5.7.2023

Amendment 43
Sara Cerdas
on behalf of the S&D Group

Report
Dolors Montserrat
COVID-19 pandemic: lessons learned and recommendations for the future
(2022/2076(INI))

Motion for a resolution
Paragraph 503 a (new)

Motion for a resolution

Amendment

503a. Welcomes the fact that the Commission has adopted a new EU Global Health Strategy with the objective of improving global health security while deepening the EU’s leadership and reaffirming the EU’s responsibility for tackling global challenges and health inequalities;

Or. en
521. Considers that Europe needs to find a constructive solution on IP protection which provides adequate certainty and incentives for investments in R&D, and should include licensing agreements in order to scale up production; notes long-standing concerns over intellectual property rights and access to affordable medicines in low- and middle-income countries and increasingly also in high-income countries; underlines the flexibilities in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), confirmed by the Doha Declaration, as legitimate policy measures that governments can use to protect and promote public health by putting limits and safeguards on the enforcement of IP rights; calls on medical product developers to share their intellectual property, knowledge, and know-how through global initiatives such as the WHO’s COVID-19 Technology Access Pool (C-TAP) in times of pandemics, epidemics and endemics; commends the efforts by the WHO to set up this instrument as a one-stop-shop for the development, licensing and manufacturing of health technologies; welcomes the support by Member States for this initiative and calls for the EU to encourage the private sector to contribute to it; 

521. Considers that Europe needs to support a constructive solution on IP protection and access to medical products and technologies; notes long-standing concerns over intellectual property rights and access to affordable medicines in low- and middle-income countries and increasingly also in high-income countries; underlines the flexibilities in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), such as compulsory licences and parallel imports, confirmed by the Doha Declaration, as legitimate policy measures that governments can use to protect and promote public health by putting limits and safeguards on the enforcement of IP rights; calls on medical product developers to share their intellectual property, knowledge, and know-how through global initiatives such as the WHO’s COVID-19 Technology Access Pool (C-TAP) in times of pandemics, epidemics and endemics; commends the efforts by the WHO to set up this instrument as a one-stop-shop for the development, licensing and manufacturing of health technologies; welcomes the support by Member States for this initiative and calls for the EU to encourage the private sector to contribute to it;
property barriers alone will not solve the problem of access, that patents are useless without technology transfer and proper industrial know-how and that export restrictions and access to raw materials were obstacles to the production of medical products; stresses, however, that sharing IP and know-how within the legal framework is key in order to ensure large-scale production and global availability of medical countermeasures during pandemics, epidemics and endemics;

Or. en
Amendment 45
Sara Cerdas
on behalf of the S&D Group

Report
Dolors Montserrat
COVID-19 pandemic: lessons learned and recommendations for the future
(2022/2076(INI))

Motion for a resolution
Paragraph 549

Motion for a resolution

549. Underlines the benefits of fair and predictable IP protection in fostering and advancing medicinal research, production and development; highlights the public importance of promoting the sharing of IP and know-how of medical countermeasures, in particular during pandemics, epidemics and endemics; stresses that this must not preclude the use of TRIPS flexibility when necessary and as provided by the TRIPS agreement; recognises the importance for the EU to stay in the lead on R&D and clinical trials and underlines the importance of revitalising R&D activities within the EU to create job opportunities and enhance global competitiveness; stresses that intellectual property protection can be an incentive for innovation and research across the globe; notes that such protection can be the basis for voluntary licensing agreements and know-how transfer and can therefore be an enabler of vaccine availability; underlines the challenges that an indefinite TRIPS agreement waiver could 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; underlines, in this regard, the importance

Amendment

549. Underlines the benefits of fair and predictable IP protection and public funding in fostering and advancing medicinal research, production and development; highlights the public importance of promoting the sharing of IP and know-how of medical countermeasures, in particular during pandemics, epidemics and endemics; stresses that this must not preclude the use of TRIPS flexibility when necessary and as provided by the TRIPS agreement; recognises the importance for the EU to stay in the lead on R&D and clinical trials and underlines the importance of revitalising R&D activities within the EU to create job opportunities and enhance global competitiveness; underlines, in this regard, the importance of transparency and welcomes the Commission’s proposal for a directive relating to medicinal products for human use, which suggests that any direct financial support received from any public authority or publicly funded body in relation to any activities or the research and development of the medicinal product must be declared; highlights the need to spur innovation and provide access to affordable medicine products; calls for the need to support innovation models that provide access to affordable medicine products in all Member States, without creating serious barriers to access and
of transparency and welcomes the Commission’s proposal for a directive relating to medicinal products for human use, which suggests that any direct financial support received from any public authority or publicly funded body in relation to any activities or the research and development of the medicinal product must be declared; highlights the need to strike the right balance between spurring innovation and providing access to affordable medicine products; calls for the need to support innovation models that provide access to affordable medicine products in all Member States, without creating serious barriers to access and affordability; calls on the Commission to support global initiatives that facilitate IP sharing such as the COVID-19 technology access pool;
Amendment 46
Sara Cerdas on behalf of the S&D Group

Report
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COVID-19 pandemic: lessons learned and recommendations for the future (2022/2076(INI)

