

## European Union's Inconsistent Policy Towards International Instruments

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The current EU stance on the Pandemic Treaty appears inconsistent with the region's internal approaches in various policies and agreements, both during the COVID-19 pandemic and in ongoing negotiations for the pharmaceutical package. From [Salud por Derecho](#) we consider these discrepancies as entry points which would help to reverse EU statements and reluctance to certain key points of the Pandemic Treaty. With this purpose we have prepared a document which includes statements, decisions, resolutions and legislative proposals coming from European Commission, the European Parliament, the Council of the European Union and European Council related to equity, affordability, intellectual property, transparency and public funding of health technologies.

### Navigation table and key points

Topic	Instrument	Key Takeaways
Non-exclusive Licensing	<a href="#">Commission Implementing Decisions C(2022) 2975</a>  <a href="#">Second call for an Expression of Interest for innovative and rapid health-related approaches to respond to COVID-19 and to deliver quick results for society for a higher level of preparedness of health systems (H2020-SC1-PHE-CORONAVIRUS-2020-2):</a>  <a href="#">Manifesto for EU COVID-19 Research</a>	<p>Grant recipients must provide non-exclusive licenses for results in response to public emergencies if requested by the granting authority.</p> <p>Products developed under emergency funding frameworks had obligation to grant non-exclusive licences, waiving market exclusivities.</p> <p>Guiding principles encouraging EU-funded R&amp;D to grant non-exclusive royalty free licences on IPR</p>
Global public goods and IP Waiver	<a href="#">European Parliament Resolution “Meeting the global COVID-19 challenge”</a>  <a href="#">European Commission’s Coronavirus Global Response Pledge</a>	<p>EC urged to support IP Waiver at WTO</p> <p>Pandemic countermeasures such as the vaccine to be available, affordable and common good</p>
Equitable access	<a href="#">Council Decision (EU) 2022/451 of 3 March 2022 authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005)</a>	<p>European Commission (EC) negotiating directives (Pandemic Accord and IHR) should be framed by the principle of equity and equitable access to medical countermeasures; principle of equity should guide the work</p>
Transparency	<a href="#">Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (Art. 57)</a>  <a href="#">Statement of the members of the European Council on COVID-19 and health</a>	<p>Increase transparency on the contribution of public funding to R&amp;D costs.</p> <p>Transparency regarding pandemic efforts to be enhanced</p>

<p>Compulsory Licensing</p>	<p><a href="#">Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (Art 80)</a></p> <p><a href="#">Proposal for a Regulation on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (Art. 13)</a></p>	<p>Eliminate barriers to Compulsory Licensing (CL) during health emergencies, including the suspension of data and market protection.</p> <p>The Commission is entitled to request indispensable information for a CL</p>
<p>Affordability</p>	<p><a href="#">Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (Art. 85)</a></p>	<p>Increase competition by facilitating the early market entry of generic and biosimilar medicinal products to ensure the affordability of medicines.</p>

## 1. COVID-19 context

### a. European Commission's Horizon 2020 R&D Frameworks and Manifesto for EU COVID-19 research.

Regarding conditionalities of public funding, the European Commission established the following provisions in the Commission Implementing Decisions C(2022) 2975 on the adoption of the work programme for 2021-2022 within the framework of the Specific Programme implementing Horizon Europe:

“Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5). In addition to the standard provisions, the following specific provisions in the model grant agreement will apply to all grants awarded under this work programme:

*If requested by the granting authority, beneficiaries must grant non-exclusive licences to their results – for a limited period of time specified in the request and on fair and reasonable conditions – to legal entities that need the results to address the public emergency. These legal entities must commit to rapidly and broadly exploiting the resulting products and services on fair and reasonable conditions. This provision will apply up to 4 years after the end of the action*

*Unless stated otherwise in the specific call conditions, beneficiaries must, up to 4 years after the end of the action, inform the granting authority if the results could reasonably be expected to contribute to European or international standards.*

*The granting authority may, up to 4 years after the end of the action, object to a transfer of ownership or to the exclusive (for Euratom actions, also non-exclusive) licensing of results”<sup>1</sup>*

Specifically, under the special Horizon 2020 calls, the Commission included the following obligations to grant non-exclusive licensing in the “Second call for an Expression of Interest for innovative and rapid health-related approaches to respond to COVID-19 and to deliver quick results for society for a higher level of preparedness of health systems” (H2020-SC1-PHE-CORONAVIRUS-2020-2):

