

Press release

EURORDIS-Rare Diseases Europe calls for more equitable access to COVID-19 vaccines for vulnerable populations in Europe and worldwide

Call to Action

Paris, 23 April 2021 – EURORDIS-Rare Diseases Europe and its members call on European and global leaders to urgently take steps towards equitable access to COVID-19 vaccines to save lives globally and locally, protecting first those at high risk, in particular people with comorbidities, including people living with about 30 different rare diseases, as recommended by [European Reference Networks experts](#).

EURORDIS strongly supports the [WHO Vaccine Equity Declaration](#) and calls for equitable distribution of vaccines against the coronavirus globally. The international community needs to work together in solidarity to ensure that within the next 100 days the most vulnerable have access to COVID-19 vaccines worldwide.

The rapid international development and deployment of effective and safe vaccines to prevent COVID-19 have been the foremost priority of the international community. To date, over 920 million doses have been administered in 177 countries.¹ Yet, many vulnerable groups still do not have access to life-saving vaccines.

This is particularly true for people affected by some 30 rare diseases, as stated in the [European Reference Networks' \(ERNs\) recommendations on priorities and contra-indications for COVID-19 vaccinations](#).

People with comorbidities, particularly associated with high risk for severe COVID-19, are also still waiting to become eligible for the vaccination campaign in at least 10 EU/EEA Member States, according to the European Centre for Disease Prevention and Control.² These highly divergent prioritisations across the European Union and Europe at large are in no way based on sound rational medical or evidence-based policy, creating new inequalities in patient access to vaccines.

Vaccinating primary carers (parents, partners, health professionals) of people with complex medical needs is vital as well – to not only protect them from COVID-19, but also give protection to those in need of care, who are at risk of more serious outcomes from COVID-19.

EURORDIS calls for immediate actions to ensure a more equitable access to COVID-19 vaccines:

- **Fair and rational distribution of vaccines organised by governments** according to the needs of their citizens and their risk factors (vulnerable groups), ensuring that donated and/or delivered doses are part of a **well-structured vaccination framework**: those who need a vaccine should be guaranteed to receive one, at no cost for them;
- **Vulnerable populations, in particular people with well-known comorbidities and people with life-threatening rare conditions (a limited list of 30 disease groups) as well as their carers, should be included in the first group** for vaccination across Europe, based on the recommendations of ERN experts in rare diseases;
- **COVID-19 vaccine production to be increased** through **voluntary agreements** between originator companies and third parties that include technology transfer and training;

¹ Our World in Data, *Statistics and Research, Coronavirus (COVID-19) Vaccinations* (consulted on 19 April 2021).

² Information gathered from the ECDC report, *Overview of the implementation of COVID-19 vaccination strategies and vaccine deployment plans in the EU/EEA*, p. 9-11 (consulted on 12 April 2021).

- Contributions to the COVAX / GAVI should be increased by the EU and high-income countries across the globe, offering facilities and sharing doses in parallel with the national vaccine rollouts.

Vaccine equity is not just a moral test for the global community and its leaders; ending the COVID-19 pandemic depends on it.

I. The vaccination of people with rare diseases within an inclusive and evidence-based process

EURORDIS-Rare Diseases Europe urges governments across Europe to prioritise people with comorbidities and rare diseases as well as their carers in national vaccination strategies for COVID-19 vaccines, ensuring an inclusive and evidence-based vaccination process.

Many people living with a rare disease are most at risk from COVID-19, but this group is not included within the vaccine rollout in many EU/EEA Member States and other European countries. The high frequency of comorbidities and the prevalence of risk factors among people living with a rare disease are a cause for concern, as they are more likely to get severely ill from COVID-19.³ European Reference Networks' experts have provided specific guidance on the diseases and disease groups that for the above reasons need to be prioritised in countries' vaccine rollout plans.

People with rare diseases are at increased personal risk of exposure to infection through direct contact with their carers, medical professionals, and other patients at the healthcare facilities they visit or with care in their home. Rapidly emerging variants of COVID-19 infection show increased transmissibility and infection rates, posing a challenge and a threat to vulnerable populations, including people with rare diseases.

EURORDIS calls on the European Union, the WHO Regional Office for Europe, and national authorities in Europe to right this wrong and in particular, to immediately implement the following:

- Include people with rare diseases and their carers, as an at-risk population from COVID-19, on the national priority vaccination lists;
- Implement the recommendations by the 24 European Reference Networks on priorities and contraindications for COVID-19 vaccination of people with rare diseases;
- Involve patient organisations in decision-making and activities at the policy and programme level to ensure an ethical and transparent process to patients and the population.

Recognising the urgent need for action at all levels to ensure equitable distribution of COVID-19 vaccines, EURORDIS calls upon EU and national policy makers in Europe at large to step forward and voice their support for people living with a rare disease and comorbidity, as well as their carers. We also invite rare disease patient organisations across Europe to join this call and advocate for change at the national level.

Collectively, we need to bring urgent attention to this global issue of first access to the COVID-19 vaccine by the most vulnerable populations.

II. Effective Measures to Urgently Improve Global Access to COVID-19 Vaccines

As the world enters a new phase of the pandemic response, equitable access to COVID-19 vaccines is essential to protect the most vulnerable populations. To ensure that the right help goes to the right people, production of COVID-19 vaccines needs to be drastically scaled-up.

