted to assess whether, in addition to tolerability, the vaccine candidate is capable of producing a protective effect against the target pathogen or the infectious disease caused by it, where an animal model exists for this purpose. Subsequently, toxicological and pharmacological properties are evaluated in various animal models. Only when there is no doubt as to safety for use on humans is a first **clinical trial** performed to assess the vaccine candidate's safety on healthy human adult volunteers (Phase 1). In the subsequent **clinical trial phases**, the optimal dosage and vaccination schedule are tested in a larger number of volunteers (several hundred) (Phase 2) and then the efficacy and side-effect profile of the vaccine are determined in a large, randomised, controlled clinical study (Phase 3) with several thousand volunteers from different age groups.

Four COVID-19 vaccines have now been authorised for the EU market. In addition, various novel vaccine candidates (such as protein, mRNA and vector vaccines) continue to be being developed and clinically tested on a variety of manufacturing platforms. **The Federal Government supports vaccine research and production and, seeing it as a global responsibility, advocates fair global distribution of vaccines.** For example, the Federal

Government has been a full member of the Coalition for Epidemic Preparedness Innovations (CEPI) since its inception in 2017. In this connection, the Federal Government has provided additional funding for SARS-CoV-2 vaccine development in 2020/2021. The Federal Government also directly funded the development of the BioNTech and CureVac vaccines.

Table 2 focuses on COVID-19 vaccines already authorised for the EU market, plus vaccine candidates for which it is known that such authorisation is aimed for, where the vaccines or vaccine candidates are or may be available for the ongoing national vaccination campaign.

- The Federal Government (BMBF and BMG) supports research and development for new vaccine candidates.
- Pharmaceutical companies and research institutes develop vaccines and obtain their approval.

Table 2: Overview of selected approved vaccines and vaccine candidates and current status of development (manufacturers' information), subject to change

Manufacturer	Vaccine type	No. of doses; vaccination interval*	Vaccine volume; application*	Clinical development	EU approval or potential approval
BioNTech	mRNA in lipid nanoparticles	2 doses 3-6 weeks	1 dose @ 0.3 ml IM	Phase 1/2: DE, US Phase 3: US, Brazil, Argentina, Turkey, DE	**Approval** 21/12/2020 31/05/2021 for ages 12 upwards
Moderna	mRNA in lipid nanoparticles	2 doses 4-6 weeks	1 dose @ 0.5 ml IM	Phase 1: US Phase 2/3: US	**Approval** 06/01/2021 Q2/Q3 for ages 12 upwards
AstraZeneca	Vector-based ChAdOx1, non-replicating	2 doses 4-12 weeks	1 dose @ 0.5 ml IM	Phase 1/2: UK Phase 3: UK, Brazil, South Africa, India, Phase 3: US	**Approval** 29 January 2021
Johnson & Johnson/ Janssen	Vector-based Ad26, non-replicating	1 dose	1 dose @ 0.5 ml IM	Phase 1/2: BE, US Phase 2: DE Phase 3: Global	**Approval** 11/03/2021
Novavax	Recombinant, adjuvanted	2 doses at days 0 and 21	1 dose @ 0.5 ml IM	Phase 1: Australia Phase 2: US, Australia, South Africa Phase 3: UK Phase 3: US	Q3/Q4 2021
Curevac	mRNA in lipid nanoparticles	2 doses at days 0 and 28	1 dose @ 0.5 ml IM	Phase 1: BE, DE Phase 2: Peru, Panama Phase 2b/3: Europe, Latin America	Under review
SP/GSK	Recombinant, adjuvanted	2 doses at days 0 and 28	1 dose @ 0.5 ml IM	Phase 1/2: US Phase 3: Global	Q4 2021
*Note: Preliminary information based on the current knowledge, including STIKO recommendation					

2. COVID-19 vaccine approval

Approval of the approved COVID-19 vaccines and vaccine candidates listed in Table 2 is granted by the European Commission for all EU member states following a centralised assessment procedure coordinated by the EMA. The approval procedure demonstrates vaccine efficacy, pharmaceutical quality and safety, thus ensuring that the medicinal products administered to patients are of appropriate quality and demonstrate a positive risk-benefit ratio.

It is possible for COVID-19 vaccines to be assessed in a fast-track procedure. In such a fast-track procedure, which was used for the four approved vaccines, individual data packages are submitted to and assessed by the EMA as they become available, even before official marketing authorisation is granted.

If sufficient data is available to assess the pharmaceutical quality, efficacy and safety of a vaccine in terms of its risk-benefit ratio, the Committee for Medicinal Products for Human Use recommends to the EMA that the vaccine be approved if the risk-benefit ratio is favourable. Based on that recommendation, the European Commission grants central EU approval.

The Paul Ehrlich Institute or another government control laboratory in Europe tests batches of vaccine experimentally before they are marketed. Based on this testing, the Paul Ehrlich Institute issues batch release.

Subsequent to approval, vaccines continue to be assessed for a positive benefit/risk ratio as part of pharmacovigilance (drug safety monitoring), and experience with their use is continuously and systematically collected and evaluated.

- Marketing authorisation for COVID-19 vaccines at EU level is granted by the European Commission.
- The Paul Ehrlich Institute issues batch release after experimental testing of vaccine batches by PEI or another European government control laboratory.
- Subsequent to approval, vaccines continue to be assessed for a positive benefit/risk ratio as part of pharmacovigilance.

