World Health Organization

DEVELOPING COUNTRIES VACCINE REGULATORS' NETWORK (DCVRN)

TERMS OF REFERENCE

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Endorsed	

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1. Preamble

Recent decades have been characterized by an increasing number and complexity of vaccines, many of which are intended to address transmittable diseases in low and middle income countries (LMICs).

Although most Phase 1 clinical trials are conducted in the country of manufacture, it has been recognized that LMICs are increasingly likely to be the site of Phase 2 and 3 trials. At the same time, many of these countries have been challenged to undertake the regulatory oversight of vaccine clinical trials, underscoring the need for regulatory strengthening and collaboration efforts.

In the face of this situation, the World Health Organization (WHO) proposed the establishment of a global network of regulators that would focus on strengthening the regulatory oversight of clinical trials. This gave origin to the Developing Country Vaccine Regulators' Network (DCVRN) in 2004 and to the African Vaccine Regulatory Forum (AVAREF) in 2006.

The original goal of the Network was to strengthen the clinical evaluation of vaccines in LMICs by promoting the sharing of knowledge, collaboration among regulators of developing and developed countries, identification of areas in need of strengthening and training and interactions with vaccine developers and experts. While the DCVRN has been successful in strengthening the regulatory capacity and technical knowledge base of member regulatory authorities, and in producing a number of important technical documents including guidelines and templates, members recognized the need to introduce some important changes to the Network to enhance its relevance and value to members and stakeholders.

Acknowledging that the political and resource commitment of high level management of member regulatory authorities is key to the growth and sustainability of the DCVRN, the level of interaction among members and other stakeholders should be optimized to increase the impact of the Network. The scope of products and regulatory activities should be expanded in a step-wise fashion from vaccines to other medical products addressing public health priorities and over the product life cycle while avoiding duplication of effort with other existing regulatory networks. The deliverables of the Network should be tangible products that are of high value to the regulatory community. The members agreed to revise the Terms of Reference (TOR) of DCVRN as reflected in this document.

It is envisaged that further changes to the TOR may be warranted in the future to ensure that they respond to changes in the global regulatory environment.

2. Vision

"To be an international platform for promoting regulatory excellence and cooperation to facilitate the availability of safe and effective medical products of assured quality."

3. Mission

a) To support and promote the strengthening of effective regulatory oversight during the product lifecycle of medical products in developing countries.

b) To strengthen and promote active collaboration and convergence between member NRAs.

c) To support the WHO, other NRAs and regulatory networks, and strengthen engagement with stakeholders, including medical product developers.

4. Scope of the network

The DCVRN will expand its responsibilities and activities from vaccines, in a step-wise manner, to include a broader range of medical products used for the diagnosis, prevention and treatment of diseases that are a public health priority in developing countries.

5. Objectives

- Promote the harmonization/convergence of regulatory practices, policies, guidelines and technical requirements among members of the Network.

- Develop policies and practices to optimize timelines and enhance quality of regulatory functions with special focus on evaluations of clinical trial applications, registration applications and pharmacovigilance of medical products in member countries while ensuring that there is no duplication of efforts with existing regulatory networks.

- Create a forum for discussion on scientific issues on medical products to support regulatory decisions in members' countries.

- Create an environment for continuous learning and discussion on best regulatory practices.

- Promote productive interactions between members and supporting NRAs and affiliate organizations.

    - Seek opportunities for observership at working groups of other organizations on behalf of the Network.

- Seek opportunities for participation on a regular basis to meetings of manufacturers' associations and others affiliate organizations on behalf of the Network.

- Avoid overlap with the mandate of other networks.

- To support, strengthen and mentor non-member developing country NRAs.

- Promote the Network through publications and proactive advocacy.

6. Bodies of the Network

The bodies of the Network are:

a) The Steering Committee.

b) The Technical Coordination Committee.

c) The Secretariat (i.e. WHO).

A. Steering Committee

Composition

The Steering Committee (SC) shall consist of all members of the Network, represented by the Heads of Agencies. Should the Head of Agency not be able to represent the National Regulatory Authority (NRA) at the DCVRN, he/she must designate a delegate who will be well informed and have the authority to make decisions on behalf of the NRA with respect to the Network. Members should ensure consistency in representation.

A Chair and Vice-Chair of the SC will be elected from the committee members and will serve for a period of two years. Elections will be staggered by one year. Chair and Vice-Chair can be re-elected once.

Decision-making

The SC shall adopt all its decisions by consensus. The members shall, in good faith, attempt to reach consensus, assisted by the Chair and Vice-Chair.

Mandate

The role of the SC is to oversee the operational aspects on behalf of all members and it is the decision-making body of the Network. The competence of the SC is primarily in the area of policy, administrative and financial matters.

