



A Fair and Equitable Global Vaccine Strategy

S&D Position Paper July 2021

It's been more than a year since the Covid-19 pandemic spread across Europe and the world. Millions have died from this virus. The magnitude of the crisis socially, economically and on the personal level is unprecedented in the history of the European Union. Yet, through an extraordinary effort, centred on international cooperation, we managed to develop in less than ten months not only one, but several vaccines. We put our trust in science to make sure that those vaccines are safe and effective. The Union's aim is and has been to get as many safe and effective vaccines to as many people, as soon as possible. Unfortunately, the production bottleneck was underestimated, the international cooperation that had worked so well for the development and research of the vaccines vanished in the production and distribution phase. We must continue to ramp up efforts to expand vaccine manufacturing and distribution. It is crucial to boost production and incentivise to increase the current vaccine manufacturing capacity. We must also work to increase the raw materials and ingredients needed to produce these vaccines.

The S&D Group will always support a European approach towards the procurement, distribution and deployment of vaccines. However, we do recognise that there are shortcomings and failures with important lessons to be learned by the Commission and Member States. We urgently need to adapt and address these issues. We are firmly convinced that only by working together, both at the European level and internationally, can we overcome this crisis.

Furthermore, we might face a situation where the pandemic will turn into an endemic situation that will occur regularly by local or seasonal outbreaks with risks of new worldwide spreading. This may lead to the future need for additional vaccinations or even for yearly vaccinations for a substantial part of our population. We must therefore take into account lessons learnt and prepare for the long term.

Vaccines are a public good and universal access should be ensured. Billions of EU citizens' money have gone into the development and purchase of vaccines and they rightly expect results. We need to show solidarity between Member States, but also globally. Inequalities are increasing all around the world and it is of the utmost importance to protect everyone's health, in particular vulnerable populations and countries. Vaccines must be available to all and we call for real equity in the global access to vaccines, recognising health as a global common good with no territorial limit.

Fair and equitable access to vaccines

No one is safe until everyone is safe! One agreement is better than 27, and without joint procurement the EU would be in a significantly worse situation today with only the privileged few having access to any vaccine. We have faced substantial shortfalls of vaccine deliveries and although it has been mitigated in the short term by increased deliveries, future challenges still remain, notably in relation to future mutations and variants. We therefore emphasise the following:

- This pandemic has already created inevitable inequalities affecting especially vulnerable groups. The further we go into the vaccination campaign we need to recognise vulnerable groups which face particular challenges to access vaccination through normal channels such as the homeless.
- Further inequalities during this pandemic must be avoided and accessibility and affordability of Covid-19 testing must be ensured so that notably citizens that cannot or do not want to get vaccinated, do not face financial discrimination.
- We need to create a more robust framework for coordination at EU level. We call on Member States, to not go for “me first” and to primarily use vaccines which have gone through the EMA marketing authorisation process. Unilateral action may lead both to issues of unequal distribution and issues of safety and effectiveness of vaccines, as well as undermine trust in the joint procurement scheme.
- Commission should encourage Member States to engage in joint procurement procedures and to follow the EMA regulatory process in order to guarantee a secure, fair, equitable and affordable access to vaccines.
- The second generation contracts should be published in full transparency on the Commission website, since increased transparency boosts public trust, empowers the public debate and helps foreign governments to not accept anything below the EU standard during their negotiations with pharmaceutical companies.
- Regardless of the reasons why some Member States opted to purchase more of one vaccine than another, equitable distribution of vaccines needs to be ensured. More concrete solidarity mechanisms should be created to bolster the delivery of vaccines to those Member States that have fallen behind. In this regard, we welcome the agreement reached in Council on 1 April 2021 on the additional doses of vaccines which will be given to 5 Member States as solidarity vaccines. Increased rates of distribution of vaccines to Member States which have fallen behind should also be considered when negotiating future agreements.
- Vaccines and possible booster vaccines that might be needed in the future must be free for all EU citizens and residents in the EU.
- If Member States have a surplus of doses it is crucial that doses are distributed quickly to other countries in need including at international level to avoid waste due to expiry.
- As we have witnessed in previous crises women are the most vulnerable, and at the same time vital to maintaining the public life and essential services and recovery. Women are on the frontline of the Covid-19 pandemic and are disproportionately represented in professions where exposure to the virus is high. Around 70% of the global health and social workforce like doctors, nurses and care workers are women.
- A gender-sensitive approach in vaccination policies is crucial to achieve gender equality and gender mainstreaming is key at every stage of vaccination policy, from development through rollout. Women have reported more adverse effects and side effects than men after being vaccinated.
- Better access to the vaccine for care takers in private homes needs to be prioritised, as women are often primary care takers of family members not in a care facilities and at risk of being isolated. Women are highly represented in sectors where work depends on close contact with others so they come into direct contact with the virus much more frequently.
- Keeping in mind that persons with disabilities face many barriers and are less able to maintain social and physical distance and that they therefore are at a greater risk of contracting Covid-19 and fall severely ill, we urge the Member States to prioritise all persons with disabilities in their vaccination strategies.
- We welcome the recent update of the Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products contributing to the expeditious uptake of adapted vaccines.