3. Vaccine recommendations and vaccine requirements

Based at the Robert Koch Institute, the **Standing Committee on Vaccination (STIKO)**, a statutory entity, has the task of drawing up and issuing vaccine recommendations for Germany. Whereas the main focus during the approval process is on the safety, efficacy and quality of a new vaccine, STIKO decides how an approved vaccine can best be applied within the population. This goes beyond an individual risk-benefit assessment and also takes in the potential effects on the population (such as maximum reduction in the number of deaths or a reduction in virus transmission).

All STIKO vaccination recommendations are based on a detailed and thorough evaluation of the currently available evidence. In particular, this includes the assessment of risk factors (for infection or serious illness) and the safety and efficacy of the available vaccines.

At present, there is still insufficient vaccine to meet demand for COVID-19 vaccinations. For this reason, from the commencement of vaccination on 27 December 2020, vaccination was initially normally only offered to groups at a particularly high risk of a severe or fatal course of COVID-19 or to those who in their work have particular exposure to or close contact to vulnerable groups. **Prioritisation of the groups was based on infectiological, epidemiological and ethical criteria taking into account a position paper jointly developed by STIKO, the German Ethics Council and Leopoldina.**

The first STIKO recommendation for COVID-19 vaccination was published shortly after approval of the first COVID-19 vaccine (BioNTech) on 17 December 2020.

STIKO regularly evaluates its COVID-19 vaccination recommendation taking into account vaccination rates, vaccination acceptance and vaccine efficacy and safety studies. Furthermore, STIKO continuously reviews the scientifically published data on vaccines – collected among other things in the course of approval and in post-marketing surveillance subsequent to approval – and adjusts its recommendation as necessary. Updates were made on 8 and 29 January, 12 March, 1 and 8 April, 12 May and 10 June 2021. A further update on deprioritisation is imminent (as of 22 June 2021). STIKO has also issued supplementary position statements.

Prioritisation is enacted in law in the Coronavirus Vaccination Ordinance issued by BMG. This is largely based on STIKO's COVID-19 vaccination recommendation and divides those eligible for vaccination into three prioritisation groups based on the previously mentioned criteria. The Ordinance is continuously evaluated and updated in line with current developments. Prioritisation was lifted on 7 June 2021. However, the Länder may choose to retain prioritisation in vaccination centres for the time being. The legislative amendments were made in the Coronavirus Vaccination Ordinance of 1 June 2021 (Bundesanzeiger Amtlicher Teil [Official Section of the Federal Gazette] of 2 June 2021).

It is possible that SARS-CoV-2 will become endemic and continue to cause illness in the population after the pandemic, meaning vaccination against COVID-19 – including against the virus variants now in circulation – is also expected to be necessary in the longer term (in the post-pandemic phase).

- It was initially necessary to prioritise groups of persons who needed to be vaccinated first. STIKO, in collaboration with the German Ethics Council and the Academy of Sciences Leopoldina, previously developed ethical guidelines to aid that prioritisation.
- In addition, STIKO drew up a recommendation for the use of available, approved COVID-19 vaccines (STIKO COVID-19 vaccination recommendation).
- The STIKO recommendation is updated to continuously adapt and align it in accordance with the current status of evidence and the available vaccines.
- Until it was withdrawn, prioritisation was enacted in law – along with other stipulations that remain in force – in the Coronavirus Vaccination Ordinance (Coronavirus-Impfverordnung – CoronaImpfV) issued by BMG.
- Prioritisation was lifted on 7 June 2021 under the revised Coronavirus Vaccination Ordinance of 1 June 2021.

4. Production and procurement

To ensure the availability of sufficient quantities of COVID-19 vaccines in Germany as quickly as possible, the Federal Government procures vaccines centrally via an EU procurement mechanism. In view of current plans at EU level, vaccine procurement may remain with the Federal Government for the foreseeable future (and at least until the end of 2023). In the event of promising development and research projects, the European Commission agrees **advance purchase agreements with manufacturers** on behalf of the EU member states. Bilateral agreements are additionally entered into with individual companies as required.

These agreements ensure that people have early access to successfully tested, safe vaccines as soon as they are approved for use in the EU. The agreements also enable manufacturers to build up production capacity in line with the scientific onward development of the vaccines, allowing faster supply following approval.

The EU has already secured access to as many as **4.36 billion doses of vaccine for the EU population from various manufacturers**. These doses are generally shared among the EU member states in proportion to their respective populations. Negotiations with companies have also begun at EU level for the purchase of additional vaccine doses for 2022 and 2023. The European Commission has already signed a contract for 1.8 billion doses with BioNTech/Pfizer for 2022 and 2023. This also includes vaccines against mutations and for children under 12.

The Federal Government is providing the industry with support in order to secure the production processes for the supply of the required vaccine doses in 2021 and to expand production capacity in 2022 and beyond. To coordinate this task, the interdepartmental Vaccine Production Task Force was established at the Federal Ministry for Economic Affairs and Energy in March 2021. The task force also liaises with the EU, which is likewise

acting to secure production capacity. In February 2021, the European Commission issued a communication, "HERA Incubator: Anticipating together the threat of COVID-19 variants". An objective of HERA Incubator is to help secure industrial production capacity for COVID-19 vaccines and thus achieve sufficient supply quantities, including for the longer term in view of the potential need to adapt vaccines to variants.

- BMG/the Federal Government procures COVID-19 vaccines via a common EU procurement mechanism. As part of that process, Germany participates in the European Commission's Vaccine Initiative.
- The Federal Government, in cooperation with the EU member states and the pharmaceutical industry, is supporting the expansion of production capacity and helping to secure the necessary precursor and associated products.
- The interdepartmental Vaccine Production Task Force was established at the Federal Ministry for Economic Affairs and Energy in March 2021.

