Disclaimer: We kindly ask to acknowledge that due to the diverse and heterogeneous nature of the questions and the dynamic pandemic situation some of the information might be incomplete or only correct for the time being. Thus, please consider the date with the below information. All available information was provided by a country representative from the PHIRI network during or in connection to the respective meeting.

Date: 10.10.2022 Updated: 18.10.2022

Table 1: Country responses: Future Vaccine priorities and trials addressing public health needs

Country	Topic: Future vaccine priorities and trials addressing public health needs • **Which of the following issues have the highest public health priority in your country in relation to future COVID-19 vaccine (trials): Vaccine efficacy, Vaccine Development, Specific populations or any other). Please elaborate your choice of max. 2** • **Is there any example in your country of COVID-19 vaccine trials that are addressing public health needs?**
Austria	Currently 42 studies relating to COVID-19 are registered within Austria (https://www.clinicaltrialsregister.eu/ctr-search/search?query=COVID-19&country=at) A couple of trials could be identified that have explicit objectives related to public health needs, mainly focusing on the combination of vaccines, e.g. SPECIFIC POPULATIONS EudraCT Number: 2021-005094-28 Sponsor Protocol Number: VAC3_COVID-19_antibody_study_V1 Sponsor Name: Medical University of Vienna Full Title: Population-based prospective, clinical study on efficacy and safety of a booster COVID-19 vaccination Start Date: 2021-10-25 Link: https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-005094-28/AT EudraCT Number: 2021-001103-32 Sponsor Protocol Number: HEPCOViVac Sponsor Name: Medical University of Graz Full Title: The HEPCOViVac Registry - Immunological response in patients with liver disease vaccinated against COVID-19 Start Date: 2021-04-26 Link: https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-001103-32 EudraCT Number: 2021-001459-15 Sponsor Protocol Number: HS-2021-02 Sponsor Name: Medical University of Graz Full Title: Immune response to COVID-19 Vaccination in people with Diabetes Mellitus - COVAC-DM study Start Date: 2021-04-26 Link: https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-001459-15 EudraCT Number: 2021-001040-10 Sponsor Protocol Number: CoVVac Sponsor Name: Medical University of Graz Full Title: Humoral and cellular immune response to COVID-19 vaccines in immunocompromised and healthy individuals – The CoVVac study Start Date: 2021-04-26

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Link:	https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-001040-10
EudraCT Number:	2021-003277-55
Sponsor Protocol Number:	CAR-CF
Sponsor Name:	Medical University of Innsbruck, University Clinic for Pediatrics III
Full Title:	COVID-19 Antibody Responses in Cystic Fibrosis: CAR-CF
Start Date:	2021-09-01
Link:	https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-003277-55
EudraCT Number:	2021-002984-23
Sponsor Protocol Number:	33-391ex20/21
Sponsor Name:	Medical University of Graz
Full Title:	Retrospective quantification of anti-SARS-CoV-2 antibody response after mRNA COVID-19 vaccine in patients treated with peritoneal dialysis
Start Date:	2021-08-01
Link:	https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-002984-23
EudraCT Number:	2021-002693-10
Sponsor Protocol Number:	VAC3_SARS-CoV2_seroconversion_study
Sponsor Name:	Medical University of Vienna, Department for Internal Medicine III, Division of Rheumatology
Full Title:	A Phase II Study to Evaluate Safety and Efficacy to a Third Vaccination in Immunocompromised Patients with Inadequate Humoral Response after Primary mRNA SARS-CoV-2 (Covid-19) Vaccination
Start Date:	2021-07-15
Link:	https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-002693-10
EudraCT Number:	2021-000291-11
Sponsor Protocol Number:	IMRES
Sponsor Name:	Medical University of Vienna
Full Title:	Characterization of immune responsiveness after SARS-CoV-2 Vaccination in patients with Immunodeficiency or immunosuppressive therapy (COVID-19)
Start Date:	2021-05-30
Link:	https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-000291-11
EudraCT Number:	2021-002927-39
Sponsor Protocol Number:	BOOST_TX/RESCUE_TX
Sponsor Name:	Medical University of Vienna
Full Title:	Preventive strategies against SARS-CoV-2 in kidney transplant recipients: Intervention A – vaccination: Single blinded randomized controlled trial on BNT162b2 or mRNA-1273 (mRNA) vs Ad26COVS1 or C...
Start Date:	2021-06-13
Link:	https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-002927-39
EFFECTIVENESS/REAL WORLD USE:	
EudraCT Number:	2021-002348-57