The SC shall be responsible for:

i. Providing direction, oversight, and accountability for DCVRN, and monitor the performance of the Network, specifically the attainment of its objectives and expected outcomes;

ii. ensuring that decisions on development of DCVRN harmonized guidelines or adoption of existing harmonized guidelines, templates and procedures, as well as recommendations related to best practices, are communicated to and used by members;

iii. determining the host for DCVRN meetings, approving the agenda and list of participants;

iv. endorsement of the Network's multi-year work plan and development of strategic plan;

v. approving all financial matters, including annual budget and financial contributions;

vi. approval of sub-committees, working groups and task forces;

vii. exercising oversight of the TCC, working group and sub-committee process and operations to ensure the efficiency, timeliness and quality of work undertaken;

viii. endorsing technical recommendations from the TCC for adoption of new projects/topics;

ix. endorsing completed projects and withdrawal of projects;

x. acting as a liaison with other international regulatory networks;

xi. designating any persons to represent the Network vis-à-vis third parties;

xii. providing direction to and monitoring the performance of the Secretariat, including with respect to the scope of work, duties and responsibilities;

xiii. adoption and amendments of the TOR of the Network;

xiv. approval of new members and candidate members; and

xv. any other issues not explicitly reserved for other bodies of the Network.

B. Technical Coordination Committee

Composition

The Technical Coordination Committee (TCC) is composed of one representative from the NRA of each of member country, nominated by the Head of Agency, that are selected based on their expertise and experience in the regulatory functions that are relevant to the Network's scope and objectives. Ideally, the same persons will be part of the TCC for a period of two years to ensure

continuity. Should this not be possible, the appointed representative shall make sure that another staff from the NRA will attend the TCC meetings in their place and shall be properly informed on the ongoing projects.

Mandate

The TCC serves as a standing sub-committee of the SC, providing advice and guidance on all matters related to scientific and technical issues.

More specifically, the TCC performs the following functions:

i. identifies the needs related to the development of guidance documents, procedures and training through consultation among TCC members; each TCC member should keep their Head of Agency informed of the work of the Committee;

ii. prepares a proposal for the annual workplan and presents it to the SC;

iii. develops the agenda for scientific meetings, based on the endorsed workplan, product development pipelines, new technical guidelines and other topical scientific issues of interest;

iv. works with topic experts on the development of new work proposals; and

v. coordinates and oversees the work of technical working groups and task forces established as per decisions by the SC.

C. The Secretariat

Mandate

The Secretariat (i.e. WHO) shall report to the Chair of the SC or to a designated Member of the Committee. The Secretariat shall be responsible for the day-to-day management of the Network and, subject to the determination of signatory powers by the SC, represent the Network vis-à-vis third parties. The Secretariat shall assist the SC to prepare budgets, plans and reports, coordinate the activities of the Network, support any established sub-committees or working groups, and otherwise carry out the directives of the SC.

The following responsibilities have been identified for the Secretariat:

i. provide support to the SC and TCC as required;

ii. provide technical support and facilitate meetings of the SC, TCC and working groups;

iii. convey WHO priorities and recommendations to the SC and TCC for consideration;

iv. support the SC in the fulfilment of its roles and responsibilities by providing the information needed to support decision-making;

v. facilitate communication among members of the Network, publication of a newsletter, and sustain the network's website;

vi. facilitate activities coordinated by the TCC, such as the joint reviews, inspections and training organized through designated centers;

vii. facilitate the development of policies and procedures to be used by members of the Network;

viii. assist in advocacy, fundraising and financial planning to allocate funds to the planned activities. An annual financial report will be presented to the SC;

ix. develop an annual report that includes a description of the annual workplan and strategic plan;

x. maintain regulator contact with all bodies of the Network. In addition, the Secretariat will be the contact point for all communications with external stakeholders;

xi. organize and provide administrative support for DCVRN meetings, working groups and other joint activities agreed upon by the SC;

xii. establish a central repository of information and documents relevant to DCVRN;

xiii. create and maintain a contact list of members, affiliate organizations and other relevant parties;

xiv. arrange the review of documents as requested by the Network;

xv. edit, finalize and distribute the final full reports of scientific sessions, procedures or guidance documents produced by DCVRN to members, and redacted reports to other stakeholders;

xvi. communicate to the Network any request for technical assistance from member and non-member countries and facilitate the delivery of this support; and

xvii. receive and inform DCVRN of notices of termination of membership or inclusion of new members, as well as changes in representation from member countries.

D. Technical Working Groups

Although not a permanent body of the Network as the SC or the TCC, technical working groups may be created to address specific issues as needed. This will be coordinated by the TCC and supported by the Secretariat as the need arises. Different issues related to the regulatory aspects for medical products may require the establishment of ad hoc groups of experts.