5. Distribution, storage and logistics

Proper and safe transport is necessary to ensure that COVID-19 vaccines arrive unharmed at the locations where they are to be administered to vaccine recipients in all 16 Länder (primarily vaccination centres, medical practices and contracted workplace occupational physicians).

Special requirements for transport and storage conditions must be taken into account during planning: Certain vaccines (such as mRNA vaccines) require special conditions for long-time storage (cold chain with temperatures below −60 °C). By generating additional data, a number of manufacturers have already succeeded at continuously improving and simplifying the storage and transport requirements with the result that short-term storage and transport are now possible at 2 °C to 8 °C provided that certain rules are complied with.

Vaccines currently come in multi-dose vials. The manufacturers do not supply the necessary vaccination accessories (syringes and cannulas) or, where applicable, diluent solutions (such as 0.9% sodium chloride solution). For vaccination centres, the provision of vaccination accessories and any diluent solutions is the responsibility of the Länder. In the case of SHI-accredited medical practices taking part in the vaccination campaign, both the vaccines and the vaccination accessories are provided by pharmaceutical wholesalers and pharmacies.

The agreements the European Commission has reached with the vaccine manufacturers so far stipulate that the manufacturers deliver vaccine doses to central bodies in the various EU member states. The available quantities of vaccine doses for vaccination centres are distributed among the Länder according to their relative shares of the population. A

number of vaccines are currently delivered by the armed forces to sites designated by the Länder. One manufacturer delivers vaccine doses directly to these sites.

Since early April 2021, SHI-accredited medical practices have been included in the vaccination campaign. For these, a portion of the available COVID-19 vaccines are supplied through pharmaceutical wholesalers and pharmacies. Distribution is likewise organised through pharmaceutical wholesalers and pharmacies for workplace occupational physicians, occupational medicine service providers and private medical practices, all of which have been included in the campaign since 7 June 2021.

- BMG/the Federal Government organises the distribution of COVID-19 vaccines to designated locations in each of the Länder.
- The Länder are responsible for correct and safe storage and distribution of vaccines in vaccination centres, and for procuring and maintaining stocks of the vaccination accessories needed by them.
- So that vaccination can be performed by SHI-accredited medical practices, a portion of the available vaccines and vaccination accessories have been supplied to them through pharmaceutical wholesalers and pharmacies since early April 2021.
- Since 7 June 2021, distribution of vaccines and vaccination accessories has likewise been organised through pharmaceutical wholesalers and pharmacies for workplace occupational physicians, occupational medicine service providers and private medical practices.

6. Organising and implementing vaccinations

	PHASE I A Targeted centralised vaccination *Vaccination centres (plus hospitals and mobile teams)*	PHASE I B Broader centralised vaccination *Vaccination centres (plus hospitals and mobile teams); pilot practices*	PHASE II Broader, increasingly decentralised vaccination *Vaccination centres (plus hospitals and mobile teams); medical practices; occupational physicians*	PHASE III Broad, decentralised routine vaccination *Medical practices, medical facilities, occupational physicians*
Situation/ context	**Pandemic vaccination** • Reduced availability • Largely central control • Signal: "Launch of vaccination with initial priority groups"	**Pandemic vaccination** • Moderate availability (not yet exceeding vaccination centre capacity) • Largely central control • Signal: "Broadening of first vaccination phase"	**Pandemic vaccination** • Increased availability (vaccination centres operating close to capacity) • Largely central control • Signal: "Large-scale, multi-channel vaccination; campaign gradually opened to all/prioritisation lifted 7 June 2021"	**Routine vaccination** • Availability and product characteristics sufficient for routine vaccination in medical practices and by occupational physicians • Signal: "New normal"
Organisational responsibility	**Länder**	**Länder**	**Länder, ASHIPs, pharma wholesalers, pharmacies, medical profession, employers/occupational physicians**	**In SHI: Health insurance funds (in conjunction with ASHIPs, medical profession, pharma wholesalers, pharmacies)**
Where vaccinated	• Vaccination centres (plus hospitals) • Mobile vaccination teams (in some cases plus occupational physicians)	• Vaccination centres (plus hospitals) • Mobile vaccination teams (in some cases plus occupational physicians) • Pilot practices (selected by Länder in pilot trial to serve as 'satellite' vaccination centres for local vaccination)	• Vaccination centres (plus hospitals) • Mobile vaccination teams (plus occupational physicians) • From April 2021 SHI-accredited medical practices • From 7 June 2021 occupational physicians and private medical practices	• Vaccinating physicians – **Under statutory health insurance:** Medical facilities under section 132e SGB V vaccination contracts with health insurance funds/fund associations, e.g. occupational physicians – **Under private health insurance:** All medical facilities and practice-based physicians
Target group/ eligibility for vaccination	**Prioritisation under Coronavirus Vaccination Ordinance based on STIKO recommendation**	**Prioritisation under Coronavirus Vaccination Ordinance based on STIKO recommendation**	Prioritisation under CoronaImpfV based on STIKO recommendation initially continued; end of prioritisation phase **Vaccination campaign opened for all from 7 June 2021**	**Vaccination based on approval and STIKO recommendation/Federal Joint Committee (B-GA) vaccination guidelines**
Vaccine availability and product characteristics	• Little vaccine available, not exceeding vaccination centre/mobile vaccination team capacity • Multi-dose vials • Demanding storage/transport requirements for some vaccines	• More vaccine available, still not exceeding vaccination centre/mobile vaccination team capacity • Multi-dose vials • Storage/transport requirements for some vaccines still demanding but now less extreme	• Vaccine availability far exceeding vaccination centre/mobile vaccination team capacity • Multi-dose vials • Less demanding storage/transport requirements for some vaccines; most vaccines manageable in medical practices and workplaces	• Sufficient availability to generally meet demand everywhere • Single-dose vials additionally available; pharmacies dispense single-dose vials to customers on prescription • Easily manageable vaccine storage and transport requirements
Procurement and logistics	• Vaccine procured by Federal Government • Local distribution by Länder to vaccination centres (plus hospitals and mobile teams) • Distribution covers vaccine and vaccination accessories	• Vaccine procured by Federal Government • Local distribution by Länder to vaccination centres (plus hospitals and mobile teams) and contracted medical practices • Distribution covers vaccines and vaccination accessories	• Vaccines procured by Federal Government • Local distribution by Länder to vaccination centres (plus hospitals and mobile teams) • Medical practices and occupational physicians supplied by pharma wholesalers and pharmacies (vaccine plus vaccination accessories)	• Vaccines and vaccination accessories procured via Federal Government/pharma wholesalers • Distribution to medical practices and employers/occupational physicians via pharmacies • Under SHI: vaccines ordered by medical practices for drop-in surgery needs • Under PHI: vaccine vials dispensed to vaccine recipients by pharmacies on prescription and vaccinated in medical practices
Funding of vaccines	• Funded by Federal Government; outlay not recovered • Vaccines not billed and paid for individually	• Funded by Federal Government; outlay not recovered • Vaccines not billed and paid for individually	• Funded by Federal Government; outlay not recovered • Remuneration of wholesalers and pharmacies for vaccine distribution stipulated in Coronavirus Vaccination Ordinance • Vaccines not billed and paid for individually	• Vaccines billed and paid for/costs refunded individually under health insurance system or covered by civil service health care system; procurement may continue to be via the Federal Government (possibly with continued remuneration of wholesalers and pharmacies for vaccine distribution)

