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In its function as the representative of the research-based pharmaceutical and biopharmaceutical companies in Germany, the VFA welcomes the opportunity to comment on the draft report for a global strategy and plan of action of the IGWG. Our key messages to this draft report are:

- The IGWG should focus on its remit, which is to find ways of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries. These are, in essence, Type II and III diseases. Type I diseases should not be object of the draft report. The respective referrals to these diseases should be eliminated.

- For diseases that affect both developed and developing countries, the current incentive mechanism is based on the patent system and has been the source of the vast majority of the existing pharmaceuticals. The IGWG should avoid any attempts to weaken this system. Especially the proposed actions and statements about "TRIPS-flexibilities" are particularly problematic and should be eliminated, as they might disincentivize the development of new products. The IGWG should look for the support of WTO and WIPO for trade- or IP-related questions.

- Instead, the IGWG should look for additional incentives that are workable, efficient and built on cooperation with the research-based pharmaceutical industry to achieve its objectives. Proven models for successful cooperations are, e.g., WHO's Tropical Disease Research Program (TDR) or the Medicines for Malaria Venture (MMV).

- Difficult or unachievable access to medicines and medical services in developing countries is a complex problem which applies to both patented and non-patented drugs. It is a challenge for governments and societies of all countries to find solidarity-based support systems which are able to grant access to healthcare for everyone. The research-based pharmaceutical industry is a partner for all governments and civil society groups who want to cooperate with us.

- In this context, VFA appreciates the draft report's comments about the need for improved healthcare systems in developing countries. The improvement of the medical and pharmaceutical infrastructure, the training of healthcare personnel, the simplification of regulatory processes, the fight against counterfeit drugs, the abolishment of taxes and tariffs on imported drugs, the improvement of drug need forecasting systems, the fight against disease-spreading vectors, and the improvement of prevention measures in general are examples for the huge workload that has to be faced here.

- The IGWG's central objective - which is to achieve additional R&D in drugs against Type II and III diseases - will require significant public funding. Any WHO member country considering such funding should check the proposals for their potential and their risks. Besides the already proven and successful incentive mechanism of Public-Private Partnerships (PPPs), VFA considers the draft report's proposals for

- o Advanced Market Commitments (AMCs)

- o Specialized market exclusivity mechanisms

- o Research and development tax incentives

as new incentives that should be further pursued. In contrast, the proposals for

- o Compulsory Patent Pools

- o An R&D treaty

- o Compulsory access to compound libraries

- o Open-source Research Model

should NOT be further pursued, as they are not workable in the area of R&D in pharmaceuticals.