#### *“Exploitation obligations*

*In the context of the public health emergency, additional exploitation obligations apply, to ensure that results or resulting products/services (i.e. products or services developed based on results generated in the action) will be available and accessible, as soon as possible and at fair conditions. This will include an obligation to license on a non-exclusive basis and at fair and reasonable conditions.*

*The scope of the additional exploitation obligations will be discussed in more detail with successful applicants/participants at due time.*

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<sup>1</sup> [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=PI\\_COM:C\(2022\)2975](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=PI_COM:C(2022)2975)

*To enhance the exploitation of results, beneficiaries must provide a "results ownership list" (ROL) together with the final report and use the Horizon results platform.*

*The option of Article 28.1 of the Model Grant Agreement will apply and the necessary provisions will be inserted in Annex 1.”<sup>2</sup>*

Moreover, the Commission clarify via Parliamentary Question the issue of market exclusivities with regard to non-exclusive licensing obligation of the specific call:

*“1. Under the topic SC1-PHE-CORONAVIRUS-2020-2B, the results and the products or services developed based on results generated in the action must be made available and accessible, promptly and at fair and reasonable conditions<sup>3</sup> including an obligation to grant non-exclusive licences for this purpose<sup>4</sup>.*

[...]

*3. Granting non-exclusive licence means that the licensor remains free to exploit the same intellectual property and to allow any number of other licensees to also exploit the same intellectual property thus waiving market exclusivity. Beneficiaries however can protect their results before licensing on a non-exclusive basis.”<sup>5</sup>*

Furthermore, the Commission launched the “Manifesto for EU COVID-19 Research”, to facilitate access-related guiding principles for EU- funded grant recipients working on COVID-19 R&D, stating that:

*“Where possible, grant for a limited time [footnote: Until 1 year after the WHO declaration that COVID-19 is not anymore a ‘Public Health Emergency of International Concern’ but in any event not beyond 1 January 2023 unless otherwise extended by the signatories of the Manifesto.], non-exclusive royalty free licences on the intellectual property resulting from EU-funded research. These non-exclusive royalty free licenses shall be given in exchange for the licensees’ commitment to rapidly and broadly distribute the resulting products and services under fair and reasonable conditions to prevent, diagnose, treat and contain COVID-19.”<sup>6</sup>*

The Directorate-General for Research and Innovation published in June 2021 a news article to present the manifesto and to show EC position related to “Access to research results and IP in a public emergency”. The article stated that:

*“Exceptional circumstances have required new approaches and joint efforts from all research and innovation players, including the adaptation of intellectual property regimes. The Manifesto provides guiding principles for beneficiaries of EU research grants for coronavirus prevention, testing, treatment and vaccination to guarantee that their research results will be accessible for all. This will ensure that no one is left behind*

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<sup>2</sup> <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-phe-coronavirus-2020-2d>

<sup>3</sup> Article 25.3 of the Horizon 2020 MGA states that: ‘Fair and reasonable conditions’ means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged” available at: [https://ec.europa.eu/research/participants/data/ref/h2020/mga/gga/h2020-mga-gga-multi\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/mga/gga/h2020-mga-gga-multi_en.pdf)

<sup>4</sup> <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-phe-coronavirus-2020-2d>

<sup>5</sup> [https://www.europarl.europa.eu/doceo/document/E-9-2020-003677-ASW\\_EN.html](https://www.europarl.europa.eu/doceo/document/E-9-2020-003677-ASW_EN.html)

<sup>6</sup> <https://op.europa.eu/en/publication-detail/-/publication/b67a8ecc-8a29-11ec-8c40-01aa75ed71a1/language-en>

*in the fight against Covid-19, and that solutions will be developed, produced and deployed to every corner of the world.”<sup>7</sup>*

#### **b. Statement of the members of the European Council on COVID-19 and health**

On 25 February 2021, the European Council issued the statement when they asserted the following regarding transparency measures:

*“We also support the Commission’s ongoing efforts to accelerate the availability of raw materials, facilitate agreements between manufacturers across supply chains, scope existing facilities so as to help production scale-up in the EU and further the research and development efforts. Companies must ensure predictability of their vaccine production and respect contractual delivery deadlines. Transparency with regard to the overall efforts should be enhanced.”*