Figure 2: Organisation and implementation (continued on next page)

Funding of vaccinations	• Vaccination accessories funded by Länder • Vaccination centres co-funded by health insurance funds and Länder: Länder plus flat 46.5% co-funding from SHI Health Fund and 3.5% from PHI	• Vaccination accessories funded by Länder • Vaccination centres plus physicians in subspecialised practices: Länder plus flat 46.5% co-funding from SHI Health Fund and 3.5% from PHI	• Vaccination centres: Länder, with 50% reimbursed by Federal Government until 30 September 2021; vaccination accessories funded by Länder • Remuneration for vaccination in medical practices: – Remuneration of wholesalers, pharmacies, medical profession stipulated in Coronavirus Vaccination Ordinance; funded by Federal Government • Remuneration for vaccination by occupational physicians – Stipulated as for medical practices in Coronavirus Vaccination Ordinance unless paid for by employer	Case-based funding according to type of health insurance cover: • SHI funds under section 132e SGB V vaccination contracts • PHI funds (cost reimbursed) • Civil service health care system (cost reimbursed)
Appointments	**Central system**	**Central system**	**Central system for vaccination centres; otherwise with medical practices and occupational physicians on decentralised basis**	**With medical practices and occupational physicians on decentralised basis**
Vaccination rate monitoring	• Daily reporting of vaccination rates to RKI by vaccination centres (plus hospitals and mobile teams); Full dataset reported via DIM	• Daily reporting of vaccination rates to RKI • Länder, vaccination centres (plus hospitals and mobile teams), federal vaccination centres and subspecialised practices as 'satellite' vaccination centres: full dataset normally reported via DIM	• Daily reporting of vaccination rates to RKI • Länder vaccination centres (plus hospitals and mobile teams), federal vaccination centres and occupational physicians: Full dataset reported via DIM • SHI-accredited medical practices: daily reporting of aggregated totals, consolidated in NASHIP vaccination tool; full dataset provided via SHI billing system (3-6 month time lag) • Private medical practices included in vaccination rate monitoring in similar manner	• Full dataset provided via SHI billing system (3-6 month time lag) as for other vaccinations under section 13 (5) of the Protection against Infection Act (IfSG); as for other vaccinations, no provision for monitoring of vaccinations under PHI
Legal basis	**Section 20i (3) of Social Code Book V (SGB V); section 5 (2) and (3) and section 13 (5) of Protection against Infection Act (ISfG); Coronavirus Vaccination Ordinance (CoronaImpfV)**	**Section 20i (3) of Social Code Book V (SGB V); section 5 (2) and (3) and section 13 (5) of Protection against Infection Act (ISfG); Coronavirus Vaccination Ordinance (CoronaImpfV)**	**Section 20i (3) of Social Code Book V (SGB V); section 5 (2) and (3) and section 13 (5) of Protection against Infection Act (ISfG); Coronavirus Vaccination Ordinance (CoronaImpfV)**	• **Federal Joint Committee (B-GA) vaccination guidelines and contracts under section 132e SGB V** • **Civil service health care system/Insurance Contract Act (VVG)**

Figure 3: Organisation and implementation (continued)

Due to the special situation in the pandemic, COVID-19 vaccinations were carried out during the initial phase exclusively by **vaccination centres, in most cases also with the aid of mobile vaccination teams**. The reasons behind this strategy were the special transport and (long-term) storage requirements, vaccine supply in multi-dose vials, the need for prioritisation due to initial limited availability of vaccine doses and the resulting central allocation system for vaccination appointments, the availability of different vaccines and the need for increased control measures, including centrally organised data-supported monitoring of vaccinations as a component of pandemic management. Under these conditions, centralised structures were needed at the beginning to be able to conduct a controlled, efficient and effective vaccination campaign. In December 2020, as guidance for implementation throughout the country, the Federal Ministry of Health, in cooperation with experts and specialist departments in the Länder, compiled and published a set of recommendations for the organisation and delivery of vaccinations against SARS-CoV-2 in vaccination centres and with mobile teams.

