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**Meeting the Global Covid-19 challenge: effects of waiver of the WTO TRIPS agreement on Covid-19 vaccines, treatment, equipment and increasing production and manufacturing capacity in developing countries**

**European Parliament resolution of 10 June 2021 on meeting the global COVID-19 challenge: effects of the waiver of the WTO TRIPS Agreement on COVID-19 vaccines, treatment, equipment and increasing production and manufacturing capacity in developing countries (2021/2692(RSP))**

(2022/C 67/05)

*The European Parliament,*

- having regard to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), notably Article 31bis thereof,
- having regard to the Doha Declaration of 14 November 2001 on the TRIPS Agreement and Public Health,
- having regard to the decision of the WTO's Council for Trade-Related Aspects of Intellectual Property Rights of 6 November 2015 on the extension of the exemption for least developed country (LDC) WTO members to implement provisions of the TRIPS Agreement related to pharmaceutical products,
- having regard to the communication from India and South Africa of 2 October 2020 requesting a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19, co-sponsored by Eswatini, Kenya, Mozambique and Pakistan, and supported by 100 other countries,
- having regard to the revised proposal for a waiver of the TRIPS provisions as communicated on 21 May 2021 by 62 WTO Members,
- having regard to the open letter from 243 civil society organisations to the WTO Director-General of 13 April 2021 on addressing the global challenges of inadequate supply and inequitable access to COVID-19 medical products, especially vaccines,
- having regard to the statement of US Trade Representative of 5 May 2021 affirming support for a temporary TRIPS waiver,
- having regard to the open letter of the President of the Republic of Costa Rica and the Director-General of the World Health Organization (WHO) of 27 May 2021, to call once again on all WHO Member States to actively support the COVID-19 Technology Access Pool (C-TAP),
- having regard to the Rome Declaration adopted at the Global Health Summit on 21 May 2021,
- having regard to the letter of 31 May 2021 by the Director-General of the WHO, the Director-General of the WTO, the Managing Director of the International Monetary Fund (IMF) and the President of the World Bank Group calling for a new commitment for vaccine equity and defeating the pandemic,
- having regard to the joint statement of 20 April 2020 by the Directors-General of the World Trade Organization (WTO) and World Health Organization to support efforts to ensure the normal cross-border flow of vital medical supplies and other goods and services,
- having regard to the United Nations 2030 Agenda for Sustainable Development and to the Sustainable Development Goals (SDGs),
- having regard to Rule 132(2) and (4) of its Rules of Procedure,