Motion for a resolution
Paragraph 550

550. Highlights that the existing Agreement on Trade-Related Aspects of Intellectual Property Rights already offers a framework for compulsory licensing, allowing governments to provide their citizens with generic versions of patented treatments through domestic production or foreign imports; acknowledges the potential value of compulsory licensing during pandemics, epidemics and endemics while at the same time recognising its potential negative impacts, such as undermining the certainty of IP protection for future innovation, and highlights the positive role of voluntary licensing agreements in increasing production and access to COVID-19 vaccines, but regrets the limited use of this tool; recalls that 138 voluntary licensing agreements, and partnerships with multilateral organisations, have contributed to worldwide access to COVID-19 therapeutics through means other than TRIPS waivers; urges the Commission and the Member States to prioritise fulfilling the requirement in Article 66(2) of the TRIPS agreement, which mandates developed country members to provide incentives for promoting and encouraging technology transfer to least-developed country members, enabling them to establish a sound and viable technological base;
5.7.2023

Amendment 47
Sara Cerdas
on behalf of the S&D Group

Report
Dolors Montserrat
COVID-19 pandemic: lessons learned and recommendations for the future
(2022/2076(INI))

Motion for a resolution
Paragraph 552

Motion for a resolution

552. **Recalls that the EU should actively participate in** text-based negotiations **on a temporary TRIPS waiver; calls, in that regard, for the EU to support the granting of a temporary waiver from certain provisions of the TRIPS agreement for COVID-19**, in order to enhance timely global access to affordable COVID-19 vaccines, therapeutics and diagnostics by addressing global production constraints and supply shortages;

Amendment

552. **Calls for the EU to support text-based negotiations to extend** the TRIPS decision agreed at the 12th WTO ministerial conference to therapeutics and diagnostics in order to enhance timely global access to affordable COVID-19 vaccines, therapeutics and diagnostics by addressing global production constraints and supply shortages; **reiterates that in times of crisis, other mechanisms should be used by the EU to enable a global response and crisis mitigation; notes that such mechanisms could, for example, include a Union export control mechanism, enhanced cooperation agreements on the production of medical countermeasures, pre-allocating part of the Union joint procurement and both voluntary and compulsory technology know-how pools and licensing agreements between companies, which should facilitate people’s access to countermeasures, including people in Eastern Partnership and low- and middle-income countries;**

Or. en
5.7.2023

Amendment 48
Sara Cerdas
on behalf of the S&D Group

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Dolors Montserrat
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Motion for a resolution
Paragraph 553

553. Believes that similar measures would be beneficial in the event of potential future pandemics, epidemics and endemics; 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 low- and middle-income 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 could be a way to achieve this; considers that a multilateral IPR legal framework can provide protections and incentives which are critical for preparedness against future pandemics and recognises its role in facilitating the broad and unprecedented collaboration among governments, research institutions and pharmaceutical companies;

553. Believes that similar measures would be beneficial in the event of potential future pandemics, epidemics and endemics and supports the inclusion of a TRIPS waiver in the pandemic treaty; 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 low- and middle-income 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;
Amendment 49
Sara Cerdas
on behalf of the S&D Group

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Dolors Montserrat
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(2022/2076(INI))

Motion for a resolution
Paragraph 282

282. Calls on the Commission to ensure that the revision of the general pharmaceutical legislation builds on a good understanding of the root causes of medicine shortages; highlights the need for the EU’s pharmaceutical industry to have a diversified supply chain and a medicine-shortage risk-mitigation plan to cope with any vulnerabilities and risks to the supply chain, which should preferably be located within the European Economic Area, and to require pharmaceutical companies to have adequate levels of safety stocks and provide early notice of medicine shortages, backed up with supply chain transparency requirements and risk-prevention measures; reaffirms the need to enhance the security of supply through earlier notification of shortages, stricter obligations for supply and transparency, enhanced transparency of stocks and improved EU coordination and mechanisms to manage and avoid shortages;

Amendment
282. Calls for ensuring that the revision of the general pharmaceutical legislation builds on a good understanding of the root causes of medicine shortages; highlights the need for the EU’s pharmaceutical industry to have a diversified supply chain and a medicine-shortage risk-mitigation plan to cope with any vulnerabilities and risks to the supply chain, which should preferably be located within the European Economic Area, and to require pharmaceutical companies to have adequate levels of safety stocks and provide early notice of medicine shortages, backed up with supply chain transparency requirements and risk-prevention measures; reaffirms the need to enhance the security of supply through earlier notification of shortages, stricter obligations for supply and transparency, enhanced transparency of stocks and improved EU coordination and mechanisms to manage and avoid shortages;

Or. en
5.7.2023

Amendment 50
Sara Cerdas
on behalf of the S&D Group

Report
Dolors Montserrat
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(2022/2076(INI))

Motion for a resolution
Paragraph 518

518. Calls for the assessment of the current global health governance frameworks and welcomes, in this respect, the Pandemic Treaty; calls for the simultaneous strengthening of the obligations and enforceability of the IHR, while addressing the gaps (including funding, equity and global governance) through the new Pandemic Treaty; calls for the EU and the Member States to guarantee the inclusion of pandemic prevention in the treaty and to ensure that enabling the active participation of civil society and scientists is a priority in the negotiations;
Amendment 51
Sara Cerdas
on behalf of the S&D Group

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(2022/2076(INI))

Motion for a resolution
Paragraph 192

192. Suggests that **such practices** could be explored in areas such as rare diseases and cancer through clearly outlined milestones, objectives and commitments agreed on by all parties involved;

192. Suggests that **joint procurements** could be explored in areas such as rare diseases and cancer through clearly outlined milestones, objectives and commitments agreed on by all parties involved;

Or. en