For centralised COVID-19 vaccinations, **the Länder are responsible for organising** the vaccination centres and mobile vaccination teams. They are set up and operated with the support of practice-based physicians – primarily as represented by the regional Associations of Statutory Health Insurance Physicians (ASHIPs, German: Kassenärztliche Vereinigungen or KVen) – and in some cases hospital medical staff and other medical

professionals such as workplace occupational physicians. In some cases, the Länder involve other outside parties such as aid organisations, the armed forces and logistics companies.

Since early April 2021, **SHI-accredited medical practices have been included in the vaccination campaign**. This was initially limited to general medical practices and subsequently extended to include specialist medical practices. Since 7 June 2021, private medical practices have been additionally included in the vaccination campaign.

Likewise since 7 June 2021, the vaccination campaign has also been extended to involve more workplace occupational physicians and occupational medicine service providers.

Good appointment management in vaccination centres is essential for efficient vaccine delivery and so that vaccine recipients can plan ahead. This again is the responsibility of the Länder. Together with kv.digital GmbH, the National Association of Statutory Health Insurance Physicians (NASHIP, German: Kassenärztliche Bundesvereinigung or KBV) provides a standardised system for making appointments at vaccination centres. Some of the Länder have opted for the NASHIP appointment service while the remainder use appointment systems of their own. A number of the Länder also operate an invitation management system to notify those entitled to vaccination about the possibility of obtaining vaccination against COVID-19.

National Vaccination Plan

On 10 February 2021, the Federal Government and the Länder agreed to supplement the National Vaccination Strategy with a Vaccination Plan. In close consultation between the Federal Government and the Länder, the vaccination campaign was supplemented with additional delivery elements based on the latest information about volumes available from the various manufacturers. Allocation of the available vaccines was coordinated between the Federal Government and the Länder and consulted upon weekly in the German Health Ministers Conference (GMK). Regularly updated schedules published by BMG showing quantities of vaccines to be supplied to the Länder for use in vaccination centres take into account both agreed baseline quantities and current requirement levels in each of the Länder.

- The Länder are responsible for organising and setting up the vaccination centres and for ensuring that vaccines are properly dispensed to those in the priority vaccination groups and with the involvement of local stakeholders.
- SHI-accredited medical practices were gradually included in vaccination against COVID-19 beginning in April 2021. Since 7 June 2021, this has also applied to practice-based private physicians, workplace occupational physicians and occupational medicine service providers.
- In the long term, COVID-19 vaccination is to become part of the routine vaccination cycle and the statutory health insurance funds will be responsible on behalf of those with statutory health insurance for entering into agreements for the delivery and organisation of vaccinations with the regional associations of SHI-accredited physicians, practitioners, workplace occupational physicians, the health administrations in each of the Länder and other bodies.

7. Financing

COVID-19 vaccines are provided by the Federal Government free of charge. Financing of COVID-19 vaccination in vaccination centres and by mobile vaccination teams is kept simple and efficient in order to achieve high vaccination rates and speedy vaccination.

After consultation with STIKO, NASHIP, the Federal Association of Health Insurance Funds (Spitzenverband Bund der Krankenkassen) and the Association of Private Health Insurances (Verband der Privaten Krankenversicherung), BMG stipulated in the original and revised Coronavirus Vaccination Ordinance that persons with or without statutory health insurance are entitled to receive a COVID-19 vaccination.

To enable the rapid establishment and expansion of vaccination centres and so that they can be run efficiently with minimum red tape, the running costs of vaccination centres and mobile vaccination teams are shared in fixed proportions. **Under a GMK decision of 10 March 2021, 50 percent of the necessary ongoing operating costs of vaccination centres, including mobile vaccination teams, established, maintained or operated by or on behalf of the Länder are reimbursed from federal funds from 1 January 2021 to at least 30 September 2021. The other 50 percent is met by the Länder.** The Federal Government provides the vaccines it procures free of charge to vaccination centres, medical practices and from 7 June 2021 also workplace occupational physicians and occupational medicine service providers.

Since the 10 March 2021 revision of the Coronavirus Vaccination Ordinance, the Ordinance has stipulated a uniform remuneration rate for vaccination by medical practices. Under a further revision of 31 March 2021, this remuneration rate was also laid down for contracted workplace occupational physicians and occupational medicine service providers subject to the general proviso that the same service is not already paid for under other arrangements. The 1 June 2021 revision of the Ordinance supplemented

these remuneration provisions and applied them more broadly for the increased involvement of workplace occupational physicians and occupational medicine service providers. The remuneration for the services of physicians is paid for out of federal funds.

- The Coronavirus Vaccination Ordinance provides for vaccination centres run by the Länder to be co-financed by the Federal Government in 2021.
- The Coronavirus Vaccination Ordinance stipulates a uniform remuneration rate for vaccination by medical practices, workplace occupational physicians and occupational medicine service providers and for the remuneration to be paid for out of federal funds.