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- A. whereas there have been approximately 172 000 000 cases of COVID-19, resulting in over 3 700 000 deaths worldwide, bringing unprecedented suffering, distress and the destruction of their livelihoods to millions of people; whereas the consequences of long COVID affect 10 % of patients globally, resulting in job loss, poverty and stark socioeconomic vulnerabilities;
- B. whereas the current global COVID-19 pandemic requires a global strategy for vaccines, diagnostics, treatments, and equipment production and distribution; whereas a holistic, scientific and fact-based approach is required to address the health challenges related to the pandemic; whereas a gender-sensitive and intersectional approach is crucial to achieving equality and at every stage of the vaccination process, from development through to roll-out;
- C. whereas vaccines are a textbook case where huge positive externalities require them to be treated as global public goods and to be provided for free; whereas in developed countries, all citizens are getting free vaccines; whereas it would be ethically unconscionable if that principle did not apply to much poorer people in developing countries;
- D. whereas the Declaration on the TRIPS Agreement and Public Health, adopted in Doha on 14 November 2001, states that the TRIPS Agreement should be implemented and interpreted in a way that is good for public health — encouraging both access to existing medicines and the development of new ones; whereas the WTO TRIPS Council decided on 6 November 2015 to extend the drug patent exemption for the least developed countries (LDCs) until January 2033;
- E. whereas it is essential to ensure vaccinations for the most vulnerable populations in low- and middle-income countries at an affordable cost; whereas mRNA-based vaccines have proven to be the most effective, but also the most expensive vaccines on the market;
- F. whereas as of June 2021, approximately 1,6 billion vaccine doses have been administered worldwide, the vast majority of which have been in industrialised and vaccine-producing countries; whereas only 0,3 % of the vaccine doses administered globally have been given in the 29 poorest countries, home to about 9 % of the world's population; whereas the IMF estimates that if vaccine distribution is accelerated, more than EUR 7 trillion could be added to global GDP if the virus is kept under control; whereas the EU has distributed over 260 million vaccines to its Member States and exported more than 226 million vaccines to third countries, of which only 10 % goes to least developed countries (LDCs);
- G. whereas worrying new COVID-19 variants are emerging, which are more transmissible, more deadly and less susceptible to vaccines, and may require additional vaccine shots, pushing demand far beyond the 11 billion necessary doses originally estimated; whereas ramping up production is essential to achieving global vaccination; whereas increasing vaccine manufacturing is a global priority; whereas global supply chains for raw materials must not be hindered by protectionist measures or non-tariff barriers to trade; whereas most countries where vaccines are manufactured have regrettably placed export bans on vaccines and their ingredients, preventing an increase in global production and causing bottlenecks in supply chains;
- H. whereas huge amounts of private and public funds and resources have been invested in research and development, clinical trials and procurement in order to develop vaccines and COVID-19 treatments in an open and accessible way; whereas private and public sector research, health institutions, frontline workers, scientists, researchers and patients have all gathered information on the virus, which pharmaceutical companies have utilised;
- I. whereas voluntary licences should be the most effective means to facilitate the expansion of production and the sharing of know-how; whereas no private companies have participated in the COVID-19 Technology Access Pool (C-TAP) initiative, which calls on pharmaceutical companies to commit to transparent, non-exclusive global voluntary licensing; whereas, according to the WHO, 19 manufacturers from more than a dozen countries in Africa, Asia, and Latin America have expressed their willingness to increase mRNA vaccine production; whereas at present only 40 % of the world production capacities have been used for the production of vaccines against COVID-19;
- J. whereas many developing countries with insufficient or no manufacturing capacity still face significant political pressure and legal difficulties preventing their use of TRIPS flexibilities, notably Article 31bis and the cumbersome and lengthy process for the import and export of pharmaceutical products;

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- K. whereas patent and other intellectual property protections ensure safeguards for entrepreneurial risk-taking, and a multilateral intellectual property rights (IPR) legal framework provides incentives which are critical for preparedness against future pandemics; whereas 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 medicinal products, medical devices and other health technologies is one of the important contributions to this goal;
- L. whereas due to the unprecedented and alarming epidemiological situation in India, the Indian Government imposed an export ban on vaccines, leading to disruptions in global supply and the COVAX mechanism; whereas the EU is a lead contributor to COVAX; whereas the EU under Team Europe has committed to donate a further 100 million doses for use in lower- and middle-income countries by the end of 2021;
- M. whereas the polio vaccine was brought onto the markets patent-free and the disease has now been eradicated in many regions of the world; whereas the South African Government led by Nelson Mandela was forced to use the availability of compulsory licensing to push for affordable and quality generic equivalents in order to avoid paying exorbitant prices to multinational drug companies using patents for HIV treatment;
- N. whereas supply chains in developing countries must be improved; whereas the expansion of local production, awareness among the population and increased assistance for distribution in developing countries could increase the global number of persons vaccinated; whereas a worrying funding shortfall of USD 18,5 billion remains for the Access to COVID-19 Tools (ACT) Accelerator;
- O. whereas EU priorities should be to ensure equitable global access to vaccines, diagnostics, therapeutics and other medical supplies solutions, keeping supply chains open using all available tools;
- P. whereas LDCs already enjoy a waiver, granted until 1 January 2033, regarding the implementation of the TRIPS Agreement provisions on pharmaceuticals, as well as a waiver, granted until 1 July 2021 and the extension of which is currently being discussed, exempting LDCs from all the TRIPS Agreement obligations except for Articles 3, 4 and 5;
1. Expresses its strong concern about the development of the pandemic, in particular in low- and middle-income countries; recalls that the COVID-19 pandemic is not yet over and that new vaccines will need to be developed to combat mutations; underlines that the international community must do whatever it takes to get the COVID-19 pandemic under control and that exceptional circumstances require exceptional solutions; stresses therefore that a holistic approach is required, prioritising the availability and affordability of COVID-19 related health products, the scaling-up of COVID-19 vaccine production and the global geographical distribution of manufacturing capacity; emphasises that international trade policy must play a proactive role in this endeavour by facilitating trade in raw materials, health and medical products, alleviating shortages of qualified and experienced personnel, solving supply chain problems and revisiting the global framework for intellectual property rights for future pandemics; calls for support for 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;
2. Recalls that the Doha Declaration on the TRIPS Agreement and Public Health affirms that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health;
3. Points out that 11 billion doses are needed to vaccinate 70 % of the world's population and that only a fraction of that amount has been produced; points out that an approach based on pledges of excess doses is insufficient; recalls that COVAX is facing a shortfall of 190 million doses due to the current COVID-19 situation in India and will not meet its supply objectives for the foreseeable future; notes that the EU is a major donor to the COVAX Facility in terms of financing and vaccine-sharing, both via COVAX and bilaterally; calls for the EU and its partners, however, to significantly increase financial and non-financial contributions to COVAX; welcomes in this respect the pledge by certain manufacturers to supply 1,3 billion vaccine doses at production or low cost, and the Team Europe commitment to donate 100 million doses to low- and middle-income countries by the end of the year, recalling that EU Member States are estimated to receive

