Thursday 21 October 2021

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EU transparency in the development, purchase and distribution of COVID-19 vaccines

European Parliament resolution of 21 October 2021 on EU transparency in the development, purchase and distribution of COVID-19 vaccines (2021/2678(RSP))

(2022/C 184/07)

The European Parliament,

— having regard to Article 168 of the Treaty on the Functioning of the European Union (TFEU), as well as to Articles 4, 6, 9, 15(3) and 122(1) thereof,

— having regard to the Charter of Fundamental Rights of the European Union, and in particular Articles 3 and 35 thereof,

— having regard to the European Social Charter signed in Turin on 18 October 1961, and in particular Article 11 thereof,

— having regard to Article 31 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),

— having regard to the resolution adopted at the plenary of the 72nd World Health Assembly on 28 May 2019 entitled 'Improving the transparency of markets for medicines, vaccines, and other health products',

— having regard to Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark, ([1])

— having regard to Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ([2]),

— having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([3]),

— having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ([4]),

— having regard to its resolutions on combating the COVID-19 pandemic, in particular its resolution of 17 April 2020 on EU coordinated action to combat the COVID-19 pandemic and its consequences ([5]),

— having regard to the Commission communication of 17 June 2020 entitled 'EU Strategy for COVID-19 vaccines' (COM(2020)0245),

([1]) OJ L 154, 16.6.2017, p. 1.
([2]) OJ L 145, 31.5.2001, p. 43.
([3]) OJ L 311, 28.11.2001, p. 67.
([4]) OJ L 117, 5.5.2017, p. 1.
([5]) OJ C 316, 6.8.2021, p. 2.

Thursday 21 October 2021

— having regard to the Commission decision of 18 June 2020 approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, including its Annex (C(2020)4192),

— having regard to the case law of the Court of Justice of the European Union (CJEU), in particular its judgments in cases C-183/95 and C-221/10, ([6])

— having regard to the European Ombudsman's series of inquiries and initiatives looking into the transparency of the EU administration's response to the COVID-19 pandemic, ([7])

— having regard to Resolution 2361 (2021) of the Parliamentary Assembly of the Council of Europe of 27 January 2021 entitled 'Covid-19 vaccines: ethical, legal and practical considerations' ([8]);

— having regard the Oviedo Convention on Human Rights and Biomedicine and its Protocols ([9]);

— having regard to the question to the Commission on EU transparency in the development, purchase and distribution of COVID-19 vaccines (O-000046/2021 — B9-0033/2021),

— having regard to Rules 136(5) and 132(2) of its Rules of Procedure,

A. whereas the Committee on Petitions has received petitions 1477/2020, 0062/2021 and 0066/2021 raising concerns over the lack of transparency of the EU on COVID-19 vaccine development, purchase and distribution;

B. whereas the petitions received request that full details of the COVID-19 vaccine contracts concluded between the Commission, the Member States and the pharmaceutical industry, as well as patient-level clinical trial data, be published in a timely fashion and that patent law be temporarily suspended in order to enable rapid, equitable and universal access to vaccines in all parts of the world;

C. whereas full transparency regarding all details of research into and the development, purchase and distribution of COVID-19 vaccines is the fundamental prerequisite for enhancing citizens' trust in vaccines and the way in which institutions have spent huge amounts of public funds; whereas any lack of transparency in the framework of the most severe public health crisis in modern times constitutes a breach of citizens' right to information and can lead to uncertainty, the spread of disinformation and an increased risk of vaccine hesitancy, thus undermining rapid and effective action against the pandemic; whereas transparency is a fundamental pillar for the success of the EU strategy for COVID-19 vaccines;

D. whereas the European Medicines Agency (EMA) is implementing exceptional measures to maximise the transparency of its regulatory activities regarding treatments and vaccines for COVID-19 that are approved or are under evaluation, including the publication of clinical study reports submitted in marketing authorisation applications to the EMA; whereas the measures implemented by the EMA aim to address the high interest in information on and to support global research into COVID-19 medicines;

E. whereas in the first two quarters of 2021, pharmaceutical companies were not meeting their vaccine delivery commitments, causing significant delays in the vaccination process in the Member States and thus posing a serious public health threat;