8. Communication, specialist training and public information

Since the onset of the pandemic, the Federal Government has aimed to provide the public with easily understood and reliable information that is continually adapted to meet the needs of specific situations, groups and regions. Based on this precept, and under the umbrella of the "Zusammen gegen Corona" ("Together Against Corona") campaign, a public information campaign was developed around the acronym "AHA" for "Abstand-Hygiene-Alltagsmasken" ("Distance, Hygiene, Community Masks"). A similar goal is followed by a further information and education campaign on vaccination, "Deutschland krempelt die Ärmel hoch" ("Time to roll up our sleeves"). This campaign faced many and various communication challenges from the outset. In the early days especially, it was necessary to explain to the public that because so little vaccine was available, it was only possible to offer vaccination to high-risk groups and people in certain occupations. At the same time, the population had to be encouraged to "get vaccinated" while also dispelling any doubts about new vaccines and combating deliberate misinformation. A transparent, proactive and target group-specific communication strategy that also covers vaccine reactions and side effects to address deliberate misinformation therefore remains indispensable.

To ensure comprehensive and targeted communication in this way, a national-level steering committee, "Servicestelle Corona-Impfdialog" ("COVID-19 vaccination dialogue service point") has been established with representatives from BMG, BZgA, RKI (including PEI) and contracted agencies. Responsibility for the management of communication on COVID-19 vaccination lies with BMG. The steering committee coordinates communication activities and hence also the content, which is then put out on digital, social and conventional media in formats such as printed advertisements or TV and radio spots. Another focus of the steering committee's work is on developing information and communication material and making it available in digital form for use by communicators at regional and local level. Communication around vaccination is adapted on an ongoing basis with the growing body of scientific knowledge on vaccination and vaccination progress. From the outset, the focus has been on transparent information and on involving and communi-

cating with relevant social groups. In view of the high demands that the vaccination campaign places on physicians and medical staff working in the vaccination centres, mobile teams, medical practices and health care facilities, BMG also funded the development of training content on the subject of vaccination in the pandemic by the Academy for Public Health in Düsseldorf (https://impfencovid19.de). Regarding communication on COVID-19 vaccinations in statutory health insurance-accredited medical practices, a central role is played by NASHIP. With a view to the greater involvement of workplace occupational physicians and occupational medicine service providers, close consultation in particular with the Confederation of German Employers' Associations (BDA) and occupational medicine associations is especially important in order to provide occupational physicians the best possible support in the vaccination process.

- Steering committee on COVID-19 vaccination dialogue led by BMG with the involvement of RKI (and PEI), BZgA and contracted agencies.
- Planning and management of all vaccination-related communication and media relations in a 360° communication campaign continuously adapted to vaccination progress.
- Central role of the National Association of SHI-accredited Physicians regarding vaccination in SHI-accredited medical practices and close consultation with Confederation of German Employers' Associations with regard to occupational physicians.

9. Vaccination rate monitoring

Valid data on vaccination uptake **(vaccination rates) provides the basis for analysing vaccination behaviour and the success of the accompanying information campaign**. Target group-specific vaccination rates enable both management and adaptation of the vaccination campaign. For example, the campaign can be adapted if vaccination rates are particularly low in certain population groups or if there are large regional differences between the Länder. The vaccination rates also serve as a **'denominator' for ranking efficacy and safety** (differentiating between individual cases versus representative cases based on the total number of all vaccine recipients) (see Section 10).

For the purpose of vaccination rate monitoring, the following non-personal data is required:

- Data on the vaccine recipient: age, gender, place of residence (Land/district), vaccination indication
- Data on the vaccination: place of vaccination, vaccination date, vaccine product (name and batch number), vaccination dose administered (first vaccination or follow-on vaccination where applicable)

In order to ensure both **timely analysis of and transparency** in the delivery of COVID-19 vaccinations, **vaccination centres must forward this data to RKI effectively in real time**.

Secure collection and transmission of vaccination data from vaccination centres is ensured by a specially developed web application, "Digitales Impfquotenmonitoring (DIM)" ("Digital Vaccination Rate Monitoring"), which transmits the above data to the Bundesdruckerei (Federal Printing Office) using a secure internet connection. The Bundesdruckerei temporarily stores the data for retrieval by RKI. Under the Coronavirus Vaccination Ordinance, this also covers occupational medicine service providers and workplace occupational physicians.

SHI-accredited medical practices collect the above data as with other vaccinations in a dataset that the regional associations of SHI-accredited physicians transmit to RKI at up to a six-month time lag as part of statutory health insurance vaccination surveillance (see Table 3). For timely information on vaccination campaign progress, SHI-accredited medical practices additionally send the RKI a truncated, aggregated dataset recording total vaccinations per day by place of vaccination, vaccine, dose and age group (<18, 18-59 and 60+); the under-18 age criterion was added in the Coronavirus Vaccination Ordinance of 1 June 2021 in view of the BioNTech vaccine now being approved for age 12 upwards from 31 May 2021. In order to obtain statistics for private medical practices as well, these submit the data in a similar manner.

RKI analyses the vaccination rates obtained in this way on a daily basis. The results are published on the **RKI website** and the **German Vaccination Dashboard**. RKI also submits the aggregated German vaccination data to the European **Vaccine Tracker** via the European surveillance system (TESSy). This provides an at-a-glance view of vaccination campaign progress in Europe.

Realtime online data collection is combined with other components for integrated monitoring of vaccination rates in Germany (Table 3). The results are made available in aggregated form to other stakeholders (BMG, PEI, BzgA and the Länder).

