

IFPMA Response to CBD Notification 2024 – 114 on additional modalities of the Multilateral Mechanism (MLM)

We call on all stakeholders and Parties to use the inter-sessional period towards COP 17 to radically rethink the modalities and rationale of the MLM, broadly consult with affected sectors, and ensure it does not inadvertently undermine the very objectives it seeks to achieve. In that spirit, we propose that the modalities of Decision COP 16/2 should be significantly reviewed, revised and clarified.

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) welcomes the opportunity to provide comments on the Annex to COP Decision 16/2 on the multilateral mechanism (MLM) for the sharing of benefits from the use of digital sequence information on genetic resources (DSI).

The innovative pharmaceutical sector supports the objectives of the Convention on Biological Diversity (CBD), including the conservation and sustainable use of biodiversity. However, the current structure of the MLM does not effectively advance biodiversity goals nor provides clarity on how the allocation system will guarantee that funds will directly support conservation efforts.

A core assumption of the MLM is that users of DSI do not adequately share benefits. This assumption is flawed. The biopharmaceutical sector significantly contributes to society through medical innovation and global health initiatives, generating benefits that benefit society as a whole. These include:¹

- Developing life-saving treatments and vaccines to advance global health.
- Tiered pricing ensuring affordable medicines in lower-income countries.
- Voluntary technology transfer for geographically diverse manufacturing and local production capacity.
- Capacity-building initiatives to train medical professionals and strengthen healthcare systems.

¹ Further examples are available on Global Health Progress. See, <https://globalhealthprogress.org/>

IFPMA has closely followed the discussions leading to Decision 16/2 and sought to contribute despite limited opportunity for meaningful consultation and negotiation during the intersessional period. Against that background we are convinced that the modalities in Decision 16/2 are far from finished and the official launch of the MLM in February 2025 was premature. First and foremost, the modalities were adopted without a full and in-depth impact assessment on sectors that rely on DSI for research and innovation. Furthermore, the decision does not respect the criteria set by negotiators themselves at COP15 under paragraph 9 of Decision 15/9, namely that it be efficient, feasible and practical;² generate more benefits than costs;³ provide certainty and legal clarity;⁴ and not hinder research and innovation.⁵

On the contrary, the MLM's financial and regulatory burdens will have direct consequences on the innovative pharmaceutical industry's ability to innovate and respond to medical needs, and in particular health emergencies. Specific concerns include:

- *Slowed R&D on emerging health threats*: Implementation of the MLM through national law can lead to hurdles that could delay the use of data and would impede preparedness.
- *Higher costs for drug and vaccine development*: Increased financial obligations may raise costs, ultimately affecting medicine affordability and access.
- *Disruptions to existing public-private partnerships*: The industry has been actively engaged in partnerships that share benefits through innovation, but the MLM could disrupt these collaborations.

In order to advance discussions on the implementation of the MLM IFPMA outlines below a number of modalities that are insufficiently clear as included in Decision 16/2 and other elements that make the Decision unworkable in practice.

1. The truly voluntary nature of the MLM

Although Decision 16/2 makes it clear that the MLM is voluntary in principle, there are elements in the decision that do not go far enough in creating a truly voluntary mechanism. The language used in the decision is vague in a number of areas where it should be more concrete, for example, by leaving broad scope for divergent interpretations of how the decision should be implemented, leaving room for mandatory mechanisms at national level. Conversely, the decision is also concrete in areas where there is no justification to be so, for example, in relation to the indicative rates where no real analysis was undertaken on what rates should be and the impact of these on the criteria outlined in Decision 15/9.

The language included throughout the decision “without prejudice to national legislation” is problematic in particular as most national ABS legislation is based on a mandatory and bilateral

² CBD COP Decision 15/9 para 9(a).

³ CBD COP Decision 15/9 para 9(b).

⁴ CBD COP Decision 15/9 para 9(d).

⁵ CBD COP Decision 15/9 para 9(e).

vision which is incompatible with the MLM. Further clarity is needed that any implementation of the decision should safeguard the voluntary nature of the MLM and should not seek to create mandatory obligations.