F. whereas transparency in the purchase and distribution of COVID-19 vaccines establishes the basis for vaccine cooperation in Europe;

([6]) Judgment of the Court of 17 July 1997, *Affish BV* v *Rijksdienst voor de keuring van Vee en Vlees*, C-183/95, EU:C:1997:373, paragraph 43, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:61995CJ0183&from=en;
Judgment of the Court (third chamber) of 19 April 2012, *Artegodan* v *Commission*, C-221/10 P, EU:C:2012:216. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62010CJ0221&from=en

([7]) Overview: https://www.ombudsman.europa.eu/en/news-document/en/136499

([8]) https://pace.coe.int/en/files/29004/html

([9]) https://www.coe.int/en/web/bioethics/oviedo-convention

G. whereas more than 200 000 citizens have already supported the European Citizens' Initiative 'No Profit on Pandemic', which demands that 'data on production costs, public contributions and the effectiveness and safety of vaccines and medicines should be public and contracts between public authorities and pharmaceutical companies must be made public';

H. whereas the handling of the COVID-19 pandemic is a trust test for all Member States and EU institutions that will inform the response to possible future public health emergencies;

I. whereas the Commission and the Member States are obliged to work as openly as possible and as closely as possible to the citizens when negotiating the COVID-19 vaccine contracts with pharmaceutical companies; whereas the Commission refuses to disclose the names of the experts or even the seven Member States represented in the joint negotiation team; whereas democratic accountability is a prerequisite if the EU's vaccine strategy is to play an efficient and credible role in global vaccination efforts;

J. whereas society is exposed to misinformation, and whereas contradictory and misleading information is often provided about the purchase and distribution of COVID-19 vaccines;

K. whereas the Commission and the Member States have only published redacted versions of the advance purchase agreements and the purchase agreements, with key information blacked out or missing, causing unnecessary lack of transparency and trust in society;

L. whereas European citizens have the right to receive real, truthful information on the management of the pandemic and on the fight against COVID-19 from the European institutions and other official sources; whereas all European authorities are obliged to provide this information;

M. whereas the EU has funded much of the research and development of the vaccines, has facilitated the work of the pharmaceutical companies with an upfront de-risking investment, has granted conditional authorisation, has supported manufacturing capacity and has purchased vaccines with public money;

N. whereas the CJEU recognises a general principle that the protection of public health must unquestionably take precedence over economic considerations;

O. whereas the Commission must adequately and efficiently inform Parliament of all aspects of the budgetary implications of research, development, negotiations, distribution and roll-out of COVID-19 vaccines in the EU, so that Parliament can fully exercise its duty to scrutinise the implementation of the EU budget;

P. whereas the majority of the pharmaceutical companies involved in the EU strategy for COVID-19 vaccines have not provided patient-level clinical trial data at this point and whereas this data will not be published until between mid-2022 and the end of 2023;

Q. whereas the European Ombudsman, following a six-month inquiry ([10]) into the performance of the European Centre for Disease Prevention and Control (ECDC) during the COVID-19 crisis, found gaps in the ECDC's transparency practices, including in the data underlying its risk assessments and interactions with international partners, such as the WHO and the Chinese Center for Disease Control and Prevention; whereas the Ombudsman made a series of proposals to enable greater public scrutiny and understanding of the ECDC's work concerning COVID-19 vaccines;

R. whereas price confidentiality for the purchase of medicinal products is a practice that can lead to the fragmentation of the internal market at Member State level;

S. whereas speeding up the worldwide vaccination rate against COVID-19 should be considered a public health priority; whereas its current pace is insufficient to prevent the exacerbation of the pandemic attributable to the more contagious COVID-19 variants and the emergence of new and even more dangerous ones which may be able to evade the immune protection conferred by existing COVID-19 vaccines;

([10]) European Ombudsman's strategic inquiry OI/3/2020/TE on how the ECDC gathered and communicated information during the COVID-19 crisis.

