World Health Organization

EXECUTIVE BOARD
134th session
Agenda item 9.5

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Report on financial and administrative implications for the Secretariat of resolutions proposed for adoption by the Executive Board or Health Assembly

1. Resolution: Regulatory system strengthening

2. Linkage to the Programme budget 2014–2015 (see document A66/7 http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_7-en.pdf)

Category: 4. Health systems

Programme area(s): Access to medicines and health technologies and strengthening regulatory capacity — Outcome: 4.3 — Output: 4.3.3

Additional links with Categories 1, 2, 3 and 5

How would this resolution contribute to the achievement of the outcome(s) of the above programme area(s)?

This resolution would enhance strengthening of regulatory capacity worldwide to ensure the quality, safety and efficacy of medicines and other health technologies, through: improving assessment tools and their implementation; providing technical support and training to regulatory bodies; providing guidance on evaluation of new product classes; supporting and fostering regional and subregional networks and convergence of regulatory requirements; and strengthening of pharmacovigilance systems. It would also strengthen the WHO prequalification programme and allow prequalification of new classes of medicines.

Safe, effective and affordable medicines and health products are an essential element of universal health coverage, attainment of the Millennium Development Goals, dealing with the growing burden of noncommunicable diseases, and fighting epidemics and pandemics.

Does the programme budget already include the outputs and deliverables requested in this resolution? (Yes/no)

Yes.

3. Estimated cost and staffing implications in relation to the Programme budget

(a) Total cost

Indicate (i) the lifespan of the resolution during which the Secretariat's activities would be required for implementation and (ii) the cost of those activities (estimated to the nearest US$ 10 000).

Current estimates are for a duration of 10 years (2014–2024) for a total cost of up to US$ 250 million. Costs and staffing in relation to this strategy will be included in each of the biennial budgets during the lifespan of the strategy, based on a realistic costing of outputs and deliverables related to the work planned for each of the respective programme budget periods starting with the programme budget for the biennium 2016–2017.

(b) Cost for the biennium 2014–2015

Indicate how much of the cost indicated in 3(a) is for the biennium 2014–2015 (estimated to the nearest US$ 10 000).

Total: US$ 30 million (staff: US$11.5 million; activities: US$ 18.5 million)

Indicate at which levels of the Organization the costs would be incurred, identifying specific regions where relevant.

Costs will be incurred at headquarters, all WHO regional offices and certain country offices.

Is the estimated cost fully included within the approved Programme budget 2014–2015? (Yes/no)

No.

If "no", indicate how much is not included.

US$ 25 million would be required to implement the full scope of this resolution, taking into account, for example, the increased breadth and depth of support to be provided to regional regulatory networks and for global collaboration and information exchange, prequalification of essential new classes of medicines and strengthening of pharmacovigilence.

(c) Staffing implications

Could the resolution be implemented by existing staff? (Yes/no)

No.

If "no" indicate how many additional staff – full-time equivalents – would be required, identifying specific regions and noting the necessary skills profile(s), where relevant.

A total of 18 additional full-time equivalent staff members in the professional and higher categories would be needed (headquarters: three full-time equivalents; regional and subregional offices: two full-time equivalents; regional offices: two full-time equivalents per office; and in the three Intercountry Teams in the African Region: one per team.). These staff should have a background in regulatory expertise, experience working in developing countries and some experience in working in an international environment.

4. Funding

Is the estimated cost for the biennium 2014–2015 indicated in 3 (b) fully funded? (Yes/no)

No.

If "no", indicate the funding gap and how the funds would be mobilized (provide details of expected source(s) of funds).

The gap currently is estimated at US$ 25 million.

This funding gap will be tackled as part of the Organization-wide coordinated resource mobilization plan to deal with funding shortfalls in the Programme budget 2014–2015.

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