Table 3: Components of integrated vaccination rate monitoring in Germany

Components	Description
DIM (digital vaccination rate monitoring)	• Quasi-realtime collection of pseudonymised data on vaccination update and computation of vaccination rates. All vaccination centres must collect and send in the coordinated dataset comprising a small number of variables. This is also organised similarly for occupational medicine service providers and occupational physicians. • System developed by RKI and Bundesdruckerei (Federal Printing Office) • Based on Protection against Infection Act (IfSG) and statutory instrument • SHI-accredited medical practices send a truncated, aggregated dataset on a daily basis; private medical practices involved in similar manner
Regular, representative population surveys (COVIMO)	• Monthly survey of representative population sample since February 2021 • Survey conducted on behalf of RKI

	• Vaccination rates in specific groups and reasons for non-vaccination, vaccination intention and vaccination acceptance surveyed in addition to DIM dataset
Hospital staff vaccination status monitoring using KROKO	• Adaptation of OkAPII system (originally created to monitor influenza vaccination rates) to COVID-19 vaccination with a shortened survey interval of approx. 3 months from March 2021 • Documents COVID-19 vaccination status and surveys vaccination acceptance/vaccination barriers in the core target group of hospital staff
RKI vaccination surveillance using statutory health insurance data	• Established routine system, with statutory basis, for vaccination rate monitoring based on statutory health insurance billing data • Not suitable for pandemic vaccination phases I and II because of up to six-month time lag depending on the SHI fund involved • On transition to decentralised routine vaccination (Phase II/III): system based on SHI billing data used to validate data from realtime online monitoring (and also to obtain information on vaccine efficacy, duration of immunity and long-term adverse effects)

- RKI is responsible for monitoring the vaccination rates.
- RKI has developed an online vaccination rate monitoring system (DIM) for nationwide use in vaccination centres and by mobile teams. Data from occupational physicians and occupational medicine service providers is also submitted using DIM. The dataset to be submitted is specified in the Coronavirus Vaccination Ordinance.
- RKI designs and conducts parallel studies and surveys to monitor vaccination rate and vaccination acceptance.

10. Surveillance: Evaluating the safety and efficacy of COVID-19 vaccines

The introduction of new COVID-19 vaccines makes **active surveillance of the safety and efficacy of the vaccine products absolutely essential.** Large clinical trials on the clinical efficacy and safety of the vaccines are ongoing worldwide and are evaluated for approval purposes. Only vaccines with a proven positive risk-benefit ratio are approved and made available. This has now taken place for an initial group of vaccines. Due to the accelerated development and the limited duration of observation in the clinical trials, continuous monitoring and collection of further data during widespread application is necessary in order to identify any additional potential risks arising from the vaccines as quickly as possible.

Vaccine benefit and risk assessment is a continuous process spanning all stages, from vaccine development and pre-approval clinical trials through to post-marketing surveillance. While pre-marketing clinical trials provide important information on the safety and efficacy of vaccines, post-marketing surveillance is essential in order to obtain further information on the vaccine safety (such as the occurrence of rare adverse effects) in larger

and more heterogeneous populations that have not been studied in pre-approval clinical trials.

Post-marketing surveillance of vaccine efficacy and safety and of the duration of immunity ensures that the positive risk-benefit profile established at the time of approval can be continuously reviewed as a vaccine becomes widely used and that vaccination recommendations can be adapted where needed to reflect new findings.

Table 4: Overview of the systems and studies for use in evaluating vaccine efficacy and safety in COVID-19 vaccinations in Germany

	Data collection in real time or near-real time	Data collection in the medium and longer term
Vaccine efficacy	• Case reports under the Protection against Infection Act (IfSG) (vaccine breakthrough infections) • Screening methods	• Hospital-based case-control studies (efficacy, period of protection) • Outbreak studies in the form of cohort studies
Vaccine safety	• Routine pharmacovigilance • Cohort studies, including app-based	• Hospital-based case-control studies • Evaluation of digital health data • Surveillance of pregnant women

10.1. Vaccine efficacy

Information on reported COVID-19 cases, including the vaccination status, is transmitted to the Robert Koch Institute as part of reporting obligations under the Protection against Infection Act. Vaccine efficacy can be estimated in the short term by **comparing the proportion of vaccinated persons among reported COVID-19 cases (vaccine breakthrough infections) with the proportion of vaccinated persons in the population** (screening method).

In the longer term, the efficacy of COVID-19 vaccines deployed in Germany will be measured by including COVID-19 patients (vaccinated and unvaccinated) in a **hospital-based case-control study**. This study will collect data on protection against hospitalisation and severe illness from COVID-19 infection, estimate vaccine efficacy among seniors and patient groups with specific underlying conditions, ascertain the duration of immunity and compare these parameters across the available vaccines.

Outbreaks in specific types of facilities (such as retirement homes, care homes and community facilities) or at events where the group of exposed persons can be easily defined are also to be investigated using a standardised methodology and data collection tools. In such settings, depending on the institution involved and especially as regards particularly vulnerable groups, vaccine efficacy can be determined in a **retrospective cohort study**.

10.2. Vaccine safety

Routine pharmacovigilance is based on established monitoring of possible side effects or vaccination-related complications in accordance with sections 6, 8 and 11 of the Protection against Infection Act (IfSG) and section 63 (c) of the Medicinal Products Act (AMG). PEI regularly evaluates incoming reports and publishes safety reports on its website.

A **cohort study using the SafeVac 2.0 smartphone app** will prospectively track the frequency and severity of adverse effects and of SARS-CoV-2 infections in vaccinated adults over a period of one year. The app can be downloaded from the major app stores (Google Play Store and Apple App Store).

