WHO High-level meeting on Ebola vaccines access and financing

Summary report

World Health Organization

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23 October 2014

Introduction

A high-level emergency meeting, convened by the World Health Organization at the request of several governments and representatives of the pharmaceutical industry, was held on 23 October to look at the many complex policy issues that surround eventual access to experimental Ebola vaccines.

Ways to ensure the fair distribution and financing of these vaccines were discussed in an atmosphere characterized by a high sense of urgency. This sense of urgency was conveyed in many ways – from plans for the different phases of clinical trials to be performed concurrently rather than consecutively, to suggested partnerships for expediting clinical trials, to proposals for getting all development partners moving in tandem and at the same accelerated pace.

More than 90 participants, including some of the world's leading scientists, came, on short notice, from national and university research institutions, also in Africa, government health agencies, ministries of health and foreign affairs, national security councils, and several offices of Prime Ministers and Presidents. Also represented were national and regional drug regulatory authorities, the MSF (Doctors Without Borders) medical charity, funding agencies and foundations, the GAVI alliance for childhood immunization, and development banks, including the African Development Bank, the European Investment Bank, and the World Bank Group.

Main conclusions reached

- **Impact of vaccines on further evolution of the epidemic**
  The meeting concluded that vaccines will have a significant impact on the further evolution of the epidemic in any scenario, from best-case to worst-case.

- **Financing of vaccine development, clinical trials, and vaccination campaigns**
  The meeting concluded that funding issues should not be allowed to dictate the vaccine agenda. The funds will be found.

- **Liability**
  The meeting concluded that neither affected countries nor industry should be left alone to bear the burden should lawsuits arise following possible adverse reactions to an Ebola vaccine. To respond to this potential problem, a proposal was made to establish a "club" of donors, in collaboration with the World Bank.

- **The timing and quantity of vaccine supplies**
  The meeting concluded that the timing and quantity of vaccine doses should not constrain the design of clinical trials. Industry confirmed that enough vaccine doses would be available.

  GlaxoSmithKline's monthly production capacity for purified bulk vaccine was expected to rise from the current figure of 24,000 doses to 230,000 by April 2015, if they can be filled for release. NewLink's bulk vaccine manufacturing capacity for the Canadian vaccine was noted to vary, according to the dose selected, from 52,000 doses to 5.2 million doses anticipated for the first quarter of 2015.

- **Design of protocols for phase 2 and phase 3 clinical trials**
  The meeting concluded that randomized controlled clinical trials were the gold standard in terms of yielding reliable scientific data for the analysis and interpretation of efficacy. A stepped-wedge design could also yield useful and meaningful data during the special circumstances of the current epidemic.

- **Priority uses of vaccine when supplies are limited**
  The meeting concluded that health care workers, including medical staff, laboratory staff, burial teams, and facility cleaners, should have first call on vaccine doses while supplies remain limited. Vaccination of health care workers in the three countries was judged feasible during the first quarter of 2015.

- **Regulatory requirements**
  The meeting concluded that the licensure and authorization requirements of regulatory authorities should be streamlined and harmonized, enabling the rapid introduction of vaccines for clinical trials and general distribution, yet with no compromise of scientific standards. In order to deliver the number of doses on the schedules proposed by the manufacturers, regulators must work closely with the manufacturers to find ways to overcome a number of regulatory hurdles.

- **Urgent measures to improve readiness for clinical trials and vaccines**
  The meeting concluded that two preparatory measures should be given the most urgent priority: community engagement and social mobilization to prepare populations to understand and accept clinical trials and vaccination campaigns, and the building of basic public health infrastructures, especially given the considerable logistical challenges facing health services in Guinea, Liberia, and Sierra Leone.

- **Coordination and alignment among multiple partners**
  The meeting concluded that a mechanism or framework must be urgently established, relying on WHO's convening and coordination powers, to get all partners working in tandem, according to a single agreed plan and aligned with industry's "critical paths" analysis.

- **Determination to finish the job**
  The meeting concluded that all efforts to develop, test, and approve Ebola vaccines must be followed through to completion at the current accelerated pace, even if dramatic changes in the epidemic's transmission dynamics meant that vaccines were no longer needed.

  Several arguments supported this decision. First, a booster vaccine may prove essential; industry is willing to use vaccines from different companies in the same clinical trials to test the impact a booster dose may have on the duration or degree of protection. Second, as some – perhaps even all – vaccines may fail, the more products in the pipeline, the greater the safety margin. Finally, as a contribution to global health security, fully licensed and approved vaccines should be stockpiled in readiness for the next Ebola outbreak. Moreover, the transformational changes in thinking about preparedness and developing innovative ground-breaking new solutions, so evident during the meeting, would hold the world in good stead when the next new infectious disease inevitably emerges.