Proposals to establish working groups or task forces must be described in the form of a concept paper that describes the problem statement, objectives, deliverables, estimated resources and timelines. The concept paper/business plan is submitted to the SC for consideration and approval

7. Membership

(a) Members

To be eligible to serve as a Member, the candidate NRAs must: a) submit an official application, b) meet membership criteria as determined by the SC, and c) be endorsed by the SC.

Should a member wish to withdraw their membership, the Head of Agency should inform the Secretariat in writing.

To be considered for membership, candidate NRAs must:

i. support the aims, principles and policies of the Network;

ii. commit to adopt and implement the use of the products of the Network, including guidelines, templates, procedures and recommendations related to best practices;

iii. attend all SC meetings;

iv. exercise the duties and expectations of an SC member;

v. act in good faith when exercising their rights;

vi. be operating at least at maturity level 3 against all regulatory functions as determined by WHO, or commit to reach this level within 5 years (see Annex on maturity levels); and

vii. oversees the manufacturing of medical products including as a minimum, licensed vaccines.

(b) Affiliate organizations

The Network may recognize affiliate organizations based on the following considerations:

I. represents an organization or institution that supports the mission, mandate and objectives of DCVRN and does not pose a potential conflict to the network;

II. represents an organization or institution that makes a significant and substantial contribution to the attainment of the goals, mandate and objectives of the network;

III. it is endorsed by the SC following an evaluation and recommendation by the TCC following a formal evaluation process.

Affiliate organizations may include other regulatory networks, industry associations, Product Development Partnerships (PDPs), non-governmental organizations involved in the research and development of medicinal products, and donor organizations.

Affiliate organizations are invited to participate in and contribute to the meetings and open sessions of the SC but do not participate in the decision-making process of the Network.

8. Meetings

Meetings will be hosted by members on a rotational basis.

(a) Types of meetings:

i. Meetings of the SC and the TCC. These will take place twice a year, at least one being face-to-face and one of them is a joint meeting of the SC and TCC;

ii. Scientific plenary fora: these will take place once or twice a year, at least one back-to-back with a SC meeting. The forum provides a platform for the discussion of international guidelines, product pipeline developments of interest to the Network, and other scientific issues. Non-member NRAs may be invited to attend these meeting;

iii. Working group meetings: these will take place according to the plan approved by the SC;

iv. Open stakeholder meetings: DCVRN may hold an open meeting with non-member organizations, back-to-back with one of the scientific plenary fora; and

v. Special activities: In addition to the routine meetings, ad hoc meetings may be organized under the authority of DCVRN, including joint reviews of clinical trial applications and training courses (e.g. with support and coaching of the WHO/Global Learning Opportunities).

(b) Attendance to meetings:

Only members of the Network can attend the meetings of the SC and TCC. For open sessions of the SC, the Committee may invite Affiliate Organizations and Supporting regulatory agencies (see description below).

Scientific plenary fora may be attended by Affiliate Organizations, invited observers (see description below) and Supporting Regulatory Agencies.

Working group meetings will be led by TCC members and may be attended by the working group members that have been invited to participate. They may be representatives from member NRAs, invited experts and supporting regulatory agencies.

Open stakeholders meetings can be attended by all categories mentioned in this section.

Special activities may be attended by non-member NRAs, invited experts, Affiliate Organizations and Supporting Regulatory Agencies, by invitation.

Invited observers

This category includes those NRAs that are not members, but the NRA may benefit from the DCVRN open sessions. Participation of the invited observers to a particular meeting remains at the discretion of the Chair and concurrence of the SC.

Supporting regulatory agencies

These are the stringent regulatory agencies that provide technical and regulatory support to DCVRN members at annual meetings and joint review sessions. Supporting Regulatory Agencies are invited to participate in the open sessions of the SC and to voice opinions but do not participate in the decision-making process of the Network. They may also be invited to contribute to scientific sessions and working groups of
Supporting Regulatory Agencies may be invited by the SC.

Invited experts

The Network may invite individual experts with international experience in any of the topics discussed by the DCVRN, to participate on an ad-hoc basis in certain meetings of the Network (or working groups). Invited experts will not be considered as Network representatives, nor have any role in other Network activities.

9. Financial issues

i. Member NRAs must commit to cover the cost of attendance at DCVRN meetings. This budget should cover the airfare, accommodation and per diem.

ii. Member agencies should allocate the necessary human resources and time to perform activities related to DVCRN.

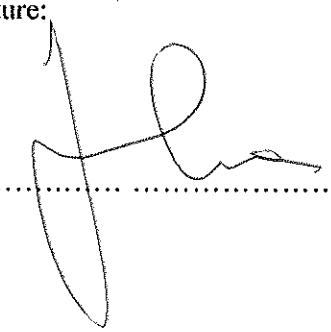
10. Language

All meetings and all documents developed by the Network will be in English.

11. Review of TOR

These TOR will be reviewed annually or as required.

Signature: .....



Date: 20th April 2017