Given that the indicative rates were chosen without any rational analysis - as acknowledged by the decision itself, which calls for a study to propose replacement realistic rates - it is critical that these placeholder rates are truly indicative. This will allow for companies to undertake internal assessments on what the true value of DSI is based on all relevant factors. If companies choose to contribute, they should be free to contribute above or below the indicative rate and still be in compliance with the MLM.

For these reasons both the expectation of contribution as well as the level of contribution must both be voluntary for the MLM to satisfy the criteria under Decision 15/9.

2. The key definitions used throughout the decision

One of the key concerns is legal certainty which the decision fails to provide. The MLM lacks clear definitions for core concepts, including what constitutes 'DSI', how it is used, and what triggers benefit-sharing obligations. Given the lack of clarity, national implementation will necessarily vary widely, leading to a patchwork of overlapping and conflicting rules.

For that reason, we call on the parties to define, and as needed, revise or adapt terminology used in Decision 16/2. During the intersessional period from 2019-2022 work was undertaken by the AHTEG to look at the concept of DSI as well as how DSI is used among other issues. This work started to provide a foundation for understanding these concepts and was unfortunately not continued in the lead up to COP16. Continuation of such work is clearly needed to help provide accurate definitions for the foundational terms used throughout Decision 16/2.

The inclusion of "indirect use" in the decision, especially without inclusion of a consensus definition, creates significant confusion on the scope of the MLM. The term should be dropped from the MLM unless a definition is agreed on that is based on real-life practice, is business-realistic, and provides certainty and legal clarity. Other key terms such as 'benefit from' and 'users' must also be clearly defined.

Without defining these terms, implementation of the MLM will necessarily lead to diverging national interpretation of the MLM itself and how it should be operationalised. This will lead to increased compliance costs and possible conflicting implementing rules that will make it extremely hard for companies operating within global supply chains to be able to ensure compliance with. IFPMA stands ready to engage in further technical work to arrive at scientifically grounded key definitions, including for 'DSI' and 'use'.

3. National implementation

The MLM fails to ensure that its financial obligations do not overlap with existing commitments under national and international frameworks. The MLM was developed without proper

consideration of the impacts of ongoing multilateral negotiations, such as the WHO Pandemic Agreement, and sector-specific regulations. This lack of coordination creates a stacking of obligations, both national-multilateral and multilateral-multilateral, increasing compliance costs and regulatory burdens on industry.

Under the current wording of the Decision, countries are able to apply both their national rules on “users of DSI” and presumably receive contributions both through the MLM and domestically – leading to a situation where a ‘user’ is in effect taxed twice. If countries are able to receive funding through the MLM and still apply their national rules on the very same DSI use, there is no incentive not to do so. Any such stacking of obligations would completely violate the principles agreed in Decision 15/9, in particular effectiveness, legal certainty and not hindering research and innovation.

Therefore, to avoid duplication with national ABS regimes, contributions to the MLM must explicitly substitute all national ABS obligations, ensuring legal certainty. Further work is also needed to avoid a stacking of obligations with other multilateral ABS instruments that are either in place or currently under negotiation.

4. The licence to operate

The MLM essentially imposes a financial burden on the free exchange of scientific data, which is critical for medical, environmental and other societal research. Open access to DSI has helped drive rapid scientific advancements, including AI-supported drug discovery, vaccine development, and biodiversity research. In addition, DSI use does not deplete material genetic resources or biodiversity. By taxing DSI use, the MLM risks creating disincentives for global scientific cooperation, slowing the pace of innovation including the response to emerging health, societal, and environmental threats.

However, the MLM could avoid these risks if it legally guarantees that entity participation in the MLM through voluntary contribution to the MLM should constitute full compliance with all ABS rules and regulations *for any use, for any purpose, at any time, and in all 196 countries* that are parties to the CBD (opt-out system).

The compliance certificate must serve as a universally recognized, legally binding proof of full compliance with benefit-sharing obligations, eliminating risk of further benefit-sharing claims. Any business unit or entity of the group mentioned on the certificate will be recognised as being in compliance with any ABS requirements, including requirements arising under other international or national ABS instruments.