	Sponsor Protocol Number: 2021-002348-57 Sponsor Name: Medical University of Vienna Full Title: A Randomized, Parallel Group, Single-Blind, Phase 2 Study to Evaluate the immune response of two classes of SARS-Cov-2 Vaccines employed as Third Vaccination in Patients under current Rituximab The... Start Date: 2021-05-30 Link: https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-002348-57 EudraCT Number: 2021-002030-16 Sponsor Protocol Number: Shieldvacc2 Sponsor Name: Medizinische Universität Innsbruck, Institut für Virologie Full Title: Immune response and breakthrough infections following an in-label vaccination with Comirnaty against SARS-CoV-2 in the district of Schwaz Start Date: 2021-05-12 Link: https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-002030-16 EudraCT Number: 2021-002171-19 Sponsor Protocol Number: HEVACC Sponsor Name: Medizinische Universität Innsbruck, Institut für Virologie Full Title: Heterologous vaccination with a Vaxzervia (ChAdOx1-S) prime and a Comirnaty (BNT162b2) boost Start Date: 2021-05-12 Link: https://www.clinicaltrialsregister.eu/ctr-search/search?query=eudract_number:2021-002171-19
Belgium	Belgian COVID Vaccine trials database: https://databankklinischeproeven.be/fr?title=covid19&medical_condition=&age_range=All&subject_type=All&eudract_number 139 studies in total • 3 studies on children below 11 years old • 11 studies with children and adolescents until 18 years old • 55 studies include volunteers • 114 include vulnerable populations • 71 include safety in their title Focus: vulnerable groups and safety **Recommendations in Belgium** Primary vaccination plus first booster dose remains priority for all adults and for children and adolescents at risk of severe outcomes Primary plus first booster dose scheme remains priority in the fight against severe forms of COVID-19 and must be continued to be strongly promoted (ECDC, HAS, UKHSA, JCVI). The SHC reiterates the importance of the timely administration of a first booster dose for all adults and for children and adolescents at risk of severe outcomes and especially for persons aged 65 years or over and for all previously determined comorbidities (SHC 9618, 05/02/2021: level 1, 2 and 3 priority and SHC 9641, April 2021), immunocompromised (SHC 9691, March 2022) and pregnant women (SHC 9622, 22/04/2021). • Vaccination of children aged 5-11 years: Yes, for all children. • Plan to expand primary vaccination to children aged <5 years old: No • Recommendations for a first booster dose for those aged 18 years and above • Recommendations for a second booster for those aged 65 years and above

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<table>
<tr><td></td><td>

Belgium will offer the possibility of a second booster dose for those aged 50 to 64 years as a part of the autumn/winter strategy.
Recommendations a second booster dose for those aged 18 years and above with underlying risk conditions

<table>
<tr><td>Belgium [18]</td><td>Recommendation:
Additional dose for individuals aged 5-11 years (extended primary three-dose vaccination series).
One booster dose (fourth dose) for individuals >12 years (extended primary three-dose vaccination series plus a booster dose). Two booster doses (fifth dose) for individuals >18 years (extended primary three-dose vaccination series plus two booster doses).

Timing:
Additional dose given at least 28 days after second dose followed by a booster dose (fourth dose) at least three months after the third dose.</td><td>Recommendation:
One booster dose for individuals aged ≥18 years (primary two-dose vaccination series plus a booster dose).
Second booster for individuals aged ≥65 years. From September, all staff in the entire healthcare sector, including primary care, residential care centres, hospitals, etc. can receive an autumn booster. After that, the age group from 50 to 64 years is actively invited, in decreasing age. People between 18 and 50 years old can request a second booster.

