ADDRESSED TO:
Convention on Biological Diversity
413, rue Saint-Jacques, Suite 800
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CANADA

Date: 30 September 2021

IFPMA submission in accordance with CBD Notification 2021-063 - Submission of views and new information on policy approaches, options or modalities for digital sequence information on genetic resources

Following on from the decision of the 3rd meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework (OEWG-3), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) would like to make two observations: (1) the need to reassess the practical impact of the current access and benefit sharing (ABS) system before any potential expansion of the ABS system to digital sequence information (DSI) is addressed, and (2) the need for the timely and predictable sharing of pathogens of endemic, epidemic or pandemic potential under any and all ABS systems.

Rethinking Access and Benefit Sharing

Current ABS mechanisms require significant human, legal and financial resources to be able to navigate and administer adequately. These costs currently outweigh the benefits to pursuing research on genetic resources (GRs) that are captured by such mechanisms. The potential value which could be gained from research on these genetic resources is not unlocked and therefore cannot be shared with providers.

The negotiations for the Post-2020 Global Biodiversity Framework (Post-2020 GBF) present us with a unique opportunity to reassess the CBD and Nagoya systems as applied to ABS on genetic resources. Despite the entry into force of the Nagoya Protocol and the increasing number of ABS regulations, the level of benefit sharing has not increased significantly, while access has become more constrained. Empirical evidence indicates that the foundations of the ABS system as it currently stands are not fit for purpose. Credible academics point out that we are in dire need of rethinking the whole ABS system before considering expanding the same flawed system.[1]

Under the current system both providers and users are faced with a lose-lose situation. Countries are incentivised to restrict access to promote benefit sharing while requesting that non-existent benefits are shared. This logic is fundamentally flawed, as without access, value from genetic resources cannot be created. We should learn from the lessons over the past years to readjust the current ABS system so that it creates more incentives for value creation.

It is our belief that the best course of action would be to seize the opportunity afforded us by the negotiation of the Post-2020 GBF to engage in a complete and impartial reassessment of the bilateral ABS system before discussions centre on building an ABS system on DSI. The risks of extending an ABS system which is not sufficiently robust and effective to such a critical subject as DSI far outweigh any potential benefits.

It is the view of IFPMA that analysis of the practical benefits of the current ABS system and possible alternatives must be undertaken with a view to improving the system so that the value of genetic resources can be unlocked more fully. It is important that this reality is fully considered before any negotiations on an

[1] Laird S, Wynberg R, Rourke M, Humphries F, Muller MR, Lawson C. Rethink the expansion of access and benefit sharing. Science. 2020 Mar 13;367(6483):1200-1202. doi: 10.1126/science.aba9609. PMID: 32165574.

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ABS mechanism on DSI take place. Furthermore, decisions about scientific research practices that have impacts not only on biodiversity but also on public health, research, biotechnology and innovation should be taken in close cooperation with experts in those fields.

Pathogen Sharing

IFPMA looks forwards to a successful Post-2020 GBF. However, we have concerns regarding the relationship between pathogens and the Nagoya Protocol and CBD system more broadly. The critical issue is that the manner in which many countries have chosen to implement the Nagoya Protocol domestically, namely disregarding public health implications as envisaged under Article 8(b), has led to delays in the sharing of pathogens, especially in the sharing of seasonal Influenza, Ebola, Zika and bacterial isolates important for assessing antimicrobial resistance, despite the willingness and efforts of pharmaceutical companies, research laboratories and the World Health Organization (WHO) to work with national governments.[2]

The importance of timely pathogen sharing in the context of public health emergencies has been highlighted by the COVID-19 pandemic and has been recognized by the WHO Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 Response.[3] Furthermore, the G7 100 Days Mission to respond to future pandemic threats places the heavy burden on industry to make available diagnostics, vaccines and therapeutics within 100 days from the beginning of a future pandemic. Aspiring to this goal requires collaboration and access to pathogen samples and their related DSI immediately after an outbreak is detected. Any delay has knock-on effects for R&D and production, and the ability for humanity to respond to an outbreak. The speed at which DSI of SARS-CoV-2 became widely available was a key enabling factor in the rapid activation of the scientific community in order to understand the virus, produce diagnostics, therapeutics and vaccines.

It is for these reasons that IFPMA believes that the Post-2020 GBF and any decision on or process related to DSI must take into account the special nature of pathogens of endemic, pandemic and epidemic potential. It is critical that the OEWG and COP processes take an 'ecosystem' approach that considers the risks which could arise if an ABS system on DSI does not ensure that pathogens of pandemic potential will be shared in a timely manner. Article 8(b) of the Protocol has proved to be insufficient. Any truly effective solution must be addressed multilaterally, followed by well-thought national implementation. We believe that *any multilateral ABS system, and therefore national ABS legislation, must provide for the timely and predictable sharing of pathogens of endemic, epidemic or pandemic potential to ensure swift access to pathogens for the rapid development of vaccines, medicines and diagnostics.*

Sincerely,

Thomas Cueni
IFPMA Director General

[2] Delays of up to 18 months have been experienced.
[3] Report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response, A74/9 Add.1, p 16.

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