Thursday 21 October 2021

1. Points to the importance of a joint, rapid and effective response to the COVID-19 pandemic as the European Union and as part of the global community, and recognises the particular responsibility of the EU in ensuring equitable and universal access to COVID-19 vaccines;

2. Expresses its deepest regret on the lack of transparency from the Commission, the Member States and pharmaceutical companies in the development, purchase and distribution of COVID-19 vaccines, especially in context of continuous breaches of contracts signed;

3. Emphasises the limitations to which Parliament has been subjected in its role as co-legislator owing to the opacity of the vaccine strategy adopted by the Commission, which has prevented Parliament from being able to exercise effective control over the vaccine purchase and distribution process, nullifying its ability to scrutinise the correct application of the Union budget;

4. Stresses the need to strengthen the dialogue with citizens for in order to better understand their genuine concerns and doubts about vaccination; calls on the Commission to improve its communication with the public regarding the EU strategy for COVID-19 vaccines, making it clear, transparent and rigorous in order to satisfy the right of EU citizens to access to information directly related to their health, including the criteria by which some vaccines are selected over others;

5. Calls on the Commission to make a legislative proposal on future joint vaccine procurement with clear provisions on transparency and competence distribution among the actors of the EU institutional framework and the Member States and on future treatments against COVID-19 and orphan treatments within the framework of the pharmaceutical strategy for Europe; calls on the Commission to review the terms of price confidentiality agreements in order to address the current fragmentation of the European internal market;

6. Calls on the Commission to disclose the members of the teams involved in negotiating advance purchase agreements and purchase agreements with pharmaceutical companies for the purchase of COVID-19 vaccines; requests that the Commission clarify its criteria for choosing the negotiating team members;

7. Urges the Commission to include the COVID-19 contact group between the Commission and Parliament, announced by the Commission President in February 2021 ([11]), in the decision-making process for the approval of future contracts in order to ensure greater transparency in the negotiation process; requests that weekly updated information be provided to this group, including a detailed study of vaccine production, imports, exports and dose forecast;

8. Calls on the Commission to ensure full transparency by publishing non-redacted versions of the advance purchase agreements and purchase agreements without further delay, disclosing, among others, the following details: the amount of public investment that has gone into the development of the vaccines; the advance and post-delivery payments by the Commission to each vaccine developer, with details of the distribution of these funds across vaccine development and production; details of cost sharing between public and private investors in vaccines research, development and production; the number of doses given to each country and to be delivered per quarter; prices per dose; the number and locations of available production sites; details of agreements on prospective further purchases; the liability and compensation regimes for any potential harm caused by the vaccines; the sanctions in case of breach of contract or delivery delays; information on the possible sharing of intellectual property rights, particularly whether the Commission conserves any influence over intellectual property rights due to its initial investments in the vaccine development process, as well as any other related information that may be of interest to the public; the role of the European Medicines Agency and national competent authorities in determining contract provisions; and details of technology transfers and donations to third countries, and any related information that may be of interest to the public;

9. Calls on the Commission to reveal the prices per dose for each manufacturer's vaccine and to give detailed information about its procurement strategy, as vaccine prices vary greatly between manufacturers;

([11]) European Commission, speech by President von der Leyen at the European Parliament plenary on the state of play of the EU's COVID-19 vaccination strategy, 10 February 2021. https://ec.europa.eu/commission/presscorner/detail/en/speech_21_505

10. Calls on the Commission to make the disclosure of all details of public interest regarding future COVID-19 vaccine contracts, and compliance with these contracts, as well as with those for the purchase of other COVID-19 technologies, a precondition for future negotiations with pharmaceutical companies;

11. Criticises the Commission's decision to refrain from using the ordinary legislative procedure through Article 168 TFEU in setting up the new European Health Emergency Preparedness and Response Authority (HERA), thereby failing to establish it as a fully-fledged independent agency that has a mandate to protect the public interest and is subject to the same rigorous scrutiny as other EU agencies; regrets the fact that the Commission's approach, which has led to Parliament being excluded from overseeing the work of HERA, can be regarded as yet another shortcoming that has undermined transparency and accountability for public spending and decision-making in the area of public health;