Overview of the meeting's discussions

Participants heard a number of progress reports from leading investigators undertaking or planning safety and immunogenicity trials, in human volunteers, of the two most promising vaccines. Plans to conduct phase 2 and phase 3 trials concurrently, to test whether the vaccines confer protection, were also described in detail, as were the reasons why these trials will need to be conducted in both affected and non-affected countries in West Africa. As noted, populations in West Africa were more likely to suffer from undernutrition and infection with multiple diseases, both of which can suppress immune responses, than their counterparts in Europe and North America.

The Chief Executive Officers of three pharmaceutical companies openly shared the development status of their Ebola vaccines, explained how the vaccines were designed to work, and gave estimates of their production capacities, month-by-month from now to end-2015.

These companies also identified several specific problems they face when aiming to produce safe and effective vaccines, in sufficient quantities, under the current emergency conditions. Their presentations demonstrated a spirit of creative innovation at a level of intensity that matches that of this extremely deadly, large, long, broadly disruptive, and complex epidemic, with is showing strong potential to spread to new countries. They also showed a willingness to set aside proprietary interests and join forces in order to make the best use of all existing resources.

As some vaccines may need a booster, industry expressed its readiness to study vaccines from different companies in the same trials. Moreover, advances for one vaccine should be regarded as advances for all. Despite this

sense of urgency and emergency, the need to adhere to standard ways of working was repeatedly emphasized.

“Pursue all vaccines until they fail”
The principle of “pursuing all vaccines until they fail” was put forward as a wise way to maintain momentum in responding to an emergency of this scale. Representatives from industry acknowledged the investment risks they are willingly undertaking despite knowledge that a vaccine might fail or not be needed in the end.

Investigators estimated that preliminary data on safety and immunogenicity, needed to define the right protective dose, would be available by December for vaccines currently undergoing clinical trials. Depending on the outcome of these phase 1 trials, Ebola vaccines could be available, in quantity, for phase 3 efficacy trials, also in West Africa, by January of next year.

As was clear during the meeting, the world’s scientific, pharmaceutical, regulatory, and public health communities are aiming to achieve, in less than 6 months, what normally takes from 2 to 4 years to do, with no compromise of international standards for vaccine safety and efficacy. As observed in side-line discussions during the one-day event, the speed of these trials is unprecedented in the history of modern medicine.

At the same time, many practical and technical hurdles need to be overcome. These very real barriers to wide-scale use of vaccines in the three most severely affected countries were frankly addressed from a variety of perspectives.

A turning point in the discussions
A turning point in the discussions came when industry representatives expressed their need for immediate decisions about recommended and harmonized protocols for clinical trials and detailed evaluations of the operational requirements of these trials. The evaluations would surely identify numerous constraints and bottlenecks; detailed plans for quickly overcoming these problems were needed right now.

On its part, the vaccine industry was working around the clock, seven days a week, to move forward with unparalleled speed. To guide these accelerated efforts, vaccine companies were using a “critical path analysis” to identify day-by-day points on the way forward where critical decisions were needed. A plea was made to others to make some clear decisions about the best designs for clinical trials, among other things. Industry also needed much more detailed operational plans for implementing these trials under very demanding conditions in countries that have literally been torn apart by the high morbidity, mortality, and social and economic upheaval caused by the outbreaks.

Several proposals were made for moving forward through small action-oriented groups that can make these kinds of quick practical recommendations. All agreed: with the first batches of vaccines ready for use

within the next six weeks, countries and their partners must be prepared to use them immediately; supplies cannot be allowed to sit in some warehouse for days or even weeks. Setting up country-specific working groups was one proposal among many. Participants asked that working groups include representatives from the countries and their ministries of health, epidemiologists, WHO staff, representatives of industry, regulatory authorities, and representatives from the donor or sponsoring countries.

In additional striking statements, CEOs of some vaccine companies called for a transformational change in the way the world thinks about preparing for health emergencies, including having essential medical products ready before disaster strikes. Again, new models of collaboration and innovative ways of identifying problems and quickly solving them would leave the global community in a better position to manage similar health emergencies going forward.

Impact of vaccines on further evolution of the epidemic

Different scenarios and results from modelling studies were used to show how vaccines could have a significant impact on the future evolution of outbreaks in the three countries. While a “worse-case” scenario was by no means thought to be inevitable, participants agreed that planning for the worst was a prudent course to follow, especially given the highly unpredictable nature of the Ebola epidemic.

Several speakers stressed the need to tackle the outbreaks with a broad range of interventions, including some specific experimental therapies which are also undergoing intensive investigation. Some suggested that the window of opportunity for containing the epidemic, using “classical” control tools, was closing.