- We need greater transparency of the contracts, the steering board and joint negotiation team, to build confidence in the Advance Purchase Agreement process especially for issues of liability and indemnity, the price and the cost and the budgetary instruments to pay for the vaccines, including the budgetary commitments by Member States, whilst avoiding price speculation. The European Parliament should have the right to scrutinise the Advance Purchase Agreements. Even when Joint Public Procurement procedures are not applied, a high level of transparency of purchase contracts should be encouraged, in order to allow financially weaker Member States to have a fair negotiation position to purchase necessary vaccines.
- We call on the Commission and Member States to urgently assess the reasons as to why there have been issues with the first advance purchase agreements notably for the AstraZeneca contract to ensure that the same issues do not reoccur again.
- We also need to ensure compliance with the commitments made by pharmaceutical companies and use the full extent of the law to enforce 'best reasonable efforts' clauses in contracts. In addition, should a contract not be respected, the Commission should use all mechanisms available including, if necessary, limiting the capacity of companies to send doses produced in the EU to other economic regions. In this regard we fully support the European Commission in its lawsuit against AstraZeneca which is a much more proportionate and sensible response than the export authorisation mechanism (which was established exactly because of the lack of compliance of AstraZeneca). In future contracts 'best reasonable efforts' clauses should be replaced by a detailed, time-bound delivery schedule in new contracts in order to make our vaccination strategy more predictable and make it easier to hold pharmaceutical companies to account.
- We call on the Commission and Member States to continuously be vigilant against new variants and mutations using all tools provided through HERA incubator and beyond. Welcome in this regard the proceedings to establish agreements with pharmaceutical companies notably for potential boosters and adapted vaccines.
- We also call for clear and transparent communication on possible adverse effects as it is crucial to maintain confidence in the EU vaccine strategy.
- We call for Member States to follow EMA's opinion on possible adverse effects of certain vaccines and to make adjustments (e.g. age restrictions) in line with EMA's recommendations. This is crucial to ensure equitable access to vaccines across the EU as well as trust in institutions.
- Recognise the important discussion on the issue of inoculation of children and adolescents, and call on Member States to follow EMA guidelines in this regard.
- The Commission-Parliament Contact Group including members of some relevant policy fields, must be included in the contractual decision-making processes in order to ensure further transparency. This Group must receive a comprehensive and detailed analysis on the production, imports, exports and forecasts of vaccines on a weekly basis. Information about the country destinations of EU exports, as well as information on the origin of vaccine and vaccine component imports should be made available to the Contact Group.
- We need to quickly develop a strong and inclusive European Health Union to ensure equitable access to vaccines and quality healthcare.

Addressing the current crisis and preparing Europe for future pandemics: increased production capacity and increased investments in R&D

Shortcomings in the supply of vaccines are reported across the EU, with clear consequences on all actors involved in protecting citizens' health. The Covid-19 pandemic has demonstrated the weakness of excessively long and fragile global supply chains for critical medical equipment and pharmaceuticals.

