Establishing a Global Coordination Mechanism of R&D to prevent and respond to epidemics – Toward implementation of the GCM

28 March 2017 – Wellcome Trust - *215 Euston Road, London NW1 2BE*

MEETING SUMMARY

EXECUTIVE SUMMARY

The WHO Blueprint convened a meeting in London, UK on 28 March 2017, to advance the establishment of a Global Coordination Mechanism (GCM) for Research and Development (R&D) to prevent and respond to epidemics. The GCM is being established in an effort to improve coordination and to foster an enabling environment for R&D, an objective defined under the R&D Blueprint Plan of Action. The meeting was held at the Wellcome Trust in London, UK, on 28 March 2017. It followed a first scoping meeting which took place at the Chatham House on 10 November 2016, where the need for a GCM was recognized by a group of key R&D stakeholders, including high-level representatives from governmental and non-governmental organizations, and from both the public and private sectors. During the first meeting, it had been agreed that the World Health Organization (WHO) would be responsible for defining the Terms of Reference (ToR) that underpin the establishment and functioning of the proposed GCM. Furthermore, participants had also agreed that data sharing policies, strengthening of regulatory pathways and identification of options to address liability/indemnification in case of deployment of yet unregistered Medical Countermeasures (MCMs) in case of emergency, should benefit from immediate attention from the global R&D community.

This March 28 meeting aimed at reviewing the proposed ToR and governance structure for the GCM, and at discussing how to formally establish the GCM. The meeting also provided an opportunity for participants to review progress in two key R&D areas outlined during the first meeting. In addition, GCM members discussed the specific case of Zika vaccine development as a concrete example of how the GCM could improve coordination and accelerate the development of MCMs and address research gaps in a collaborative manner, one of the proposed function of the GCM.

Consensus was reached that the GCM would be operationalized through a high-level discussion platform (or forum) where elements of the global R&D agenda would be reviewed and addressed collaboratively, and where progress in filling identified R&D gaps would be evaluated by GCM members. Agreed next steps are to complete the

consultation process on the ToR with additional input, finalize the core membership, develop and implement a process through which the GMC will work, and design a mechanism for regular communication among GCM members and to inform the global R&D community of any key discussions or issues.

Reaffirming objectives and key principles

Participants reaffirmed the need for a GCM for R&D to save peoples lives in case of an outbreak due to emerging infectious pathogens, and to avert a public health crisis in a rapid, effective and equitable way. More specifically, the GCM aims to increase global collaboration to reduce the time lag between an epidemic and the availability of MCMs to affected communities. Building on existing initiatives, the R&D Blueprint GCM will provide a coordination platform by convening key R&D stakeholders in order to collectively share strategic directions and investments. Through a consensual voluntary (i.e. non-binding) framework, GCM members will engage into a transparent and evidence-based discussion to address identified R&D gaps, in a collaborative and coordinated manner, in an effort to avoid duplication of efforts and promote research symbiosis.

Seeking the 'right' level of coordinations

To be effective, the GCM must strive towards the "right" dose of coordination. It was noted that the GCM is essential to align various (sometimes divergent) streams of work towards a same goal, which a whole variety of stakeholders are committing to support. However, too much emphasis on coordination may add complexity, inhibit creativity and participation and finally results in an ineffective R&D response. Also, it was noted that an optimal size of membership should be sought in order to increase efficiency of the mechanism. Furthermore, the GCM must ensure to prioritize a global R&D agenda in a way that captures the evolution of knowledge and evidence about priority diseases and potential MCMs. In particular, the two modes of R&D configuration, preparedness and response, require different level of coordination and flexibility to switch between modes and to "expect the unexpected". Epidemic stages can evolve rapidly and it is therefore crucial for the GCM to be able to build trustful relationships between members. In order to establish such trustful relationships in advance of a crisis, parties need to establish solid experience working together, identifying and filling gaps, and sharing information.

GCM: Reviewing Zika Vaccine Development

At a time when the most advanced Zika vaccine candidates will soon Phase 2B clinical trial evolution, the GCM focused on a dialogue among members on potential tools and options to accelerate the development of needed tools to fight the Zika epidemics. Participants in the meeting agreed that the GCM was not designed to issue technical

recommendations, but rather to facilitate interactions between stakeholders (including national decision-makers).

An updated and comprehensive Zika vaccine landscape was presented and reviewed by the GCM members. Discussions were held on how close they match the preferences set by the WHO/UNICEF Zika vaccine Target Product Profile. Challenges associated with vaccine efficacy trial designs were then reviewed and complemented with results from a collaborative modelling exercise to address some of these challenges. The feasibility of the evaluation of multiple vaccines in the context of a fading epidemic was discussed, especially as the role of pre-existing immunity is uncertain. It was further noted that - when used as a preparedness tool - infectious diseases models can help address some of the unanswered research questions before outbreaks occur, notably the contribution of a research intervention used alone or in combination with other interventions.

