

Global strategy and plan of action on public health, innovation and intellectual property

Report by the Secretariat

BACKGROUND

1. The global strategy on public health, innovation and intellectual property and the agreed parts of the related plan of action were adopted by the Sixty-first World Health Assembly,¹ with the final plan of action being adopted by the Sixty-second World Health Assembly.²
2. The World Health Assembly asked for biennial reporting on implementation, in addition to comprehensive evaluation of the strategy after four years.³ Furthermore, the Health Assembly requested the Director-General “to conduct an overall programme review of the global strategy and plan of action in 2014 on its achievements, remaining challenges and recommendations on the way forward to the Health Assembly in 2015 through the Executive Board”.⁴
3. In its report to the Executive Board at its 133rd session,⁵ the Secretariat proposed an approach of combining the evaluation and the overall programme review into a single instrument and provided additional information on the scope, modalities and process for the combined exercise.
4. Building on the discussions on this subject at the 133rd session of the Executive Board, the Secretariat presented to the Executive Board at its 136th session a proposal⁶ for a process and timeline for the comprehensive exercise (combining the evaluation and the overall programme review) that would foresee presentation of the evaluation report to the Health Assembly in May 2017.
5. Having considered the report, the Executive Board decided by decision EB136(17) to recommend to the Sixty-eighth World Health Assembly to extend the deadline of the overall programme review to 2018. It further requested the Director-General to provide a report to the Sixty-eighth World Health Assembly on options, in consultation with Member States, for the conduct

¹ Resolution WHA61.21.

² Resolution WHA62.16.

³ See document WHA61/2008/REC/1, resolution WHA61.21, Annex, paragraph 41.

⁴ Resolution WHA62.16, paragraph 6.

⁵ Document EB133/7.

⁶ Document EB136/31.

of the comprehensive evaluation and the overall programme review, including whether to combine the two instruments, sequencing, terms of reference, timing and options for establishing an evaluation management group with the goal of completing this exercise by 2018.

6. In response to that request, this paper outlines options for the following:

- (a) combining the two instruments, including terms of reference, timelines and process;
- (b) undertaking the comprehensive evaluation and overall programme review separately in a staggered manner, including terms of reference, timelines and processes for each of these instruments;
- (c) establishing the evaluation management group in support of the comprehensive evaluation.

7. Although the biennial reporting requirements are well defined, there is no specific guidance in the global strategy and plan of action on how to conduct the overall programme review and the comprehensive evaluation. For the purposes of this paper, the broad definitions described below are proposed for (i) the comprehensive evaluation and (ii) the overall programme review.

8. The comprehensive evaluation will comply with the WHO evaluation policy and be guided by the processes and methodology proposed in the *WHO evaluation practice handbook*.¹ In the current context, this evaluation is envisaged as a formative evaluation i.e. an evaluation conducted during the implementation phase of the global strategy and plan of action, with the intention of documenting achievements, gaps and remaining challenges and of making recommendations on the way forward.

9. The overall programme review will be a more policy-oriented, forward-looking exercise. Using specific terms of reference, the programme review will consider the findings of the comprehensive evaluation, together with other technical and managerial aspects of the programme, with a view to identifying what needs to be improved and modified in the next stages of the global strategy and plan of action. The programme review will add a broader policy perspective to the assessment, but it will not apply the methodology of an evaluation. Furthermore, while it will also seek to undertake an assessment of implementation of the global strategy and plan of action (both success factors and challenges), it also offers possibilities for broader engagement of different stakeholders at various stages of the process.

OPTIONS FOR CONSIDERATION

Combining the two instruments

10. As noted above, a suggested approach to combine the two instruments and terms of reference for such an exercise were outlined in document EB133/7. This was further elaborated in the proposal for a process and timeline set out in the Secretariat's report to the Executive Board at its 136th session (document EB136/31).

¹ WHO evaluation practice handbook. Geneva: World Health Organization; 2013.

Undertaking the comprehensive evaluation and overall programme review separately in a staggered manner

11. The approach for undertaking the comprehensive evaluation and overall programme review separately in a staggered manner, starting with the evaluation and following with the programme review, is presented below. It is further illustrated in Annex 1.

Terms of reference of the comprehensive evaluation

12. The overall purpose of the comprehensive evaluation is to assess the status of implementation of the eight elements of the global strategy:

- (a) prioritizing research and development needs
- (b) promoting research and development
- (c) building and improving innovative capacity
- (d) transfer of technology
- (e) application and management of intellectual property to contribute to innovation and promote public health
- (f) improving delivery and access
- (g) promoting sustainable financing mechanisms
- (h) establishing monitoring and reporting systems.

13. Covering the period 2008–2015, the evaluation would document achievements, gaps and remaining challenges and make recommendations on the way forward. It would also inform the overall programme review.

14. The scope of the evaluation would cover implementation of the eight elements of the strategy itself and the 108 specific actions defined in the action plan. It would look at such implementation by all stakeholders listed in the action plan at different levels (global, regional and national), including looking at implementation by national governments, the WHO Secretariat and other relevant stakeholders.

15. The evaluation would comply with the WHO evaluation policy. It would be commissioned and managed by the WHO Evaluation Office, supported by an ad hoc evaluation management group.

