Policy development: from research to policy and practice

OC - (8431) - CLINICAL RESEARCH AND SUSTAINABLE DEVELOPMENT IN SUB-SAHARAN AFRICA: THE IMPACT OF NORTH-SOUTH PARTNERSHIPS

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1 - European Medicines Agency

Background

The European legislation introduced in 2004 (under article 58) a collaboration tool to increase access to high quality and effective medicines in low-and middle-income countries. The European Medicines Agency can provide scientific opinions on medicines intended for significant public health needs, in partnership with the World Health Organisation (WHO) and the relevant ‘target’ non-EU regulatory authorities. This EU-Medicines4all (EU-M4all) initiative contributes to the broader Global Health Mandate of the EU.

Methods

We contacted the pharmaceutical companies holding ‘article 58’ scientific opinions and compiled the number of actual approval based on these opinions.

Results

Nine medicines have been assessed so far, most of them for HIV/AIDS, tuberculosis, malaria and maternal/new-born health. Although this figure may appear low, the impact of the corresponding scientific opinions is much wider. Approvals were granted in 66 different countries worldwide, 38 of which are in Africa, based on these opinions.

Discussion

Such scientific opinions on the quality, safety and efficacy of the medicines are provided by the EMA’s Committee for Medicinal Products for Human Use (CHMP). Prior to this, it is recommended to agree on the data to be generated through scientific advice. The opinions are based on the same standards as used for those approved for Europe, with considerations for local conditions of use.

To promote reliance on EMA scientific outputs and awareness of the procedure, two training events with regulators from Southern and from Western Africa are organised in partnership with WHO, NEPAD and local regulators in June 2018.

Conclusion

We have shown that this ‘article 58’ procedure has a true impact and we encourage applications by companies developing medicines, aimed to prevent or treat diseases of significant public health interest, to be marketed outside the EU. This will ensure timely access of medicines by patients in target countries all over the world.