All presentations underscored the need and importance for high-quality real-time sharing of relevant data, and for clear regulatory pathways.

GCM: Reviewing Data sharing

Research is an essential part of being ready for and responding to public health emergencies. It's critical that any new knowledge is shared in a timely manner in a way that's equitable, ethical and transparent. Wellcome Trust is leading efforts on data sharing. The data sharing working group is developing a strategy for data and knowledge sharing in public health emergencies. It will identify: defining principles and norms; the skills, capacity and tools needed to develop systems for data sharing; incentives that could encourage data sharing and; ethical, legal and governance issues.

In February 2016, a number of global health bodies called for all research data gathered during the Zika virus outbreak, and future public health emergencies, to be made available as rapidly and openly as possible.

All participants noted that all collaborators need to adhere to fundamental ethical principles of data use. It was underlined that, we must ensure that people in all affected countries benefit from timely access to evidence-based interventions in emergencies.

GCM: Reviewing Regulatory pathways

This session discussed the importance to prepare now for regulatory review of vaccine candidates in countries where the next outbreak is likely to occur. Advance agreement on the design of clinical trials that could be used in an outbreak was noted as an important part of the preparedness effort. Likewise involvement on the parameters for a potential clinical trial by regulatory authorities in countries most likely to be affected was also mentioned as important.

Participants noted the WHO Secretariat efforts in facilitating regulatory convergence and support to national regulatory authorities to develop consensus on regulatory pathways that would allow the development and registration of candidate vaccines. Participants noted that communication between manufacturers of candidate vaccines and regulatory experts early on to proactively engage about licensure requirements is welcomed and necessary.

Terms of Reference – general comments

Terms of Reference (ToRs) were sent to participants before the meeting and then collectively reviewed during the meeting. It was agreed that ToRs should be seen as a guiding document for GCM principles and members responsibilities. The WHO R&D Blueprint Secretariat underscored that the GCM should be co-owned by members.

Scope

The initial focus on the priority pathogens for the R&D Blueprint was widely accepted. For each pathogen, a specific R&D roadmap will identify R&D gaps, define strategic goals and key priorities to support the development of MCMs and to accrue important new knowledge (e.g. on epidemiology, transmission pathways, social sciences). Attention should also be brought to the need for adaptability as it is possible that the next outbreak could be caused by a completely new pathogen.

Delivering Research

The GCM's overarching goal is to reduce the time lag between the onset of an epidemic and the availability of MCMs for those in need. It was noted that R&D failures exist along the path from discovery to delivery, and that the GCM must be attentive of communities' and countries' needs and aware of risks and benefits associated with research. Close interaction with countries and non-governmental organizations present in the field was deemed essential to set the stage for a range of research interventions.
In particular, good participatory practices and adequate community engagement approaches must be agreed upfront with countries at-risk, to better capture the communities' needs and facilitate the delivery of research to the affected populations and the design of research interventions. Lessons learnt from field experiences during Ebola, MERS, and Zika epidemics are essential and shall be leveraged for future interventions. National research capacity building will also be essential for countries to be able to participate in the global research response. Strengthening national regulatory authorities and ethics review committees will be crucial to reinforce the role of national authorities in protecting the affected communities.

Responsibilities

GCM members will share with the WHO R&D Blueprint Secretariat responsibility for GCM objectives and outcomes. Membership is voluntary and members are expected to facilitate, as much as possible, work undertaken by dedicated GCM working groups. The WHO R&D Blueprint Secretariat's role would not be to coordinate members but to serve as a hub for facilitating interaction and forging consensus. The Secretariat will be in charge of convening members to the annual meeting, and of activating an "emergency" mode upon members' request. Lastly, the WHO Secretariat will take responsibility for mapping relevant key R&D stakeholders and activities.

Next Steps to finalize the ToRs and to operationalize GCM principles

GCM members agreed to complete the consultation process on the ToRs. Each proposed member will be individually contacted by the R&D Blueprint Secretariat to provide further inputs over the next 3-4 months. GCM members also agreed to take action through the establishment of working groups on the priorities identified during the meeting, and on which focused work will be needed before the 2018 GCM meeting: data sharing policies, strengthening of regulatory pathways, mainstreaming of ethical reviews, identification of options to address liability/indemnification in case of deployment of yet unregistered Medical Countermeasures (MCMs) in case of emergency, and consensus building on pathways for Zika vaccine clinical development. The R&D Blueprint Secretariat will follow up with GCM who have expressed interest in the above topics to facilitate establishment of working groups. The Secretariat will also develop and implement a mechanism for regular communication among GCM members and to inform others in the community of any key discussions. Finally, after consultation with GCM members, the Secretariat will also propose agenda items for the next GCM meeting.