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S&D Policy Paper
A Fair and Equitable Global Vaccine Strategy

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. 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.

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.

We would like to begin with establishing that 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 we would be in a significantly worse situation today with only the privileged few having access to any vaccine. We are now facing a serious situation with a substantial shortfall of vaccine deliveries. With some Member States having prioritised vaccines which are substantially affected, we are now facing a situation that at least for the first half of 2021 it is not clear that the distribution of vaccines will be carried out in an equitable manner. We therefore emphasise the following:

- 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. Joint procurement and following the EMA regulatory process should be the norm.
- 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. Existing agreements should be adapted in that regard to ensure a pro-rata distribution.
- A gender-sensitive approach in vaccination policies is crucial to achieve gender equality and gender mainstreaming at every stage of vaccination policy, from development through to rollout.
- We need to urgently update the regulatory framework to ensure an expeditious approval process 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.
- 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.
- We also call for clear and transparent communication on possible adverse effects as it is crucial to maintain confidence in the EU vaccine strategy.
- 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.
- We need to quickly develop a strong and inclusive European Health Union to ensure equitable access to vaccines and quality health care.

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.

- 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 and for this reason we reiterate our plea for an ambitious renewed industrial strategy.

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 new 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 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 which 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.

Ensure vaccines are a global public good

Studies indicate that widespread vaccine coverage will not be achieved before 2023, with the poorest countries having to wait until at least 2024 before herd immunity can be achieved. Therefore, the EU must play a key role in making sure vaccines truly become global public goods. It should set up a clear and coherent global vaccination strategy, together with other partners, in order to save lives and reduce the negative economic consequences. Failure to do so would risk the EU losing influence on the world stage. Promoting global cooperation among companies is also a priority. Our global efforts to provide vaccination for all countries in need must go hand in hand with our increased global development 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. This would include:

- Supporting the WHO's COVID-19 technology access pool initiative aimed at achieving equitable global access to health technologies to tackle COVID-19. Due to the complexity of vaccine production, it is clear that lifting patents is insufficient to increase global vaccine capacity overnight. Active transfer of technology is required to enable more companies/production sites to produce vaccines. The EU should work jointly towards a holistic WTO-WHO initiative with developing countries, which must entail investments in local production sites and setting up a system of non-exclusive licensing for COVID-19 related products.
- Work with international partners on a global investment plan for increasing global production capacities, including in low and middle-income countries, to prioritise rapid technology transfers and to negotiate a temporary TRIPS waiver for COVID-19 related health technologies in order to ensure that governments retain the full regulatory space needed to develop health strategies during the pandemic.
- 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. Furthermore, increased funding need to be provided through the COVAX facility.
- To share excess doses under Team Europe. Advance Purchase Agreements should neither prevent sharing doses, nor should producers escape liability in case EU-procured vaccines are used in third countries.
- Increased cooperation under the WTO to remove trade barriers for COVID-19 essential equipment. It is of the utmost importance that trade in COVID-19 related products remains open, and that export barriers such as export bans, export licenses

and tariffs are removed. The WTO Trade and Health initiative proposed by the Ottawa group must be concluded by the next WTO ministerial conference, at the end of the year. The European Union could play a critical role in strengthening global trade cooperation, but first it must replace its own export authorisation mechanism by an import/export notification requirement and engage with other producing countries to do the same.

- We need to build resilience against pandemics by fulfilling the SDGs. The EU needs to establish a comprehensive strategy and roadmap for the achievement of the SDGs, taking into account the impact of COVID-19. The S&D Group reiterates its call for an effective long-term EU global health strategy. 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

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, , which any choice made now will have in the future including that of setting a precedent.

- We call on the European Commission and Member States to duly consider measures such as compulsory licensing or waiver of IPRs, albeit as a last resort, both within and beyond EU territory, in anticipation of future needs resulting from the conditions imposed by pharmaceutical companies on certain medical products that ultimately put the lives of EU patients who need them at risk and jeopardise their access to medicines.

- 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.

Digital Green Certificate

The S&D group in the European Parliament welcomes the Commission's efforts to coordinate the lifting of national COVID-19 travel restrictions by introducing Digital Green Certificates as proof of vaccination, a recent negative test or having recovered from COVID-19. In scrutinising the legislative proposals, S&D MEPs will seek assurances that public health is not put in danger, and also that personal data and the freedom of movement across Europe, in light of the upcoming summer tourist season, are equally protected and ensured. We need to quickly reach an agreement on a future certificate, but with full respect for Parliament's responsibility of scrutiny as a co-legislator. 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. We therefore urge the European Council to come to an agreement on the rights and obligations that can be attached to these certificates, so as to ensure a certain degree of uniformity across Europe.

- Research needs to be carried out on the long-term effects on immunity of vaccines and whether citizens receiving vaccines are still able to spread the virus.
- The scope of the vaccines included in the certificate and how this will affect citizens of third countries is an important issue to be addressed especially considering third country workers and tourists that might not have access to vaccines authorised by the EMA.
- To avoid discrimination, a vaccination certificate must never become a document required to cross the internal borders of the Schengen area; third-country nationals legally residing in a Member State must also be offered the certificate upon request.
- We recall that Art 3(2) TEU requires the Union to offer its citizens an area of freedom, security and justice without internal frontiers in which the free movement of persons is ensured... ; Art
  77(2)(e) requires the Union to develop a policy with a view to the absence of any controls on persons, whatever their nationality, when crossing internal borders.
- The Schengen Borders Code lays down the rules to be applied regarding temporary reintroduction of internal border controls. Since it seeks to provide circumstances in which Member States can require the production of documentation in order to cross an internal border of the Union, a proposal that does not form part of the Schengen Borders Code would pose certain difficulties.

- As this measure should be temporary in nature and not create ongoing obligations on persons crossing internal borders, it is essential that the measure is clearly time-limited with a sunset clause, which is now not clearly indicated in the proposal.
- Privacy and data protection: Compliance with GDPR and e-Privacy rules need to be fully ensured;
    - Purpose limitation for the processing of the data will need to be clear and strictly limited, with clear rules on who has access to such data and under which circumstances.
    - Processing of the data should happen nationally, and no EU database should be created.
    - There should be no cross border or other data transfers necessary for the functioning of the system.
    - All necessary data should be stored only on the certificate and no access to any database should be necessary when verifying the certificate.