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a surplus of at least 400 million vaccine doses in 2021; welcomes also the support made available for the delivery of the vaccines and ancillary material by the EU Civil Protection Mechanism; underlines the need to prioritise supplying COVAX; regrets moves by the UK and the US in developing a secondary re-sale market to sell surplus vaccines to other industrialised countries;

4. Stresses that the global response to health emergencies should encompass, on the one hand, a needs-oriented 'demand-side' approach providing joint financing and globally coordinated advance purchases and, on the other hand, an integrated 'supply side' strategy for scaling-up production capacity across the whole value chain; considers that increased global vaccine production, better coordination of supplies and strengthened, diversified and resilient value chains for vaccines are necessary for vaccines to be distributed globally; urges the Commission to engage with vaccine-producing countries to rapidly eliminate export barriers and to replace its own export authorisation mechanism with export transparency requirements, and insists on receiving timely and comprehensive access to such data; calls on the US and the UK to immediately abolish their export ban on vaccines and raw materials that are required for vaccine production; calls for an urgent increase of international investment and coordination for the scaling up of production of critical vaccine inputs such as disposables and active pharmaceutical ingredients in order to solve bottlenecks across vaccine value chains;

5. Underlines that, in the long term, global production of vaccines must urgently be expanded to meet global demand, and that investment in the production capabilities of developing countries is therefore needed to make them more self-sufficient; points out the need for effective transfer of technology and know-how to make this happen; recognises that incentivising voluntary licensing agreements and voluntary technology and know-how transfer to countries with pre-existing vaccine-producing industries should be the most important way to achieve this; is, however, open to discussing all effective and pragmatic solutions to further boost global vaccine production and calls on the Commission, in particular, to engage with the US and other like-minded countries in this respect;

6. Stresses that intellectual property protection is a key incentive for innovation and research across the globe; notes that such protection is the basis for voluntary licensing agreements and know-how transfer and is therefore an enabler of rather than a barrier to vaccine availability; cautions that under a paradigm of unenforceability for patents, companies would have to resort to secrecy or exclusivity to protect their innovations; underlines the threat that an indefinite TRIPS Agreement waiver would pose to research finance, in particular for researchers, investors, developers and clinical trials; emphasises that the protection of property rights, including intellectual property rights, is a constitutional obligation of the European Union and its Member States;

7. Takes note of the Commission's announcement that it is open to the possibility of facilitating the use of compulsory licensing where necessary in order to ensure swift global access to vaccine production; calls on the Commission to provide objective criteria regarding if, when and in which cases it will resort to compulsory licensing; stresses that the TRIPS Agreement does not specify the reasons that might be used to justify compulsory licensing; emphasises that the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licences and to determine what constitutes a national emergency; stresses that compulsory licensing requires an effective legal framework, and that this could lead to legal difficulties in developing countries; calls on the Commission to explore if and how it will provide legal support for compulsory licensing in least developed countries; welcomes the Commission's assessment that cooperation and voluntary licensing are the most effective tools to facilitate the expansion of production;

