IFPMA

STATEMENT

Second meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information (DSI)

12 AUGUST 2024, MONTREAL, CANADA – The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has been engaged in the DSI discussions since the beginning and we will continue engaging constructively in the process. We recognize the importance of achieving an outcome that results in a good solution for both providers and users of DSI.

The world is facing an increasing number of existential crises, including in relation to biodiversity loss. The biopharmaceutical industry is acutely aware of this and, as a sector dedicated to the health and well-being of humanity, it is something that we take seriously. Advances in R&D have meant that the sector is less reliant on natural resources and is able to develop and produce new medicines through synthetic and computational methods. Such approaches contribute to targets under the Kunming Montreal Global Biodiversity Framework (KM-GBF): Targets 4, 5, 7, 8, and 14 in particular.

The mission of the biopharmaceutical sector is to safeguard public health. A number of challenges are on the horizon, including the spread of disease due to climate change and habitat loss. The ability of the sector to respond to such challenges relies on increasingly rapid innovation, which is only possible through rapid and timely access to key data, in particular pathogenic DSI. This was most recently seen during the COVID pandemic.

Beyond health emergencies, policies regulating access to DSI may significantly increase due diligence costs, legal uncertainty, and lead to underinvestment in technologies that are critical to address unmet medical needs.

Through decision COP15/9, parties requested the CBD Secretariat to provide more technical, fact-based information, which was expected to allow a better understanding of policy options including an impact assessment. Furthermore, the studies were supposed to compare how different policy options score against criteria identified in paragraph 9 of the mentioned decision.

IFPMA is supportive of an approach that puts the evidence and facts at the heart of the negotiations. Nevertheless, we are disappointed by the outcome of the mentioned studies, which have oversimplified R&D processes, leading to a misrepresentation of key issues, such as how DSI is used and the specificities around the various sector-specific value chains analyzed. The limitation of the studies to only five sectors and the inclusion of financial data, which is unrelated to the use of DSI

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or, for example, is based on revenues from human DSI that is not under the scope of the CBD, are of further concern. More importantly, authors of the study recognize that, based on existing information available, they cannot compare the options on the table with the MS agreed criteria from paragraph 9.

IFPMA is concerned by the way in which the studies have and may be used in the negotiations, especially as there are certain aspects of the studies that do not provide an accurate representation of business realities, in particular for the pharmaceutical sector. For example:

1. The case studies used are only for COVID-19, which had been an exceptional situation and does not represent normal business realities. Overall, less than 10% of the sector works on infectious diseases.
2. The sectors chosen for the study have been represented as 'highly DSI dependent' without qualifying this with any concrete evidence.
3. Detail on the value chain is lacking, including misleading points of revenue generation. Sales and revenue does not equal profit, and hence the study ignores the significant reinvestment of funds back into the R&D pipeline, which is characteristic for the pharmaceutical sector.
4. There is no separation of the use of human DSI from other DSI. Revenues are based on products that have no link to DSI, which is entirely misleading.

While we appreciate the need to find a solution, the two options put forward in the co-chairs' proposal, which look extremely simple, are inappropriate to address such a complex mechanism that Member States are trying to establish. In addition, they are neither based on any evidence nor are representative of all the divergent positions expressed by experts during the Informal Advisory Group process. It is concerning that, since COP15, there has been no formal discussion on the other options that were put forward.

IFPMA remains committed to engage constructively in the discussions for the multilateral mechanism (MLM). Negotiators should keep in mind that they have already agreed the criteria a potential MLM needs to adhere to, namely, the criteria under paragraph 9 of decision 15/9. Furthermore, they should be guided by the need to avoid a stacking of obligations between any access- and benefit-sharing (ABS) instruments, both national and multilateral, and that the solution is aligned with user and provider realities and, therefore, clearly based on evidence and facts.

Overall, it should not be forgotten that this is a unique opportunity to reform the present ABS system, which is neither satisfying the needs of providers nor users of genetic resources (GRs), and to create a completely new, harmonized, and more efficient system that would apply to both DSI and GRs.

Although the two options on the table today are enticing due to their simplicity, these would not work in reality and just add further complexities to the already existing inefficient ABS system for GRs.

We look forward to further discussions.

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