Scaling up production to meet global demand is an epic challenge. Before this pandemic, there were no existing networks of contract manufacturers for several of the leading vaccine candidates

that feature innovative technologies. Additionally, the volume of vaccines that is needed places pressure on global supply chains for inputs, such as glass vials, syringes, and stabilising agents. The production of Covid-19 vaccines is limited by the highly concentrated state of global vaccine manufacturing capacity, and the relationships established between lead developers and contract manufacturers.

- The Commission must engage with partner countries to increase the supply of critical materials, minerals, active pharmaceutical ingredients (API), medicines and medical equipment and help companies to strengthen and diversify their existing value chains.
- In the context of Europe's strategic autonomy, it is important to strengthen European manufacturing and to look into options for reshoring (including back-shoring and nearshoring) and diversifying sourcing strategies for essential active pharmaceutical ingredients.
- We ask the Member States, in close cooperation with the Commission, to encourage more inter-company agreements and dedicate the maximum existing capacity to expand vaccine production capacity while accompanying manufacturers in building new capacity; we insist on directly supporting the increase in manufacturing capacity including through a risk-based approach.
- We need to ensure a level-playing field and a regulatory environment that is conducive to innovation and competitiveness. The updated Industrial Strategy should drive the transformation to a more resilient and globally competitive economy.
- Regardless of the type of vaccines being used, production has to scale up significantly and be flexible to ensure timely and equitable access for everyone. There are still many European sites not being used in the roll-out of vaccines, while these sites are surely able to contribute to the upscaling of the production and distribution of the vaccines, albeit in some cases just as a labelling, packaging and/or distribution facility for vaccines.
- Consortia that apply for funding or supplier contracts have to cover the entire supply chain of vaccine production to prevent unavailability of materials and delays. European authorities have to be able to give directions and instructions on which vaccines will be produced and exert leadership and control over these fundamental decisions and production targets. A strong and well-defined partnership between the public and private sector is essential to make future vaccine production in Europe a success.

Research and innovation are pivotal in responding to ongoing challenges, not only of the Covid-19 pandemic, but also of other health threats that Europe is facing.

- We call on Member States to keep boosting investment in research and development (R&D) and reach the target of investing at least 3% of GDP in R&D, in order to increase Europe's leading scientific and technological position and enable the deployment of essential innovations and technologies in the field of health.
- Horizon Europe funding must be efficiently allocated to further support research and development to complement EU investments in vaccines (including, for example, through the proposed Innovative Health Initiative, a joint undertaking aiming to bring in private sector investment). Substantial amounts of decommitments from H2020 (which were not anticipated and consequently not incorporated in the MFF agreement) should be made available in their entirety to Horizon Europe (in accordance with Article 15(3) of the Financial Regulation) to support research and development of vaccines, especially in light of new variants.
- We welcome the HERA incubator that will bring together researchers, biotech companies, manufacturers, regulators and public authorities to monitor variants, exchange data and cooperate on adapting vaccines. HERA incubator will serve as a blueprint for future HERA functions.
- We request transparency in setting up the European HERA, as HERA is expected to bring an incentive for industry to invest in unmet public health needs, such as research and development of scarce medical countermeasures, market failures, or addressing antimicrobial resistance or other major health issues. HERA is expected to advance

science and develop innovative health solutions in specific areas including through applied sciences and digitalisation and will strengthen the competitiveness of Europe's health tech industry.