#### **c. European Parliament Resolution “Meeting the global COVID-19 challenge”**

In June 2021 the EU Parliament The European Parliament adopted by 355 votes to 263, with 71 abstentions, a resolution on ‘Meeting the global COVID-19 challenge’. The text adopted in plenary was tabled as a joint resolution by the EPP, S&D, Renew and Greens/EFA groups. The text supported a temporary waiver by stating:

##### *“Temporary lifting of the WTO TRIPS agreement on patents*

*Expressing its deep concern about the evolution of the pandemic, particularly in low- and middle-income countries, Parliament called for support for negotiations on the text of a temporary waiver of the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), with a view to enhancing global access to affordable COVID-19-related medical products and addressing production constraints and supply shortages worldwide.”<sup>8</sup>*

#### **d. European Commission’s Coronavirus Global Response**

On 4 May 2020, the President of the European Commission Ursula von der Leyen stated the following:

*“We need to develop a vaccine. We need to produce it and to deploy it to every single corner of the world. And make it available at affordable prices”<sup>9</sup>* Additionally, she asserted the vaccine would be *“our universal, common good”*.

## **2. Pandemic Treaty negotiating mandate.**

In March 2022, the Council of the European Union (EU) authorized the European Commission (EC) to negotiate an international agreement on pandemic prevention, preparedness, and response, as well as amendments to the International Health Regulations on behalf of the EU.<sup>10</sup>

<sup>7</sup> [https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/access-research-results-and-ip-public-emergency-2021-06-22\\_en](https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/access-research-results-and-ip-public-emergency-2021-06-22_en)

<sup>8</sup> Resolution 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 <https://oeil.secure.europarl.europa.eu/oeil/popups/summary.do?id=1666076&t=e&l=en>

<sup>9</sup> [https://ec.europa.eu/commission/presscorner/detail/en/ac\\_20\\_749](https://ec.europa.eu/commission/presscorner/detail/en/ac_20_749)

<sup>10</sup> <https://eur-lex.europa.eu/eli/dec/2022/451/oj>

In Article 1, paragraph 2, it is stated that the negotiations should be conducted in accordance with the negotiating directives, which read:

*“The substantive obligations should be framed, including in the Pandemic Agreement’s preamble, by a series of general objectives and principles, such as the right to enjoyment of the highest attainable standard of health, international solidarity, equitable access to medical countermeasures (e.g. personal protective equipment, access to vaccination, therapeutics and diagnostics, health and social services as well as medical care), the timely sharing of data and information, including for facilitating research and enabling the public to avail, use and understand verified and timely information, the “One Health” approach, the need to address the close links between human, animal and environmental health, the links between health and human rights, including sexual and reproductive health and rights as per the new European Consensus on Development, and the centrality of WHO and role of multilateral cooperation in the global health governance. The principle of equity should guide the work, including through disability-sensitive and gender-responsive approaches.”<sup>11</sup>*

### **3. The European Commission proposal of the EU Pharmaceutical Legislation**

In April 2023, the European Commission (EC) adopted a proposal to revise and replace pharmaceutical legislation. Alongside this, the EC published a package of proposals for regulations on intellectual property (IP) legislation, addressing issues such as EU-wide compulsory licensing. Within these EC proposals, there are a number of relevant articles and justifications with regards to transparency of public support and compulsory licensing. It is therefore critical to emphasize the importance of aligning with the EC’s position in the negotiation of the pandemic accord. This alignment is crucial for policy coherence and ensuring a connection to the equitable access goals outlined in the negotiating mandate.

#### **A. Transparency of public support**

The proposal for a *Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC* presents in the explanations of the provisions and articles different pieces showing its position towards a more transparent approach:

*“Increased transparency on the contribution of public funding to research & development costs*

*Marketing authorisation holders will be required to publish a report listing all direct financial support received from any public authority or publicly funded body for the research and development of the medicinal product, whether successful or not **successful**. Such information will be easily accessible to the public on a dedicated webpage of the marketing authorisation holder and in the database of all medicinal products for human use authorised in the EU. Greater transparency around public funding for medicinal products development is expected to help maintain or improve access to affordable medicinal products.”<sup>12</sup>*

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<sup>11</sup> ANNEX to the Recommendation for a COUNCIL DECISION authorising the opening of negotiations on behalf of the European Union for the conclusion of an international agreement on pandemic prevention, preparedness and response as well as for the negotiations of complementary amendments to the International Health Regulations (2005), document ST 6133/22 ADD 1, available at: <https://data.consilium.europa.eu/doc/document/ST-6133-2022-ADD-1/en/pdf>

