To,

The Honorable Members,

The Committee on Economic, Social and Cultural Rights,

The Office of the High Commissioner for Human Rights

Geneva

February 14, 2020

**Subject: IFPMA Submission on Draft General Comment on Science dated January 02, 2020**

The International Federation of Pharmaceutical Manufacturers & Associations (“**IFPMA**”) appreciates this opportunity to provide inputs on the Draft General Comment on Article 15: Science and Economic, Social and Cultural Right dated January 02, 2020 (“**Draft General Comment**”).

IFPMA represents the world’s leading research-based biopharmaceutical companies and associations. Our members, and the millions of people they employ worldwide, are dedicated to inventing, developing, and delivering valuable medicines and vaccines that enable people to live longer, healthier, and more productive lives.

Human rights are fundamental rights that recognise the inherent dignity of all people. Some view intellectual property rights, that support biopharmaceutical innovation and promote the development of new treatments and cures, in conflict with the right to health. However, new treatments and cures exist because advancements in science are valued and protected by way of intellectual property rights. By extending and improving the lives of patients, new medicines are an essential means to achieve the right to health. Both sets of rights, the right to health and the rights of inventors to protect their intellectual property are well established in international law.

The Universal Declaration of Human Rights (“**UNDHR**”) and the International Covenant on Economic, Social and Cultural Rights (“**ICESCR**”) also support the proposition that intellectual property protection should be considered a coextensive human right. Article 27(2) of the UNDHR recognises that “everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” Article 15(1)(c) of the ICESCR recognises the “right of everyone . . . to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." Article 15(2) provides that “[t]he steps to be taken by the States Parties”, “shall include those necessary for the conservation, the development and the diffusion of science and culture.” Thus, these rights do not conflict each other. Rather, they are co-existing and mutually supporting.

In trying to provide guidance to these provisions, Draft General Comment of the United Nations Committee on Economic, Social and Cultural Rights (“**Committee**”)[[1]](#footnote-1) misinterprets the importance of intellectual property rights for the right to health. There are several references that do not align with core principles of intellectual property rights. In particular we would like to offer some key observations:

1. The Draft General Comment states that “*IP can create distortions in funding of scientific research”[[2]](#footnote-2),* that “*scientific research made or financed by private actors can create acute conflict of interests,*”[[3]](#footnote-3).

Industry’s scientific research model, which is underpinned by strong intellectual property rights, has contributed to nearly every important medicine in use today. The research-based pharmaceutical industry is estimated to have spent USD 179 billion globally on pharmaceutical research and development (R&D) in 2018.[[4]](#footnote-4) Pharmaceutical R&D has dramatically improved the lives of patients. Medical discoveries, big and small, have increased life expectancy and resulted in a better quality of life for many. In the past 5 years alone, 220 medicines have been approved that offer new hope to patients with hard-to-treat diseases.[[5]](#footnote-5) More than 7,000 medicines are in development worldwide, 208 drugs HIV/AIDS; 1,919 for cancer; 401 for diabetes; and 563 for cardiovascular diseases.[[6]](#footnote-6) In 2018, the private sector invested a total of $694 million in neglected disease R&D a $118 million increase from 2017.[[7]](#footnote-7) In 2018, 240 vaccines were in development for 25 infectious diseases, with a focus on HIV/AIDS, malaria, pneumococcal infections, tuberculosis, and Ebola.[[8]](#footnote-8) All this could not be done without private funding for scientific research.

1. “The Draft General Comment states that “*IP can negatively effect the advancement of science*”.[[9]](#footnote-9) That “*IP can also block the necessary sharing of results of scientific research and its methods, which is crucial for the advancement of science*.”[[10]](#footnote-10) Further, that “*large privatization of scientific research might have negative effects on the enjoyment of the right to participate in scientific development.*”[[11]](#footnote-11)

IP protection is granted to the author for the scientific production, which can be enjoyed by society.[[12]](#footnote-12) The World Intellectual Property Organisation in its introduction to IP states “ *IP system aims to foster an environment in which creativity and innovation can flourish.*”[[13]](#footnote-13) Further that, IP is promoted and protected for the “*progress and well-being of humanity rest on its capacity to create and invent new works in the areas of technology and culture*”.[[14]](#footnote-14) “*The promotion and protection of intellectual property spurs economic growth, creates new jobs and industries, and enhances the quality and enjoyment of life*.”[[15]](#footnote-15)

Thus, the patent system too is intended to advance the interests of both inventors and society. The public good is served when there is disclosure of the information and knowledge necessary to practice an invention so that the innovative community can continue to learn and build upon prior advances.  In return, the public is willing to grant time-limited exclusive rights to an innovator. This is reflected in Article 29 of the TRIPS Agreement sets out the conditions for a patent, which requires the patent applicant to “disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention.”[[16]](#footnote-16) These disclosures are made so that research continues and for the advancement of science.

1. The Draft General Comment states that “*IP pose very serious obstacles for persons wishing to access the benefits of scientific progress, which might also be crucial for the enjoyment of other ESCR, such as the right to health.*”[[17]](#footnote-17)

The improvement of global health is a commitment shared by the research-based pharmaceutical industry. Without strong intellectual property protection, companies would have little incentive to invest billions in R&D for products that could be easily copied. Developing and launching a medicine is a long and investment-intensive process. Studies have shown that the development time of pharmaceutical products have increased from around 10 years between the period of in 1995-2005 to around 15 years in the period 2005-2015.[[18]](#footnote-18)  Moreover, recent studies show that strong IP protection results in faster launch and faster access to new medicines for patients in developing countries, and creates incentives for the introduction of many medicines that would not otherwise be available in those countries, in either brand or generic form.[[19]](#footnote-19) In addition, industry has undertaken numerous multi-faceted initiatives to improve access to medicines and facilitate broader medicine. These practical measures include patient access programs, tiered pricing, voluntary licenses, training of researchers and healthcare workers, as well as strengthening of local healthcare infrastructure.