- We welcome the Commission's Communication on the EU Strategy on Covid-19 therapeutics, including the intention to finance up to €40 million support to flexible manufacturing and access for Covid-19 therapeutics under the EU Fab project, which will set up a network of 'ever-warm' production capacities for vaccine and therapeutics manufacturing at EU level. We need more information from the Commission on the timeline for implementation and the long-term funding of the EU FAB project as well as its future 'integration' into HERA.
- We call on the Commission, in close cooperation with the competent national authorities to deliver on obtaining, detecting and analysing new variants of the virus more rapidly and upscaling the production of existing, adapted, or novel Covid-19 vaccines. This objective can be achieved through the mobilisation of breakthrough research with substantial long-term effects - such as a comprehensive vaccine that could cover the wider spectrum of Covid-19 and its variants. In particular, we ask for increased research and production of specialised tests for new variants, making sure that not only 5% but 10% of positive tests across the bloc undergo genomic sequencing.
- We reiterate the importance to monitor the strains of the virus that are circulating, as well as the need to share the collated data.
- We insist on the relevance of digital technologies, such as AI, High Performance Computing and quantum that are key for the acceleration and discovery of vaccines, as well as to predict the virus spread and to distribute scarce medical resources. Europe must remain the leader in these applications in a wider range of areas such manufacturing, crisis management and personalised medicines, while reducing dependency on foreign providers.
- Research funding contracts should include clauses outlining clear accessibility conditions and full access to data resulting from research carried out with EU public funds, as open science is key in achieving results, as well as to possible IPRs and know-how transfers. Taxpayers should not be paying twice.
- The EU must strive for more transparency regarding the decision-making processes in all aspects of research and development financing, especially those focusing on Covid-19. This could be done, inter alia, by improving transparency of the markets for medicines, vaccines and other medical devices and by putting in place all the mechanisms necessary to know the research and development costs of vaccines, medicines and other health technologies.
- Compared to traditional vaccines, the mRNA technology can require less time to advance due to its synthetic nature and the potential for generic, low-cost manufacturing processes. In view of the development of mRNA vaccines and scientific and regulatory challenges faced, it is necessary to establish international consensus on the technical expectations for the development and evaluation of mRNA vaccines. It is expected that safe and efficacious mRNA vaccines will play an important role in combating infectious diseases in response to public health emergencies and other diseases. The EU should take a firm leadership on research and development of mRNA-based vaccines.

Ensure vaccines, diagnostics and treatments are a global public good

As long as not the whole world is fully vaccinated, people's lives and livelihoods will continue to be endangered and the global economy will not recover. Studies indicate that widespread vaccine coverage will not be achieved before 2023, with the poorest countries having to wait until at least 2024. As a result, it looks like the goal of herd immunity will be difficult to achieve in the short to medium term. The SARS-CoV-2 virus is mutating too quickly and global vaccination programmes are too slow to catch up. It is clear that governments will need to adopt a long-term management strategy that combines regular inoculation with extensive testing and effective treatments.

Therefore, the EU must play a key role in making sure that not only vaccines, but also diagnostics and treatments truly become global public goods. In order to achieve this, we must 1) scale up production of scarce essential medical products (most importantly vaccines), 2) ensure the wide accessibility and affordability of Covid-19 related products, and 3) secure geographically fair distribution of manufacturing. This would include:

- Increasing production of vaccines globally through technology transfers and cooperation between developers and production sites, especially those in the most affected regions and the Global South. There is an urgent need to increase production of raw materials and ingredients in order to scale-up vaccine output; an international investment strategy to address bottlenecks should also serve to integrate more emerging and developing countries in the vaccine production value chains.
- We need to actively negotiate an effective and targeted TRIPS waiver, in order to increase the production, accessibility and affordability of Covid-19 related medical products.
- The WHO's Covid-19 technology access pool (C-TAP) and Technology Transfer Hub initiatives must be reinforced and integrated into a wider WTO-WHO led action plan for establishing manufacturing sites in developing countries. Such a plan must build on active technology transfers, open access to scientific research and clinical trials data, investment plans for local production sites, logistical support for local pharmaceutical market approval systems (to make them more efficient) and eliminating trade barriers that hamper production value chains.
- Proactive mapping of all the companies worldwide (including sub-contractors) that by now possess the necessary know-how for manufacturing Covid-19 vaccines and therefore could take part in global technology transfers.
- Supporting the African Union's Partnership for African Vaccine Manufacturing initiative, which aims at setting up new mRNA manufacturing plants on the African continent.
- Increased cooperation under the WHO notably where the ACT Accelerator initiative must become a top priority for the EU in its global response in all of its pillars of diagnostics, therapeutics, vaccine and strengthening of health systems. The EU together with partners in the G7 and G20 must urgently increase funding to all ACT-A pillars and fill the existing funding gap. Furthermore, increased funding need to be provided through the COVAX Facility.
- Share excess doses under Team Europe as a matter of priority, especially given that the outbreaks in India have delayed COVAX's delivery schedule. The European Union, together with the US and other G7 and G20 partners must step in and support COVAX in this period.
- Advance Purchase Agreements should neither prevent sharing doses, nor should producers escape liability in case EU-procured vaccines are used in third countries. If necessary, the EU must use the sharing mechanism under COVAX to guarantee that liability cannot hinder sharing doses between Europe and the Global South as well as the European Neighbourhood.
- Remove trade barriers for Covid-19 essential equipment. Open, and immediately lift export restrictions on trade in vaccines. The negotiations by the WTO Trade and Health initiative (proposed by the Ottawa group) must be concluded by the next WTO ministerial conference (MC12), at the end of the year. Discouraging export bans must be considered.
- A Trade and Health Committee should be established on MC12, in order to draw lessons from the pandemic, make proposals to increase the effectiveness of the WTO response during international (health) crises and to prepare a trade pillar for an international pandemic treaty. The Committee should outline how to prepare for the extreme demand shocks that we saw during the crisis, as well as how to avoid the eye-watering inequalities in access to scarce essential products that we are still experiencing today. The current flexibilities in the global IPR framework must be revisited to render them more effective.
- Negotiating an international treaty to prepare for future pandemics, comprising a health pillar, a development cooperation pillar and a trade pillar. The initiative should work along the lines of monitoring bottlenecks, production capacities and stockpiles, and be able to take immediate measures against extreme price speculation. It should be able to rapidly establish an international coordination mechanism for scaling up production and

strengthening supply chains (including deterrent measures against export bans). We must also strive to come to a new understanding with the pharmaceutical industry about transparency requirements on profits, government contracts and contracts with third party manufacturers. Research and development that was funded by the government must come to the public domain, and fall under public-private contracts that bring new commitments in terms of (non-exclusive) licensing, research sharing and technology transfers. The treaty must establish a Public Goods legal framework, where special sets of rules apply to minimise global health threats and other crises in the future.

- Building resilience against pandemics by fulfilling the UN's Sustainable Development Goals (SDGs) will be crucial. The EU needs to establish a comprehensive strategy and roadmap for the achievement of the SDGs, taking into account the causes and impact of Covid-19. The S&D Group reiterates its call for an effective long-term EU global health strategy. The S&D underlines the importance of an effective strategy that protects biodiversity in order to help prevent future pandemics. The pandemic has undone much of our global progress on the SDGs. Instead of adapting our goals and ambitions, we now need to strengthen our global commitments and increase our development efforts, following the build back better approach.
- Establishing a mechanism to map the production cost per vaccine at the different manufacturing sites, the investments governments and companies have made respectively, and the vaccine sales prices around the world. This would strengthen initiatives on the affordability of vaccines, and lead to agreements where, for instance, rich countries pay more per vaccine dose, in order to allow COVAX to purchase below production cost price.
- Our global efforts to provide vaccination, diagnostics and treatments for all countries in must go hand in hand with increased international development cooperation efforts, following the build-back-better approach, in order to strengthen our global health resilience and the capacity of developing countries to better handle future crises. Gaining back lost progress and even regress on achieving the SDGs especially in those countries already lacking behind most drastically calls for ambitious action and scaling up finances for development cooperation and increased coherence in existing programmes to empower the most vulnerable and ensure that they do not fall behind even more as a result of this crisis. We cannot afford to lose a whole generation in terms of skills, education and overall socio-economic progress.
- Europe should take control of the production of vaccines. Production should be well and evenly distributed across different locations within the EU, which can switch and scale up fast to ensure a network that can handle the logistics and distribution of vaccines. For this, we need to invest in our infrastructure and new public-private partnerships will help to ensure long-lasting production facilities across Europe.
- The European post-Covid recovery fund contains 1.8 trillion euro. Access to these European funds and developing (new) facilities should depend on clear conditions that contribute to achieving equitable distribution and accessibility of vaccines for all Europeans.