A **hospital-based case-control study** to investigate the efficacy of vaccination in hospitalised COVID-19 patients (vaccinated and unvaccinated, see 10.1) also aims to investigate the **severity of the clinical outcomes** and look for any **indications of a more severe outcome following vaccination**.

A research project on the safety of COVID-19 vaccines will also include an **analysis of treatment and billing data**. This will cover electronic data from five large health insurance funds that serve about 70 percent of the population covered by statutory health insurance in Germany. Data on potential risk signals from Phase I-III studies and new risk signals detected in broad use after approval are examined on a quarterly basis. Modelling and artificial intelligence are used to estimate the risks for subsequent quarters. To perform these analyses, it is necessary for treatment and billing data to be linked with the data recorded at the time of vaccination.

Surveillance of pregnant women: To the extent that pregnant women are vaccinated in individual instances, the safety of the vaccines is to be investigated for this vulnerable group, who are mostly not included in pre-marketing clinical trials (pregnancy complications in pregnant women who have been vaccinated shortly before or during pregnancy – such as abortion, premature birth, stillbirth and eclampsia, compared with unvaccinated pregnant women – foetal malformations, low birth weight, postnatal adaptation disorders compared to non-exposed newborns).

- As higher federal authorities and within the scope of their remits, RKI and PEI are actively involved in monitoring the efficacy and the safety of COVID-19 vaccines.

11. Proof of immunity to COVID-19: Digital vaccination certificates

Once a person has been vaccinated against COVID-19, the vaccination is recorded in the World Health Organization (WHO) standard international vaccination certificate. If a person does not have a vaccination certificate, a 'reserve documentation on vaccination' form can be issued. The digital vaccination certificate provides a new, additional and easy means of verifying vaccination status towards third parties. Instead of showing their vaccination

date, vaccine and name in analogue, printed form, users can now conveniently store this information on their smartphones. However, the digital vaccination certificate cannot be used as a substitute for the documentation of vaccination under the Protection against Infection Act (IfSG).

The contract to develop the system was put out to tender and awarded to a consortium on 19 March 2021. With implementation now underway, the rollout of the digital vaccination certificate will continue step by step during June. Germany is also participating in the EU pilot. The digital vaccination certificate meets the EU-level interoperability requirements enabling the certificates also to be used in other European countries.

The digital vaccination certificate system consists of a certificate app (CovPass App) and a certificate check app (CovPassCheck App). People who have been vaccinated can store and display their vaccination certificate in the certificate app. Alternatively, the vaccination certificate can be stored and displayed in the Corona Warn App (CWA). The CovPassCheck App can be used to scan a vaccination certificate. It then indicates whether the person concerned has a valid vaccination.

The CovPass App and the Corona Warn App will also be updated on a timely basis to integrate the remaining parts of the EU Green Certificate, meaning certification of testing and recovery. The two apps are generally available free of charge. Integration of their functionality into third-party apps is expressly encouraged on the basis of the open source approach.

12. International coordination and cooperation

The SARS-CoV-2 pandemic is a global challenge and the Federal Government attaches great importance to its containment across the whole world. Coordination and cooperation with international partners is thus an essential component of the vaccination strategy in order to accelerate the development of effective and innovative responses and solutions.

BMG is actively involved in various international forums and promotes cooperation between stakeholders from civil society, foundations and the public and private sectors. The Federal Government has committed to globally equitable access to vaccines as a global public good and favours **multilateral solutions** to this end.

Activities at global level centre on the Access to COVID-19 Tools Accelerator (ACT-A) platform, which was initiated in the context of G20 and launched by WHO in April 2020, and the associated COVAX vaccine platform. ACT-A targets the development, scale-up and equitable distribution of COVID-19 vaccines, therapeutics and diagnostics, underpinned by the strengthening of health systems. COVAX is spearheaded by the Coalition for Epidemic Preparedness Innovations (CEPI), the WHO, and Gavi, the Vaccine Alliance, and aims to accelerate research and development of new vaccines. It also supports the establishment of production capacity. The COVAX Facility, which is part of COVAX and is managed by

Gavi, has the goal of providing vaccines to 20 percent of the population of participating countries in 2021. It has already secured over two billion doses of vaccine through to the end of 2021, with about one billion earmarked for developing countries and up to five percent for acute and humanitarian emergencies. In total, the Federal Government is providing over €2 billion in support for ACT-A.

Combating the COVID-19 pandemic and the provision of vaccines is also an important issue for both the G7 and the G20.

BMG, together with the agencies in its remit (RKI and PEI), also provides support in the aid of international knowledge transfer. This includes various projects and committee-based activities.

PEI is represented in the WHO/Europe Regional Working Group on COVID-19 Vaccination and Deployment and also in the WHO SAGE Working Group on COVID-19 Vaccines. In the ECDC-coordinated EU Network of National Vaccination Commissions, RKI is the lead organisation in a "living systematic review" on the efficacy and safety of the COVID-19 vaccines and thus provides key input to aid decision-making concerning COVID-19 vaccination strategies in other EU countries.

As a collaboration centre for vaccines and blood products, PEI supports, among others, the WHO, the regulatory authorities in African partner countries, WHO AFRO and regulatory bodies of the African Union in establishing structures and procedures to promote the approval and implementation of clinical trials for medicines and vaccines and to establish effective pharmacovigilance in the use of medical products.

- The Federal Government is responsible for cooperation and coordination at international level.
- German activities at global level centre on the Access to COVID-19 Tools Accelerator (ACT-A) platform launched by WHO and others in April 2020.
- The authorities that fall within BMG's remit (RKI and PEI) conduct specific projects for international cooperation, including in relation to the vaccination strategy.