1. The Draft General Comment states that “*ultimately IP is a social product that has a social function”[[20]](#footnote-20)* and that *“it is* *duty of States to prevent unreasonably high costs of essential medicines, from undermining the right of the population to health*.”[[21]](#footnote-21)

Developing sustainable healthcare solutions and getting them to patients is no easy task and it cannot be done by one stakeholder. The solution lies in the building a robust healthcare system built on six building blocks: service delivery; health workforce; information; medical products, vaccines, and technologies; financing; and leadership/governance.[[22]](#footnote-22) A well-functioning healthcare system also promotes productive relationships between governments, patients, and the healthcare industry. Strong healthcare systems also require strategic long-term planning and political commitment.

Therefore, access depends on so much more than just price, and hinges on strengthening local healthcare systems, educating and training health care workers, strengthening supply chains, tackling waste and inefficiencies, corruption and falsified medicines, mobilizing domestic resources, achieving Universal Health Care Coverage. Using pricing to discuss about inadequate access falls far short of addressing the complexity of the challenges we have to tackle together.

Underinvestment in healthcare systems, prevention and primary care results in disproportionate spending on pharmaceuticals. Strengthening these systems require investment in creating reliable infrastructures and supply chains, training skilled providers who can deliver diagnostic and preventative care, as well as ensure adherence to treatments for patients.

IFPMA thanks the Committee for requesting and allowing us to provide feedback on this very important issue. We welcome the opportunity to continue to engage in future dialogues and are happy to provide any additional information.

Respectfully yours,

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Head of Intellectual Property and Trade Policy

The International Federation of Pharmaceutical Manufacturers and Associations

1. <https://www.ohchr.org/EN/HRBodies/CESCR/Pages/DraftGeneralComment_Science.aspx> [↑](#footnote-ref-1)
2. Para 65 of the Draft General Comment [↑](#footnote-ref-2)
3. Para 63 of the Draft General Comment [↑](#footnote-ref-3)
4. Evaluate Pharma (2019) World Preview 2019, Outlook to 2024. London: Evaluate Ltd., p 18. <https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma_World_Preview_2019.pdf> [↑](#footnote-ref-4)
5. IFPMA analysis based on U.S. Food and Drug Administration Official Website. <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm> Visited February 2020 [↑](#footnote-ref-5)
6. PhRMA (2016) Chart Pack Biopharmaceuticals in Perspective. Washington DC: Pharmaceutical Research and Manufacturers of America, p 22. http://phrma.org/sites/default/files/pdf/chart-pack-biopharmaceuticals-in-perspective.pdf [↑](#footnote-ref-6)
7. G-Finder Report 2019, published January 2020 at <https://s3-ap-southeast-2.amazonaws.com/policy-cures-website-assets/app/uploads/2020/02/11150341/G-Finder2019.pdf> [↑](#footnote-ref-7)
8. Health products in the pipeline for infectious diseases. WHO website. (2018) <https://www.who.int/research-observatory/monitoring/processes/health_products_September_2018/en/> [↑](#footnote-ref-8)
9. Para 64 of the Draft General Comment [↑](#footnote-ref-9)
10. Para 65 of the Draft General Comment [↑](#footnote-ref-10)
11. Para 62 of the Draft General Comment [↑](#footnote-ref-11)
12. Article 27 (2) UDHR “the right to benefit from the protection of moral and material interests resulting from authorship of scientific, literary or artistic productions” [↑](#footnote-ref-12)
13. <https://www.wipo.int/about-ip/en/> [↑](#footnote-ref-13)
14. <https://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf> [↑](#footnote-ref-14)
15. Ibid. [↑](#footnote-ref-15)
16. TRIPS 29.1 <https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5> [↑](#footnote-ref-16)
17. Para 65 of the Draft General Comment [↑](#footnote-ref-17)
18. KYLE, Economic Analysis of SPCs in Europe, 2017 or COPENHAGEN ECONOMICS, Study on the economic impact of SPCs, pharmaceutical incentives and rewards in Europe (2018), both referenced and compared p66 or p67, e.g. “… the development times of medicinal products have increased from around 10 years in 1995-2005 to around 15 years in the period 2005-2015. “In Kyle, development times have increased from around 10 years in the period 1990-1994 to a little more than 12 years in the period 2010-2015” [↑](#footnote-ref-18)
19. *See, e.g.* Ernst R. Berndt and Iain M. Cockburn, “The Hidden Cost of Low Prices: Limited Access to New Drugs in India,” Health Affairs 33, no. 9 (2014): 1567–75; Iain M. Cockburn, Jean O. Lanjouw, and Mark Schankerman, “Patents and the Global Diffusion of New Drugs” (National Bureau of Economic Research, 2014), http://www.nber.org/papers/w20492; Margaret Kyle and Yi Qian, “Intellectual Property Rights and Access to Innovation: Evidence from TRIPS” (National Bureau of Economic Research, 2014), http://www.nber.org/papers/w20799; [↑](#footnote-ref-19)
20. Para 66 of the Draft General Comment [↑](#footnote-ref-20)
21. Ibid. [↑](#footnote-ref-21)
22. WHO (2016) The WHO Health Systems Framework. Geneva: World Health Organization. http://www.wpro.who.int/ health\_services/health\_systems\_framework/en [↑](#footnote-ref-22)