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Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?

Amendment[1] No. 1

In the draft resolution, insert the following two paragraphs before paragraph 6.2.4:

" evaluate the quality of biosimilar medicines, derived from biotechnologies, to develop the evaluation of analytical methods, the characterisation and knowledge of medicines derived from biotechnologies, and to ensure that the effects of reference products are fully equivalent in terms of effectiveness, quality and security;"

" strengthen the role of the European Directorate for the Quality of Medicine and HealthCare (EDQM) by mandating it to certify processes for the certification of biological medicines with a view to approving sites producing biosimilar medicines and by proposing to add to the International Non-Proprietary Names (INN) the place, the laboratory and the manufacturing process;"

Explanatory note

These two paragraphs address the specific case of new medicines manufactured by biotechnological procedures, which some people would treat in the same way as generic products whereas the manufacturing process is of vital importance. It guarantees the primacy of public health interests, as indicated in the title of this report.

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