<sup>12</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192>

Article 57 of the Proposal for a Directive refers to the above -mentioned and offers a good case on the need of attaching mandatory transparency conditions to public support. Recital 131 of the proposal, states:

*“To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines”<sup>13</sup>*

The article 57 “Responsibility to report on public financial support”, states:

*“1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.”*

*2. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall:*

*(a) draw up an electronic report listing:*

*(i) the amount of financial support received and the date thereof;*

*(ii) the public authority or publicly funded body that provided the financial support referred to in point (i);*

*(iii) the legal entity that received the support referred to in point (i).*

*(b) ensure that the electronic report is accurate and that it has been audited by an independent external auditor;*

*(c) make the electronic report accessible to the public via a dedicated webpage;*

*(d) communicate the electronic link to such webpage to the competent authority of the Member State or, where appropriate, to the Agency.”<sup>14</sup>*

## **B. Compulsory Licensing**

Article 13 of the Proposal for a Regulation on compulsory licensing for crisis management and amending Regulation (EC) 816/2006, deals with the need to request additional information to achieve the objective of the CL. Recital 32 offers the justification by asserting:

*“The relation between the rights-holder and the licensee should be governed by the principle of good faith [...] In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made available in the Union. Such additional measures may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence.”<sup>15</sup>*

Article 13, “Relations between rights-holder and licensee”, states:

<sup>13</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192>

<sup>14</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192>

<sup>15</sup> [https://single-market-economy.ec.europa.eu/system/files/2023-04/COM\\_2023\\_224\\_1\\_EN\\_ACT\\_part1\\_v11.pdf](https://single-market-economy.ec.europa.eu/system/files/2023-04/COM_2023_224_1_EN_ACT_part1_v11.pdf)



*“1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation.*

*2. In compliance with the good faith obligation, the rights-holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests.”<sup>16</sup>*

Additionally, article 80 of the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, the EC recognizes the need to eliminate barriers to compulsory licensing, particularly in the context of health emergencies.

Recital 61 provides the grounds for this article:

*“When a compulsory licence has been granted by a relevant authority in the Union to tackle a public health emergency, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and thus access to the medicinal products needed to address the crisis. For this reason, data and market protection should be suspended when a compulsory licence has been issued to tackle a public health emergency.”<sup>17</sup>*

Article 80, “Regulatory data and market protection”, states on the paragraph 4:

*“4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence.”<sup>18</sup>*

### **C. Bolar exemption**

The EC recognized as well in article 85 of the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC the need to increase competition from earlier market entry of generic and biosimilar medicinal products to achieve affordability of medicinal products. According to the EC’s rationale:

*“The ‘Bolar exemption’ (under which studies can be carried out for subsequent regulatory approval of generics and biosimilars during the patent or supplementary protection certificate protection of the reference medicinal product), will be broadened in scope and its harmonised application in all Member States ensured. [...]. Taken together, these measures will facilitate earlier market entry of generics and biosimilars, thus increasing competition and contributing to the objectives of promoting affordability of medicinal products and patient access.”<sup>19</sup>*

Additionally, Recital 64 states that:

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<sup>16</sup> [https://single-market-economy.ec.europa.eu/system/files/2023-04/COM\\_2023\\_224\\_1\\_EN\\_ACT\\_part1\\_v11.pdf](https://single-market-economy.ec.europa.eu/system/files/2023-04/COM_2023_224_1_EN_ACT_part1_v11.pdf)

<sup>17</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192>

<sup>18</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192>

<sup>19</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192>



*“(64) It will allow, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.”<sup>20</sup>*

Article 85, “Exemption to the protection of intellectual property rights”, finally states that:

*“Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when a reference medicinal product is used for the purposes of:*

*(a) studies, trials and other activities conducted to generate data for an application, for:*

*(i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;*

*(ii) health technology assessment as defined in Regulation (EU) 2021/2282;*

*(iii) pricing and reimbursement.*

*(b) the activities conducted exclusively for the purposes set out in point (a), may cover the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.*

*This exception shall not cover the placing on the market of the medicinal products resulting from such activities.”<sup>21</sup>*

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<sup>20</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192>

<sup>21</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52023PC0192>