8. Underlines that the health systems connector pillar of the Access to COVID-19 Tools (ACT) Accelerator must be reinforced to increase processing, storage, distribution and delivery capacities worldwide, particularly in vulnerable countries; calls for the EU and its Member States to increase engagement at the WHO, prioritising the ACT Accelerator as part of the EU's global response in all of its pillars of diagnostics, therapeutics, vaccine and the strengthening of health systems; underlines the need to support manufacturing capacities on the African continent and strongly welcomes the Team Europe announcement of a EUR 1 billion initiative aimed at improving manufacturing and access to vaccines, medicines and health technologies; stresses also the importance of an adequate regulatory framework for pharmaceutical products; underlines that the EU now has a responsibility to invest in regional distribution centres, in particular in Africa, and to support the establishment of an African Medicines Agency; calls in this respect for support for local approval authorities, for training qualified medical and technical personnel to administer vaccinations, and for supporting vaccine distribution chains and helping to overcome limitations such as cooling infrastructure, geographical and socioeconomic outreach and vaccine hesitancy;

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9. Reaffirms its support for the WHO COVID-19 C-TAP initiative and the mRNA vaccine technology transfer hub; regrets that so far pharmaceutical companies have decided not to engage in the C-TAP initiative; urges the Commission to incentivise pharmaceutical companies to share their technologies and know-how through C-TAP and include commitments on technology transfer partnerships with third parties, particularly developing countries, in the EU's future advance purchase agreements; urges the Commission to make full use of its leverage during negotiations for the contracts for the next generation of COVID vaccines to ensure developers transfer their technology at low cost to low- and middle-income countries; calls for the active mapping of companies, including sub-contractors, with the necessary know-how to transfer technology and to pair them with companies with idle production facilities;

10. Calls for the EU to ensure that future advance purchase agreements are fully disclosed, particularly for next generation vaccines; calls for the EU to integrate commitments with regard to non-exclusive global licensing, trade secrets, proprietary data and technology transfers and to include transparency requirements for suppliers, including a cost-profit analysis per product; stresses that these transparency requirements should not prevent the Commission from acting as a competitive bidder if necessary; reiterates the need for the utmost transparency in the negotiation of COVID-19 vaccine contracts, including through directly involving Members of the European Parliament through the vaccine contact group in the contractual decision-making processes; expects the European Parliament to regularly receive a comprehensive and detailed analysis of the production, imports, exports and forecasts of vaccines, including information on the country of destination of EU exports, as well as the origin of vaccine and vaccine component imports;

11. Recognises that trade facilitation and disciplines on export restrictions, the expansion of production, including through pledges by vaccine producers and developers, and the facilitation of TRIPS Agreement flexibilities relating to compulsory licences all play a role in increasing global vaccination; welcomes efforts made by the Director-General of the WTO in bringing members towards a dialogue-based solution; notes the communications from the European Union to the WTO General Council and TRIPS Council on the urgent trade policy responses to the COVID-19 crisis, which present three complementary pillars, including trade facilitation and disciplines on export restrictions, and the expansion of production; expects the Commission to increase its engagement to conclude the WTO Trade and Health initiative by the 12th WTO Ministerial Conference in November 2021; calls, furthermore, for the establishment of a Trade and Health Committee at the 12th WTO Ministerial Conference 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 in order to address supply chain disruptions, increase production capacities, take action against price speculation and revisit the WTO law framework in light of lessons learned;

12. Underlines that the EU should show leadership and continue to engage in multilateral and global efforts in vaccine distribution, coordination and multiannual planning at the upcoming TRIPS Council meetings of 8 June and 14 October 2021, the G7 Summit of 11 to 13 June 2021, the 2021 G20 Summit, the 2021 EU-US summit, the 2021 UN General Assembly, the 2021 World Health Assembly, and at the WTO 12th Ministerial Conference and beyond;

13. Instructs its President to forward this resolution to the Council, the Commission, the governments and parliaments of the Member States, the European External Action Service, the Director-General of the World Health Organization, the Director-General of the World Trade Organization, the governments of the G20 countries, the International Monetary Fund, the World Bank, the Secretary-General of the United Nations, and the members of the UN General Assembly.

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