EURORDIS fully supports the WHO Vaccine Equity Declaration addressed to UN Member States, vaccine manufacturers, and regulatory bodies to work together in solidarity – and in each of their best interests – to scale

³ Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19), Associated Hospitalization Surveillance Network (COVID-NET)* (consulted on 21 April 2021).

up vaccine manufacturing, accelerate approval processes, and ensure that people at risk can be vaccinated as quickly as possible.

Globally, the production and supply of COVID-19 vaccines need to scale up to ensure that people living with a rare disease, like other vulnerable populations and people at risk, are not left behind, and doses are made available.

EURORDIS calls on national leaders, industry and other actors to reduce barriers to administering vaccines and encourages vaccine manufacturers to increase their production capacities, particularly through **voluntary agreements** with third parties.

1. To increase global production capacity and ensure the distribution of large quantities of COVID-19 vaccines, technology transfer, scale-up expertise, and manufacturing reservation fees are essential

When it comes to producing COVID-19 vaccines, only the inventor has the expertise and technology to ensure the highest quality standards and create a sustainable supply chain.

Compulsory licensing and IP rights waivers can be effective solutions when the product is an easy-to-make chemical. A third party authorised to produce it does not necessarily need training or technology transfer. The expertise of its engineers and technicians is usually sufficient to maintain a safe product supply. However, it is not the case for COVID-19 vaccines.

To date, no generic pharmaceutical company in the world has the technical expertise to produce safe and high-quality viral vector vaccines in large quantities. Such biological products require large-scale bioreactors. The mRNA vaccines, which constitute a brand new vaccine technology, can only be produced by their developers, such as Pfizer, Moderna and Curevac. Lifting IP rights would not translate automatically into what is, in fact, most needed – the technology transfer.

If intellectual property rights are waived, it may take even a longer time for third companies to deliver large quantities of COVID-19 vaccines, e.g. eight months or more.⁴ It is unlikely that vaccine manufacturers will transfer their technology without compensation or provide any assistance to set up manufacturing and distribution with a compulsory license. Such a move might also further hamper the deployment of vaccines as originator companies may curtail the research and development of the product resilient to emerging viral variants of SARS-CoV-2.

In order to expand the global production capacity and the distribution of COVID-19 vaccines in large quantities, it is vital to ensure technology transfer, scale up expertise, and utilise manufacturing reservation fees.

2. Voluntary licensing agreements between originator companies located in high-income countries and third parties in low- and middle-income countries can be used to address the global shortage of COVID-19 vaccines

Voluntary agreements between an originator company and a third party demonstrate that the subcontractor can already start producing large quantities of COVID-19 vaccine within three to four months after signing the agreement. Many complex medicinal products, including treatment for HIV infection, have been distributed worldwide through such voluntary agreements, in particular as part of the WHO Patent Pool Initiative.⁵

Efforts to boost local manufacturing capacity in low- and middle-income countries (LMICs) could also contribute to faster distribution of COVID-19 vaccine among citizens in underserved communities. For example, AstraZeneca has partnered with Serum Institute of India (SII), the world's largest vaccine manufacturer, to produce its adenovirus-based vaccine. In March 2021, India joined the list of countries able to vaccinate large numbers of people, precisely one million citizens per day. This agreement includes:

- The right to use the patent of the originator company;
- The technology transfer and staff training;

⁴ European Parliament, ENVI-ITRE hearing on the production of COVID-19 vaccines, 25 February 2021

⁵ Ellen 't Hoen, LLM, PhD 4th PPRI Conference, Vienna, 23 -24 October 2019

- Access to suppliers and raw materials.

Many others have already started to share their knowledge, expertise, licenses and patents, invest in scale-up and manufacturing reservation fees to increase global manufacturing capacity.

3. Vaccine manufacturers and high-income countries should increase their contributions to the COVAX/GAVI facilities and share doses with LMICs in parallel with their national vaccine rollout plans

The world's leading vaccine originators have committed to supplying and securing LMICs access to the vaccine. AstraZeneca will reserve 300 million doses to LMICs during the first half of 2021, Johnson & Johnson – 500 million doses via Gavi in 2021, and Pfizer – 36 per cent of their production.⁶

COVAX, the global initiative co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the World Health Organization (WHO), is mobilised to ensure rapid and equitable access to over two billion COVID-19 vaccine doses in 190 participating states.⁷

Governments and regulatory authorities in Europe and around the world should organise fair and rational distribution of vaccines according to the needs of their citizens and their risk factors, e.g. age or living with comorbidities.

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EURORDIS-Rare Diseases Europe

EURORDIS-Rare Diseases Europe is a unique, non-profit alliance of 962 rare disease patient organisations from 73 countries that work together to improve the lives of the 30 million people living with a rare disease in Europe.

By connecting patients, families and patient groups, as well as by bringing together all stakeholders and mobilising the rare disease community, EURORDIS strengthens the patient voice and shapes research, policies and patient services. Follow @eurordis or see the EURORDIS Facebook page. For more information, visit eurordis.org.

Rare diseases

The European Union considers a disease as rare when it affects less than 1 in 2,000 citizens. Over 6,000 different rare diseases have been identified to date, affecting an estimated 30 million people in Europe and 300 million worldwide. Due to the low prevalence of each disease, medical expertise is rare, knowledge is scarce, care offering inadequate and research limited. Despite their great overall number, rare disease patients are the orphans of health systems, often denied diagnosis, treatment and the benefits of research.

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⁶ European Parliament, *ibid.*

⁷ Gavi the Vaccine Alliance, [COVAX vaccine roll-out](#) (consulted on 21 April 2021).