16. The evaluation would be conducted by an external independent evaluator, selected through an open tender. The evaluator would be an independent external organization or team with appropriate knowledge of the subject of the evaluation and skill mix, as well as relevant experience in performing evaluations involving innovation strategies in public health and access to medical products and technologies.

17. The evaluation would be conducted using a combination of methods in order to answer the evaluation questions adequately, including: a review of available literature; use of existing data and

information from various existing sources; collection of qualitative and quantitative data, including through questionnaires to stakeholders listed in the action plan; and country case studies as appropriate. The evaluation methodology will be further elaborated by the evaluation team in its inception report and discussed with the ad hoc evaluation management group. The salient points of the inception report and comments from the evaluation management group will be included in the report of the Secretariat to the Executive Board at its 138th session.¹

18. The evaluation team would conduct the analysis and deliver a report setting out its findings, including recommendations. The Secretariat would provide the necessary support to the evaluation team during the evaluation exercise.

19. It is proposed that the process for the comprehensive evaluation is initiated shortly after the Sixty-eighth World Health Assembly in June 2015, with the final evaluation report presented to the Executive Board in January 2017 for forwarding to the Health Assembly in May 2017.

Role and composition of the ad hoc evaluation management group

20. In view of the scope and complexity of this evaluation, and in line with the WHO evaluation policy, an ad hoc evaluation management group would be convened to assist in selecting the evaluation team, reviewing the evaluation inception report and the draft evaluation report, and ensuring that the final draft meets appropriate quality standards. The evaluation management group would be kept informed of progress and should be available to respond to queries from the evaluation team. As the evaluation process progresses, the evaluation management group may refer additional ideas and provide suggestions to the evaluation team for consideration.

21. Options for consideration concerning the composition of the ad hoc evaluation management group include:

- (a) six independent external experts (four subject matter experts and two evaluation specialists);
- (b) the six Officers of the Executive Board (the precedent for this is the evaluation management group for the stage two evaluation of WHO reform);
- (c) 12 independent external experts (all subject matter experts; identified from a pool of experts proposed by Member States, representing all six regions) and two evaluation experts from the United Nations Evaluation Group;
- (d) a combination of options (a) and (b), i.e. six independent external experts and the six Officers of the Executive Board.

Terms of reference of the overall programme review

22. The overall programme review will be a more policy-oriented, forward-looking exercise. The programme review will consider the findings of the comprehensive evaluation, together with other

¹ In addition, a progress report on implementation of the global strategy and plan of action will be presented to the Executive Board at its 138th session.

technical and managerial aspects of the programme, with a view to identifying what needs to be improved and modified in the next stages of implementation of the global strategy and plan of action. The programme review will add a wider perspective to the assessment by looking at the broader political and policy environment influencing the implementation of the global strategy and will make recommendations on the way forward. A key characteristic of the programme review is that it would actively engage relevant stakeholders during various stages of the process, including all stakeholders identified in the global strategy and plan of action: Member States, the WHO Secretariat, other intergovernmental organizations such as UNCTAD, WIPO and WTO, and other relevant stakeholders.

23. Different models for conducting programme reviews exist in WHO, and these cover different levels of complexity; examples include the mechanisms for review of the International Health Regulations (2005). For the overall programme review for the global strategy and plan of action, the model described below is proposed for consideration.

24. The overall programme review would be conducted by a panel of experts with a broad mix of expertise, practical experience and backgrounds covering the eight elements of the strategy, including experts from developed and developing countries (options: (a) independently identified by the Director-General without inputs from Member States, or (b) identified by the Director-General from a pool of experts proposed by Member States). In either case, adequate regional representation would be ensured.

25. Building on the high-level objectives of the review, more detailed terms of reference would be developed. The terms of reference and composition of the programme review panel would be presented to the Executive Board at its 140th session in January 2017. The review panel would elaborate its method of work and conduct a major portion of its work through plenary meetings at WHO headquarters. It would be supported by a small secretariat working closely with the Evaluation Office.

26. The panel would review documents and hear evidence from individuals representing all stakeholders identified in the global strategy and plan of action: Member States, the WHO Secretariat, other intergovernmental organizations such as UNCTAD, WIPO and WTO, and other relevant stakeholders. The panel may also seek broader inputs to the process through a public hearing and web-based consultations. As deemed necessary, the review panel may undertake country and site visits. Furthermore, the panel's deliberations would be informed by the report of the comprehensive evaluation undertaken by the external evaluation team.

27. It is proposed that the process for the overall programme review starts in November 2016. A progress report will be presented to the Seventieth World Health Assembly in May 2017, and the final report of the comprehensive review, which will be presented to the Executive Board at its 142nd session in January 2018 and to the Seventy-first World Health Assembly in May 2018, will make specific recommendations on the way forward for implementation of the global strategy and plan of action until 2022.

ACTION BY THE HEALTH ASSEMBLY

28. The Health Assembly is invited to note the report and to take a decision on the options for the conduct of the comprehensive evaluation and the overall programme review of the global strategy and plan of action on public health innovation and intellectual property.

ANNEX

PROPOSED TIMELINES AND LINKAGES BETWEEN THE COMPREHENSIVE EVALUATION AND OVERALL PROGRAMME REVIEW

