134th session **EB134.R19**

Agenda item 9.5 **25 January 2014**

Access to biotherapeutic products and ensuring quality, safety and efficacy

The Executive Board,

Having considered the report on Regulatory system strengthening,

RECOMMENDS to the Sixty-seventh World Health Assembly, the consideration and adoption of the following resolution:

The Sixty-seventh World Health Assembly,

Recalling the WHO Constitution, which affirms that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition;

Noting with particular concern that for millions of people, the right to the enjoyment of the highest attainable standard of physical and mental health, including access to medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly remote, that millions of people are driven below the poverty line each year because of catastrophic out-of-pocket payments for health care, and that excessive out-of-pocket payments can discourage the impoverished from seeking or continuing care;

Recalling resolution WHA55.14 on ensuring accessibility of essential medicines, which recognizes "the responsibility of Member States to support solid scientific evidence, excluding any biased information or external pressures that may be detrimental to public health";

Further recalling that resolution WHA55.14 urged Member States, inter alia, "to reaffirm their commitment to increasing access to medicines, and to translate such commitment into specific regulation within countries, especially enactment of national drug policies and establishment of lists of essential medicines based on evidence and with reference to WHO's model list into actions designed to promote policy for, access to, and quality and rational use of, medicines within national health systems";

Considering that one of the objectives of pharmaceutical regulation is the assurance of the quality, safety and efficacy of pharmaceutical products through the regulatory processes of authorization, vigilance and monitoring;

Considering also that national pharmaceutical regulation should contribute to the performance and sustainability of health systems and the general welfare of society;

Considering that an update of the norms and standards applicable to medicines is required in the light of advances made in biotechnology, and the new generation of medicines introduced as a result, in order to ensure the entry into the market of medicines that are affordable, safe, efficacious, of quality and accessible in a timely and adequate fashion;

Recognizing that the use of such medicines has a positive impact on morbidity and mortality rates and that, while there are multiple barriers to access, their high cost affects the sustainability of health systems and could in many cases affect access to them;

[Noting that WHO Expert Committee on Biological Standardization guidelines of 2009 on evaluation of similar biotherapeutic products and that the placing on the market of these types of products is expected to significantly increase;]

Conscious that similar biotherapeutic products could be more affordable and offer better access to treatments of biological origin, while ensuring quality, safety and efficacy;

1. URGES Member States:[1]

(1) to develop or strengthen, as appropriate, national regulatory assessment and authorization frameworks, with a view to meeting the public health needs for biotherapeutic products, and in particular similar biotherapeutic products;

[(2) to ensure that a solid, scientifically-based regulatory review process for reviewing, approving, and monitoring reference biotherapeutic products has been conducted before embarking on the review and approval of similar biotherapeutic products;]

(3) to work to ensure that the introduction of new national regulations, where appropriate, does not constitute a barrier to access to quality, safe, efficacious and affordable similar biotherapeutic products;

2. REQUESTS the Director-General:

(1) to support Member States in strengthening their capacity in the area of the health regulation of biotherapeutic products and in particular similar biotherapeutic products;

(2) to support, as appropriate, the development of national regulatory frameworks that promote access to quality, safe, efficacious and affordable similar biotherapeutic products;

(3) to encourage and promote cooperation and exchange of information, as appropriate, among Member States in relation to biotherapeutic products, in particular similar biotherapeutic products.

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[1] And, where applicable, regional economic integration organizations.