Proposal Name: Consideration of an Essential Health and Biomedical R&D Treaty


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<th>Please provide a description of the proposal (up to 500 words):</th>
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<td>The attached is a joint submission on the topic of the proposal before the WHO Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) on a possible essential health and biomedical R&amp;D treaty, an issue that has been discussed in the CIPIH Report, the WHO Global Strategy and Plan of Action (GSPOA), and in several submissions to the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property and the previous WHO Expert Working Group on Research and Development Financing (EWG), including but not limited to the submission to the EWG by the governments of Bangladesh, Barbados, Bolivia and Suriname.</td>
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<td>Our proposal is for countries to begin negotiations for such a treaty without delay, and under the auspices of the World Health Organization, which is mandated by its Constitution to propose such international agreements. Our submission outlines a proposed set of principles and goals that we believe should guide such negotiations, and suggests the key elements that should be contained in such a treaty. While important details would need to be negotiated among Member States, we believe these principles and elements provide a sound foundation from which to begin such negotiations.</td>
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<td>The rationale for the development of the Treaty is outlined in section I of the submission. We call on the CEWG to propose a process for taking this work forward with Member States.</td>
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<th>Describe and justify the potential public health impact of the proposal:</th>
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<td>The proposal to develop an essential health and biomedical R&amp;D Treaty would have a huge impact on public health, in that its aim is to create a new global framework for supporting priority medical research and development that is based upon the equitable sharing of the costs of research and development and incentives to invest in needs driven research and development. The proposed treaty would provide the framework for ensuring that sufficient, regular, predictable and sustainable financing for R&amp;D for type I, II and III diseases is secured; and that mechanisms to facilitate health needs assessment, priority setting and the assessment of funding needs are developed and operationalised.</td>
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<td>Please see Section IV of the submission for further details on the public health impact of this proposal.</td>
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<th>Describe and justify the technical feasibility of the proposal:</th>
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<td>Our proposal is for negotiations on an essential health and biomedical R&amp;D Treaty to be opened. This would involve the facilitation of negotiations by the WHO and active participation from member</td>
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states. As the scope of the Treaty would be decided in the process of these negotiations and not before, it is not possible to outline the exact feasibility of the creation of the Treaty, since this will depend on the form it will take.

Describe and justify the financial feasibility of the proposal:

As with the above question, the financial feasibility of establishing the Treaty would have to be considered once negotiations on the shape and form of the Treaty had taken place. However, the establishment of such a Treaty must be seen in light of the WHO’s mandate as outlined in its constitution, which states that in order to achieve its objectives, the functions of the Organization shall be:…(k) to propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective...\textsuperscript{ii}

Describe in what way the proposal addresses cross-cutting issues:

Developing an essential health and biomedical R&D treaty would ensure that criteria 9 on ‘Equity/distributive effect including on availability and affordability of products and impact on access and delivery’, and criteria 11, ‘the Impact on capacity building in, and transfer of technology to, developing countries’ were met. As outlined in section IV, element 3 of the attached proposal, the Treaty would secure financing for ‘R&D that results in quality health products that are accessible, affordable, acceptable and appropriate for the target populations… [and]…Initiatives that build and strengthen the local R&D capacity of developing countries.’

Criteria 8, on the ‘Potential for de-linking R&D costs and price of products’, is covered extensively in the proposal.

In terms of criteria 10 on accountability, the Treaty’s aim is to establish the politically and financially sustainable institutional arrangements that are necessary to ensure sufficient global investment in medical R&D, fair arrangements for burden-sharing, efficient knowledge-sharing for scientific progress, and equitable access to the fruits of scientific progress. In this way it provides accountability at every level. As outlined under section IV on ‘elements’, the proposed Treaty must also ensure transparency and openness.

The proposal is synergistic with all proposals to enhance the funding of priority medical R&D and address the de-linkage of the cost of R&D and the price of products, since it is an overarching proposal that would provide a framework for R&D financing and coordination.

Identify key steps necessary to begin implementation and key issues to be resolved for implementation to begin:

As stated above, the proposal submitted by the above named groups is for the members of the CEWG to establish a process for the initiation of member state negotiations on an essential health and biomedical R&D Treaty. Such negotiations would be facilitated by the WHO and led by WHO member states.

Provide the evidence base for the proposal including literature references and other relevant information:

4. Colleen Daniels, Health Action International Europe Submission to the World Health


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1 WHO Constitution, Article 2(k): “In order to achieve its objective, the functions of the Organization shall be:...(k) to propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective;” Article 19: “The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes.”

ii ibid