Export authorisation scheme

Considering that the EU sources 70% of its vaccine ingredients from other vaccine-producing countries. We must step away from the dangerous zero-sum logic of export restrictions and prohibition, and replace the EU authorisation mechanism with an import-export notification requirement.

We look with concern at the rhetoric and discussions about introducing export bans. Although we welcome the notion of having increased transparency of exports in light of recent shortfalls in deliveries, we need to ensure that exports to countries under the COVAX Facility and neighbouring Western Balkans as well as other countries in need are not impeded. Furthermore, in case of any shipments blocked under the present scheme, we need increased transparency to know where

the doses actually end up. We also need more cooperation and transparency in the supply chain in order to increase the manufacturing and facilitate the distribution of vaccines.

Going forward, the EU must be a leader against protectionism and show international solidarity given that this is a global fight. Although countries such as the US have hindered essential exports to the EU we need to continue to export essential components as well as vaccines, as the long-term consequences of entering a spiral of further protectionism would be dire.

Intellectual property rights including voluntary and compulsory licensing

With the unprecedented challenges posed by this pandemic, the ongoing discussion on compulsory licensing or waiver of Intellectual Property Rights (IPRs) certainly merits further reflection on the long-term impact, as any choice made now will have an effect in the future including that of setting a precedent.

- Global equitable access to affordable vaccines, diagnostics and treatments is the only way to mitigate the global public health and economic impact of the pandemic, and the temporary waiving of international intellectual property protection obligations for Covid-19 related health products is one of the important contributions to this goal. We therefore call to support proactive, constructive and text-based negotiations for a temporary waiver of the WTO TRIPS Agreement, aiming to enhance global access to affordable Covid-19-related medical products and to address global production constraints and supply shortages.
- The current TRIPS rules significantly limit exports and imports of compulsory licensed products and therefore have only been used once to help developing countries with no manufacturing capacity. We call for a revision of the international rules for compulsory licensing in order to enhance global affordable access to health products. Furthermore, the Commission must assess the TRIPS+ commitments in EU trade agreements in order to ensure they are effectively in line with the 2001 Doha Declaration. Last, we ask the Commission to come forward with a legislative proposal to simplify and harmonise compulsory licensing at the EU level.
- Sharing of vaccine patents in itself is nevertheless not enough, i.e. technology transfers (entailing, inter alia, knowledge and skills concerning the processes of vaccine development and production once their patent protected formula is available) are necessary as well and key to boosting companies' capacity for vaccine production and distribution. The Covid-19 Technology Access Pool (C-TAP) platform, established one year ago within the World Health Organization (WHO) and aimed at promoting the voluntary transfer of intellectual property rights and the pooling of all forms of knowledge related to the virus, should be promoted. The upcoming World Health Assembly should be used to express our joint commitment to C-TAP in order to encourage industry to facilitate the necessary transfer of know-how so as to effectively enable production capacity.
- Clear rules and agreements have to be made between the European authorities and pharmaceutical companies on the sharing of intellectual property rights and knowledge and expertise, compensations, ownership and competences. This means production facilities have to be divided strategically across Europe to ensure fast and equitable distribution and should be capable and flexible in modifying or even switching to alternative vaccines. Not only to be able to produce the best available vaccine, but also to react to mutations. Pharmaceutical companies will have to share their knowledge and expertise with these local production facilities for the mRNA-vaccines to be produced under the conditions of Good Manufacturing Practices.

EU Digital Covid-19 Certificate

The current crisis has taken a heavy toll on the free movement of people and goods in our Union, with restrictions impacting the everyday life of citizens. The S&D Group in the European

Parliament recognizes the tremendous efforts made by transport workers during the sanitary crisis, who have been in the frontline and ensured the continuous flow of goods across the EU, including essential goods such as food and medical supplies and equipment, as well as the distribution of vaccines. Furthermore, many Member States have high dependence on the hospitality sector for economic sustenance. Especially, considering the immense suffering with families being separated and workers not being able to go to work across borders, we can't let citizens wait.