Timing:
Booster given at least four months after primary vaccination with mRNA-based vaccines; four months after primary vaccination with Vaxzevria; two months after single dose of COVID-19 vaccine Jcovden.
An interval of at least three months, and ideally six months must be maintained between the two boosters.</td></tr>
<tr><td>Belgium</td><td colspan="2">The Belgian Superior Health Council has published recommendations that all risk groups should be vaccinated with an additional booster by the end of September 2022 at the latest and that the campaign should be ‘as compact as possible’ to maximise the benefits of vaccinating against COVID-19 (the interval should be at least three months, but preferably six months for the administration of an additional booster dose). For the autumn/winter season 2022-2023, a proactive mass vaccination campaign will target adults aged 65 years and above, any patient with immune suppression due to disease or treatment, any patient with at least one comorbidity, all pregnant women, all ‘persons active in the care sector’ in and outside care institutions, and people living in the same household as those at high risk of severe disease. After that, the age group from 50 to 64 years will be invited. People aged between 18 and 50 years can volunteer [55].</td></tr>
</table>
References

1. https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/20220706_shc-9721_covid-19_booster_automn-winter_2022-2023_vweb.pdf
2. https://www.ecdc.europa.eu/sites/default/files/documents/Overview-vaccination-strategies-COVID-19-8-September-2022.pdf
3. https://databankklinischeproeven.be/fr?title=covid-19+AND+safety&medical_condition=&age_range=All&subject_type=All&eudract_number=
4. https://www.afmps.be/fr/humain/medicaments/medicaments/covid_19/vaccins

</td></tr>
<tr><td>Czech Republic</td><td>Reply will follow in written.</td></tr>
<tr><td>Denmark</td><td>Plan for this winter to give people 65+ booster shot and sme interest in how immune system reacts when you got 2 or 3 boosters on the same day. Stine Jakokbsen ganz am LSchluss nochmals abhören.</td></tr>
</table>

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Estonia	At the moment there is no information about ongoing trails available. Further reply will follow after a request to the MoH.
Italy	• As part of the COVID-19 epidemiological emergency, the Italian medicine Agency (AIFA) was entrusted with the task of evaluating all clinical trials on medicines for patients with COVID-19 (Decree Law "Cura Italia" Art. 17). Italy is participating in several multicentric trials, still ongoing, on development, safety and immunogenicity of SARS-CoV-2 vaccines (just to name the most recent trial: 'HIPRA-HH-5 - HIPRA SCIENTIFIC', a Phase III, open-label, single-arm, multicenter study to evaluate the safety and immunogenicity of a booster vaccination with candidate recombinant heterodimeric RBD fusion protein (PHH-1V) against SARS-CoV-2 in vaccinated adults). • To my knowledge, COVID-19 vaccine trials specifically addressing public health needs are not currently ongoing. For upcoming winter season, for COVID-19 vaccination, priority has been given to 60 years and older and, from the 5th of September, recommendation has been extended to 12 years and older.
Ireland	Reply will follow in written.
Moldowa	At the moment there is no information available. Further reply will follow after investigation.
Poland	The National Immunization Program against COVID-19 (approved in December 2020) is designed to plan activities that are to guarantee safe and effective vaccinations among Polish citizens. It includes not only the purchase of an appropriate number of vaccines, their distribution, but also monitoring of the course and effectiveness of vaccination and the safety of Poles. https://www.gov.pl/web/szczepimysie/narodowy-program-szczepien-przeciw-covid-19 The main goal presented in the program is the delivery of vaccines: - safe and effective, - in sufficient quantity, - in the shortest time, - free, - voluntary, - easily accessible. The document consists of 9 chapters describing, among others vaccine effectiveness and safety, purchasing and financing, distribution and logistics, medical recommendations and organization of vaccination points, or the order of vaccination. The European Commission is responsible for approving COVID-19 vaccines. First, the European Commission must obtain a positive recommendation from the Committee for Medicinal Products for Human Use operating within the European Medicines Agency (EMA). Intensive cooperation with national agencies is also carried out. Opinions on the vaccine are issued, among others, by experts from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (https://urpl.gov.pl/en) working for scientific committees and EMA working groups. Polish specialists also take part in the meetings of the special EMA group dedicated to COVID-19.
Portugal	Portugal runs a trail to access the safety and emergency of Covid-19 vaccination in cooperation with Italy and Spain: https://covid19.trackvaccines.org/country/portugal/
Serbia	An adaptive phase I/II/III trial to evaluate the efficacy and safety of a combination of monoclonal antibodies against SARS-CoV-2 (SCTA01C and SCTA01) for the outpatient treatment of patients with COVID-19 https://www.alims.gov.rs/humani-lekovi/pretrazivanje-odobrenih-klinickih-ispitivanja/?id=177
Slovenia	Slovenia relies on information from other countries.

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