12. Calls on the Commission to make public any potential breaches of contract by pharmaceutical companies, as well as the reasons behind them, and to use all instruments at its disposal to penalise any possible breaches or unjustified delays;

13. Calls on the Commission to provide Parliament with detailed information on how EU payments were used by the contracted companies, including the methodology for measuring payments and the means of control and verification; calls on the Commission to disclose in detail all budgetary implications of the EU strategy for COVID-19 vaccines;

14. Calls on the Commission to ensure that the contracted companies make full clinical trial results and protocols of potential COVID-19 vaccine research available for evaluation, as soon as possible, by independent scientific experts, beyond experts at the EMA, including statistical analysis plans, clinical studies and reports; points out that in the event that severe and/or frequent side effects are detected during clinical trials, these events should be communicated immediately;

15. Calls on the Commission to ensure that contracted companies publish data from pharmacovigilance reports in full accordance with the rules concerning respect for the personal data of the patients involved, and to promote and monitor public scrutiny of adverse reactions that occur during the administration of vaccines;

16. Calls on the Commission to conduct research into the correlation between the level of vaccine contract transparency, public trust in the EU vaccine strategy and the level of exposure to disinformation, with a view to addressing the causes of vaccine hesitancy;

17. Calls on the Commission to conduct and publish an assessment of the EU strategy for COVID-19 vaccines and of its public communication, reviewing all elements in detail and making recommendations on a framework for future European joint procurement, especially in relation to transparency;

18. Asks the Commission to continue to show solidarity with other countries of the world, in particular those belonging to the neighbourhood policy, and to support their efforts to prevent and combat the COVID-19 virus;

19. Stresses that the Commission must guarantee that COVID-19 vaccines are considered a global public good for the benefit of all, ensuring universal access to them; highlights that this aspect must also be reflected in all related contracts signed with pharmaceutical companies by including the strongest safeguards in this regard for the availability, accessibility and affordability of COVID-19 vaccines; supports the global effort towards making COVID-19 vaccines, equipment and treatments available to all countries including developing countries; underlines the paramount importance of technology transfers and the export of essential components to third countries to scale up production and distribution of COVID-19 vaccines globally with a view to accelerating the vaccination rate throughout the world and thus averting a further surge of deaths and hospitalisations and the dissemination of COVID-19 variants; recognises that a key barrier to vaccine availability is production capacity; highlights the importance of cooperating with the mRNA technology companies to establish new production sites for COVID-19 vaccines and equipment, and of increasing the contributions of the EU and the US to the COVAX initiative, making transparent all donations per time period, in order to save lives in those countries that have been left out of vaccine distribution;

20. Calls on the Commission to ensure that the pharmaceutical companies share their knowledge and data through the World Health Organization COVID-19 Technology Access Pool (C-TAP), and that they use all available options for increasing production and distribution worldwide, including association with other companies for development and distribution processes;

21. Strongly believes that the Ombudsman's proposals, made following strategic inquiry OI/3/2020/TE, for improving the work of the ECDC and its transparency practices must be fully and consistently implemented in order to reinforce public trust in the EU COVID-19 vaccination strategy, given the key role played by the ECDC in gathering and publicising crucial information on COVID-19 vaccines;

22. Calls on the Commission to publish and assess the EU's global strategy to ensure the fast and equitable distribution of vaccines worldwide, including its involvement in the COVAX initiative, C-TAP and the cross-border supply of materials needed for vaccine production, as well as its strategy for increased production capacity and criteria for dose distribution between countries;

23. Calls on the Commission to set fast and equitable access to vaccines worldwide as one of the main objectives of the EU when signing future contracts with pharmaceutical companies, considering clauses related to intellectual property rights and non-exclusive licences, prices and best efforts to enhance production and distribution of vaccines;

24. Calls on the Commission to reinforce dialogue, through the appropriate channels, with developing countries in order to study and learn about the challenges and difficulties they face in producing vaccines against COVID-19 with a view to providing them with the necessary means to make COVID-19 vaccine production possible in their territories and thus to achieving a more effective fight against the pandemic worldwide;

25. Instructs its President to forward this resolution to the Council, the European Commission and to the governments and the parliaments of the Member States.