- The S&D Group in the European Parliament welcomes the agreement reached with the Council on the EU Digital Covid Certificates in the form of proof of vaccination, a recent negative test or certified recovery from Covid-19. The certificates should serve as a major step in efforts to coordinate the gradual lifting of national Covid-19 travel restrictions, and put an end to more than a year of patchwork responses.
- The S&D Group pushed to ensure that the certificates would have real benefit by committing the Member States to refrain from introducing additional travel restrictions for those holding the certificates, as long as the epidemiological situations so allows. This will facilitate freedom of movement across Europe and bring an end to the immense suffering of separated families and the difficulties faced by cross-border workers struggling to get to work. The certificates will also be in place in time for the upcoming summer tourist season. For all those reasons, it was essential to reach an agreement quickly, while fully exercising Parliament's responsibility as co-legislator. On this, we duly delivered.
- It was equally important to prevent vaccination certificates becoming a document required to cross the internal borders of the Schengen area, and this is something the Regulation now clearly states. Furthermore, it was crucial to avoid discriminating against persons who were not yet able, cannot or do not want to be vaccinated. For such persons, the test and recovery certificates will allow them to continue to exercise their right to free movement.
- Still, costs for tests required for these certificates, especially for PCR tests, can be prohibitive. Despite our strong political message and repeated calls, Member States were not able to agree on providing free testing in the context of the EU Digital Covid Certificate, which we deeply regret. Nonetheless, as a result of our negotiations the Commission committed to mobilise at least an additional EUR 100 million for the purchase of free tests for those most in need of free testing. Our Group continues to call on the Member States to support a European solution to facilitate free testing for the use of the Digital Covid Certificates.
- In that regard, we reiterate that exercising the right to free movement should not depend on financial means because of the costs of Covid testing. Freedom of movement is a fundamental freedom under EU law and the lack of a harmonized approach on testing constitutes an obstacle to this fundamental freedom.
- We also made sure that these certificates will be temporary in nature and not create ongoing obligations on persons crossing internal borders. This was guaranteed by including a sunset clause after 12 months. In addition, we strengthened data protection and data minimisation provisions, ensured a public key infrastructure that does not require the transfer of personal data at EU level, and improved the accessibility of certificates. To be able to quickly draw conclusions on the use and added value of the certificates, we have also successfully insisted on a Commission report four months after the Regulation enters into force.
- The legal and technical framework for the certificates is now in place to allow freedom to travel again in time for the summer. The onus is on the Member States to implement swiftly all aspects of the Regulation and make use of the possibilities that these certificates offer.
- We reiterate that continuous research needs to be carried out on the long-term effects on immunity of vaccines and after recovery and whether citizens are still able to spread the

virus after vaccination and recovery. In that regard as stated in the legislation, the validity of the different certificates should be updated expeditiously according to the latest scientific evidence.

We further reiterate that in accordance with the obligations of the EU and the Member States under the UN CRPD and the European Disability Rights Strategy, persons with disabilities must be able to access their personal information in the digital or paper EU Digital Covid Certificates on an equal basis with others. It is important to ensure that issuance of vaccination certificates are done according to the recently agreed text on EU Covid-19 certificates. The regulation notably stipulates that vaccination certificates must be issued in relation to vaccines approved through the EMA marketing authorisation process. Member States may also issue certificates for other vaccines, but there is no obligation on Member States to accept them.

Public confidence and trust in Covid-19 vaccines and those who deliver them to ensure uptake are as important as the vaccines' safety, efficacy and affordability

- EU Institutions need to urgently engage with communities to improve confidence in vaccines and combat misinformation around Covid-19. Developing successful, tailored strategies requires an understanding of influences of vaccine hesitancy and refusal.
- Regulatory authorities safeguard public health by assessing whether the benefits of pharmaceuticals compensate their risks. Regulatory decisions and their motivation should be clearly communicated to the public to provide reassurance that authorised products are safe and efficacious. Vaccine manufacturers should also contribute to ensure maximum transparency and scrutiny of their clinical trial data to build public trust.