20 March 2013

JOINT EFPIA-IFPMA POSITION PAPER

on the European Commission Proposal for a REGULATION ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILISATION IN THE UNION COM(2012) 576 final

Introductory remarks

EFPIA and IFPMA welcome the draft Regulation proposed by the European Commission to implement the Nagoya Protocol[i] in the EU and believe that the framework of the proposal will support the objective of facilitating responsible use of the genetic resources covered by the Protocol.

EFPIA and IFPMA fully support the goals of the Convention on Biological Diversity (CBD) and stand ready to work with the EU to ensure the Protocol's fair and balanced implementation across the EU. As referred to in the International Chamber of Commerce (ICC) comments on the draft Regulation, a key driver in the legislative process should be to ensure legal certainty for potential users of genetic resources in the EU, via a stable and proportionate regulatory framework. Hereof, we welcome the establishment in the Regulation of a system of due diligence based on users' best practices (art. 8) and flexibility (art. 4).

The Regulation should however be based on an accurate appraisal of current and future uses of genetic resources. According to lead researchers, research on genetic resources covered by the CBD represents only a small part of the pharmaceutical industry R&D spending[ii]. In this regard, it is unfortunate that the pharmaceutical sector is specifically singled out in the Explanatory Memorandum. This mention sends out a misleading and unbalanced message regarding one sectors involvement in the debate. EFPIA and IFPMA encourage the European Parliament to further consider how to foster the collaborations involving academia and large and small companies which we believe represent the future of bio-prospecting for research purposes. As potential downstream users of their results, the pharmaceutical industry strongly supports such collaborations, whose potential in terms of new medicines can be significant.

However there are a number of specific areas where the Commission's proposal could be improved and these are identified below.

Scope

The material scope of the draft Regulation should be defined in close relation to the intended scope of the CBD and the Nagoya Protocol and with due consideration to other relevant international frameworks and instruments. For example, this Regulation should not apply to genetic resources which are available as commodities in the normal channels of trade or which have only pathogenic properties.

Due diligence obligation

The draft Regulation imposes on users of genetic resources a due diligence obligation throughout the EU, which, if breached, will be sanctioned by "effective and dissuasive penalties". EFPIA and IFPMA therefore believe that clarity is necessary so that users can foresee for whom and under which circumstances these obligations arise (art 4.1, 4.2) and know what steps must be taken to be in compliance (art 7.2).

Competent Authorities

Competent authorities should not have disproportionate powers to monitor compliance. The checks on user compliance should only be exercised if the authority is in possession of relevant information, which raises a reasonable suspicion of non-compliance by the user (art.9).

Process

In accordance with the legal principle of due process, we believe that some procedural safeguards, including the right of appeal and the right to be notified, should be provided for in the draft Regulation.

Intellectual Property Rights (IPRs)

The draft Regulation is consistent with the CBD objectives on IPRs and there is no conflict with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which introduces global standards for protecting and enforcing almost all forms of IPRs.

EFPIA and IFPMA look forward to working with our EU partners to address these issues and are committed to reaching a fair, balanced and sustainable solution.

About EFPIA: *The European Federation of Pharmaceutical Industries and Associations (EFPIA) is the representative voice of research-based pharmaceutical industry operating in Europe. Through its direct membership of 30+ companies and 34 national associations, EFPIA represents more than 2000 biopharmaceutical companies striving at saving and improving quality of life of patients. EFPIA member are committed to delivering innovative medicines to address the needs of patients and reducing the burden of chronic diseases for Europe's ageing population. EFPIA believes in close cooperation with stakeholders to help create sustainable healthcare systems and to develop prompt responses to health threats.*

About IFPMA: *IFPMA represents research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 1.3 million employees research, develop and provide medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.*
IFPMA manages global initiatives including: IFPMA Developing World Health Partnerships initiative studies and identifies trends for the research-based pharmaceutical industry's long-term partnership programs to improve health in developing countries, IFPMA Code of Practice sets unsurpassed standards for interactions with the healthcare community, IFPMA Clinical Trials Portal helps patients and health professionals find out about on-going clinical trials and trial results.

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[i] The Nagoya Protocol was adopted by Parties to the Convention on Biological Diversity (CBD) on 29 October 2010 and provides a framework for implementation of the Access and Benefit Sharing (ABS) provisions set out in the CBD

[ii] "Dramatic advances in sciences and technology […] changed the nature of the demand for genetic resources and the ways in which they were used. […] Many of the large [pharmaceutical] companies with active natural products programmes and associated bioprospecting efforts overseas have closed their programmes […]. Today natural product discovery is found largely in smaller discovery companies, semi-governmental or governmental entities and universities around the world. Elements of large pharmaceutical natural products programmes have been spun off into non-profits or semi-governmental entities, and compound libraries have been given away or sold off cheaply." – LAIRD, WYNBERG, *Bioscience at a Crossroads: Implementing the Nagoya Protocol on Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change*, published by the CBD, 2012.