5. Indicative Contribution Rates

As mentioned above, there was a complete lack of rational analysis underpinning the indicative rates. Limited and very basic financial examples were used to arrive at ballpark figures for the funds that may be collected by the MLM. The studies that proposed crude rates overestimate the economic benefits derived from DSI use while ignoring the true costs of R&D utilizing DSI.

For example, the high failure rate in drug development is not considered: on average only 0.01% to 0.02% of compounds synthesized in laboratories will make it to market⁶ and more than 90% of compounds that enter clinical trials⁷ do not result in a commercial product, meaning that for most applications, DSI has no direct monetary return.

Furthermore, differences in business models and use of DSI between sectors and companies were not considered in the establishment of the rates. The inherent value of DSI will vary from company to company, let alone between sectors. More broadly, there was no attempt to arrive at a conclusion of what value DSI really brings; in other words, the benefit that DSI brings was not identified, yet rates were established. How can benefits be shared when the original 'benefit' has not been identified?

As is now common knowledge among CBD negotiators, the value of DSI largely lies in the ability of analyzing large numbers of sequences and comparing them with one another, including through machine learning and other methods. Therefore, the R&D value of DSI in public databases is directly related to the amount of DSI available, the quality of the available DSI, the diversity of that DSI and the accessibility of that DSI. In other words, DSI has a value that increases the more of it there is, and there is clearly a real need for more sequencing to be undertaken as only 0.43% of all species were sequenced, as of March 2021.⁸ In short, the 'DSI infrastructure' should also be factored into the calculation of the benefits that DSI brings.

Overall, establishing indicative contribution rates in Decision 16/2 was premature and the rates themselves are commercially unrealistic, are not based on the underlying value that DSI brings, lack scientific justification, do not take into account sector-specific differences, and serve as a disincentive to participation. Countries should first establish a clear rationale for why rates are needed (if at all) and explain the criteria on which they are based. Therefore, it is critical that the existing "indicative" rates be reconsidered.

6. Accountability and allocation

The lack of an allocation methodology in Decision 16/2 is a critical oversight that may severely limit companies' engagement. Establishing the MLM in an effective manner requires visibility over the entire mechanism as aspects related to the allocation can have an impact on how the funds should be gathered. There is a strong relationship between allocation and ensuring the effectiveness of the MLM. Allocation can serve as a means of ensuring that funding only goes to projects in countries where the national ABS rules recognise, for example, the certificate of compliance and give it legal weight.

As companies already contribute to biodiversity through their own nature-related projects, any funds diverted to the MLM will likely be reported as part of such projects. This is one of the

⁶ See, <https://www.ifpma.org/initiatives/alwaysinnovating-pharmaceutical-industry-facts-figures/>

⁷ Sun D, Gao W, Hu H, et al. Why 90% of clinical drug development fails and how to improve it? . Acta Pharm Sin B. 2022 Jul;12(7):3049-62 <https://pubmed.ncbi.nlm.nih.gov/35865092/>

⁸ <https://www.pnas.org/doi/10.1073/pnas.2115635118>

reasons why robust financial auditing, transparent reporting, and third-party oversight mechanisms must be established to guarantee that contributions directly and demonstrably support biodiversity outcomes and are not misallocated or used to finance general budgets in the same manner as a tax.

7. Governance

Decision 16/2 specifically calls out seven sectors yet only two private sector representatives are able to join the steering committee. There are significant differences between companies within sectors let alone across seven completely distinct sectors. Ensuring that the MLM meets the criteria of Decision 15/9, in particular not hindering research and innovation and providing legal certainty, will require serious engagement in the governance of the MLM with all private sector actors that are called on to contribute to the MLM, including those that are not included in the seven sectors called out in the decision.

Given that the steering committee is being tasked with suggesting how the certificate of compliance should work and other fundamental elements of the MLM, it is even more important that an appropriate number of private sector representatives are full members of the steering committee.

The decision to create the Cali Fund at COP16 does not get the balance right between the intended benefits of such a mechanism and the significant costs to society and science that it has the potential to create. We have outlined a number of areas where more work is needed to both clarify and refine modalities of the MLM.