World Health Organization

EXECUTIVE BOARD
134th session
Agenda item 9.5

EB134/CONF./3
20 January 2014

Biological medicines: access to medicines and ensuring safety, quality and efficacy

Draft resolution proposed by Argentina, Colombia, Costa Rica Paraguay and Uruguay

The Executive Board,

Having considered the report on Regulatory system strengthening,

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

The Sixty-seventh World Health Assembly,

PP1 Considering that health is a fundamental human right recognized in various international human rights treaties;

PP2 Recalling United Nations Human Rights Council resolution A/HRC/RES/23/14, which stressed "the responsibility of States to ensure the highest attainable level of health for all, including through access, without discrimination, to medicines, in particular essential medicines, that are affordable, safe, efficacious and of quality";

PP3 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";

PP4 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 (…) into actions designed to promote policy for, access to, and quality and rational use of, medicines within national health systems";

PP5 Considering that resolution WHA66.7 on implementation of the recommendations of the United Nations Commission on Life-Saving Commodities for Women and Children recognized that millions of women and children die needlessly every year from conditions that are easily prevented by the use of existing inexpensive medical commodities, and further recognized the need to overcome the barriers that prevent women and children from accessing and using appropriate commodities;

PP6 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;

PP7 Considering also that national pharmaceutical regulation should contribute to the sustainability of health systems and the general welfare of society;

PP8 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 good quality and accessible in a timely and adequate fashion;

PP9 Recognizing that, although the use of such medicines has a positive impact on morbidity and mortality rates, their high cost could affect access to them and the sustainability of health systems;

PP10 Conscious that biological medicines proposed as being similar to medicines taken as comparators could be more affordable and offer better access to new treatments of biological origin, while maintaining quality, safety and efficacy,

(OP1) 1. URGES Member States:

(1) to provide appropriate national regulatory frameworks for the health regulation of medicines of biological origin, with a view to meeting the needs of public health, in particular of medicines of biotechnological origin developed to be similar to medicines taken as comparator in terms of quality, safety and efficacy;

(2) to ensure that the introduction of new national regulations applicable to the medicines referred to in the paragraph above does not constitute a barrier to access to medicines that are affordable, safe, efficacious and of quality;

(OP2) 2. REQUESTS the Director-General:

(1) to support Member States in strengthening their capacity in the area of the health regulation of medicines of biological origin, and in particular of biotechnology medicines developed to be similar to medicines taken as comparator in terms of quality, safety and efficacy;

(2) to encourage and support the development of health regulation frameworks consistent with access to medicines that are affordable, safe, efficacious and of quality.

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