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European Commission
Directorate-General Health & Consumers
The Commissioner
Mr. John Dalli
B-1049 Brussels
Belgium

December 6, 2010

Pandemic Influenza Preparedness (PIP): sharing of influenza viruses and access to vaccines & other benefits

Dear Commissioner Dalli,

we are writing to you with regard to the above-mentioned matter in view of the recently concluded negotiations on the Nagoya Protocol on Access and Benefit Sharing and the upcoming WHO negotiations on above matter that will take place in Geneva from 13-17 December 2010.

The ABS Protocol negotiations have established that the scope of the Protocol and as such the Convention of Biological Diversity (CBD) extends to pathogens including influenza viruses being shared under the auspices of the World Health Organization.

One of the core objectives of the CBD is the fair and equitable sharing of benefits arising from the utilization of genetic resources. This objective is to be achieved through Article 15 of the Convention (elaborated upon by the Protocol) which explicitly states that access to genetic resources will be subject to prior informed consent and fair and equitable sharing of benefits arising from the commercial and other utilization of genetic resources. According to the Convention, both access and benefit sharing should be on "mutually agreed terms".

It is generally accepted that these elements envisage a contractual access and benefit sharing agreement that would be binding on the provider and user of genetic resources.

However in the context of the WHO PIP negotiations we are concerned that while there is recognition of the need for sharing influenza viruses there is little emphasis on achieving fair and equitable benefit-sharing as foreseen by the CBD. In particular EU has been resisting calls by many developing countries to negotiate a Standard Material Transfer Agreement (SMTA) that includes concrete benefit-sharing obligations for sharing of influenza viruses with the WHO Network laboratories as well as with third party entities.

The EU being a Party to the Convention is legally bound to ensure implementation of Convention where access to genetic resources is provided in order to achieve the core objectives of the CBD, as mentioned above.

While access to influenza biological materials is a valid concern, achieving public health objectives also requires rapid sharing of benefits particularly those arising from the use of the materials. A PIP Framework that stresses on sharing of influenza biological materials but that fails to obligate recipients of such materials to share fair and equitable benefits is inconsistent with CBD's objectives and the EU's obligations under the Convention. Such a Framework is also inequitable and will fail to deliver a sustainable predictable system for purposes of public health.

We would also highlight Article 6(b) of the recently adopted Nagoya Protocol on ABS which, with regard to national legislation and regulation, stresses on "expeditious access to genetic resources" and on an equal footing also to "expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries" in cases of present or imminent emergencies.

Moreover, Article 3bis of the ABS Protocol requires "specialised access and benefit-sharing agreements" to be supportive of and not run counter to the objectives of the Convention and this Protocol".

We are of the view that the approach of a SMTA that contains the "mutually agreed terms" for sharing of influenza biological materials as well as concrete benefit sharing obligations for recipients of influenza biological materials (be they commercial or non-commercial entities) is a minimum requirement for achieving the objectives of the CBD and the ABS Protocol and those of public health.

SMTA will ensure legal certainty and predictability with regard to fair and equitable benefit sharing and thus is an incentive for timely sharing of influenza viruses.

The EU being a Party to the Convention needs to ensure that WHO negotiations build on the minimum standards and requirements established by the CBD.

We also request the EU to ensure that influenza biological materials and/or products developed using such materials are not appropriated through the use of intellectual property rights. Just as access to influenza biological materials is stressed upon to enable measures to address public health, the EU must equally support the principle that claims to intellectual property rights by recipients of influenza biological materials be relinquished. In this regard we request the EU to support our view that private intellectual property rights must also not obstruct the ability to take measures in situations that threaten human health.

Yours sincerely,

Dr. Rudolf Ficker
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