A background paper, submitted by the UK government, expressed the view that, although a range of control interventions should be used, governments and their partners were unlikely to contain the outbreaks without deploying vaccines on a massive scale. The UK further proposed that WHO establish a framework for quickly developing a “backbone” infrastructure to support clinical trials and mass vaccination campaigns, expedite the clinical trial process, with no compromise of protocol design, and deploy additional vaccines for health care workers.

As many speakers stressed, this must be the last Ebola outbreak that takes the African people and their governments by surprise, totally unprepared. As others stressed, this must be the last time that the international community is likewise taken by surprise, with clinicians courageously risking their own lives to save those of others, with no therapies or vaccines in hand.

Financing of vaccine development, clinical trials, and vaccination campaigns

The discussions of financing moved forward quickly: funding issues must not be allowed to drive the agenda; the funds will be found. Vaccine companies said they were using their own money, having invested hundreds of millions of dollars, and did not depend on stimulation from external funds.

MSF announced its plans to establish a special fund to support Ebola vaccine activities. A WHO consortium, established in late August, was another important funding source, drawing support from donations made by the Wellcome Trust, the UK Medical Research Council (MRC), and the UK Department for International Development (DFID). Funds from the consortium were initially used to allow a team from the Jenner Institute at the University of Oxford to begin some of the earliest safety tests of the cAd3-ZEBOV vaccine, and a WHO-coordinated consortium to conduct testing of the rVSV-ZEBOV vaccine.

Other commitments to make the necessary funds available came from a wide range of sources, including individual governments, charities, existing partnerships for financing health development, and development and investment banks.

Officials from GAVI explained the alliance's use of Advance Market Commitments, which can frontload large and predictable funds, and the International Finance Facility for Immunization (IFFIm) as possible models for accelerating the availability and predictability of funds for Ebola vaccines.

Liability

Relevant lessons from the 2009 influenza pandemic were used to clarify the difficult issues of liability and indemnity, which could stand in the way of the most strategic and effective vaccine use, especially in the hardest-hit countries. Participants agreed that neither affected countries nor industry should be asked to be the sole bearers of the burden of this added potential expense. Ways of relieving countries and industry of this responsibility were explored. Priority proposals included the formation of a "club" of donors, in collaboration with the World Bank.

The timing and quantity of vaccine supplies

The two most advanced vaccines

Two candidate vaccines have clinical-grade vials available for phase 1 pre-licensure clinical trials.

One (cAd3-ZEBOV) was developed by GlaxoSmithKline in collaboration with the US National Institute of Allergy and Infectious Diseases. As a vector, it used a chimpanzee-derived adenovirus (a common cold virus) and has an Ebola virus gene inserted.

The second (rVSV-ZEBOV) was developed by the Public Health Agency of Canada in Winnipeg. The license for commercialization of the Canadian vaccine was held by an American company, the NewLink Genetics company, located in Ames, Iowa. The vaccine used an attenuated or weakened vesicular stomatitis virus, a pathogen found in livestock; one of its genes has been replaced by an Ebola virus gene.

The GSK vaccine was currently undergoing clinical trials, in healthy volunteers, in the UK and in Mali. It will enter clinical trials in Lausanne, Switzerland, in the next few days.

The Canadian vaccine was being tested on healthy volunteers in the US. Some 800 vials of the vaccine, donated by the Canadian government, arrived at WHO headquarters in Geneva Tuesday evening. The vaccine will be tested among volunteers at the University Hospital of Geneva and additional volunteers in Hamburg, Germany, Gabon, and Kenya.

Reports from the principal vaccine companies

GlaxoSmithKline: major steps to tighten the timelines

GSK identified sterile filling capacity as the most critical issue. As the vaccine used a genetically modified organism, sterile filling must be done in a biosafety level 2 facility. Only a few companies have this capacity: GSK, Merck, Sanofi, Novartis, IDT, and Emergent. A lifting of the biosafety level 2 requirement by regulatory agencies would relieve some of the constraints.

If alternative sterile filling capacity could not be found, and GSK was forced to use its own capacity to produce an Ebola vaccine, its production of several other essential public health vaccines, including those for rotavirus and measles, mumps and rubella, would suffer. These vaccines protect against some of the world’s biggest killers of infants and young children.

GSK presented several proposals for reducing timelines for the release of the first batches of vaccine for use to protect health care workers in the three countries. The company recommended, for example, that regulatory agencies agree to a single harmonized set of release tests to shrink timelines further.

GSK pointed to the unprecedented challenge of demonstrating the protective effects of a vaccine in the unique situation where trials take place while the incidence rate of a high-morality disease is increasing dramatically and no baseline data exist. In such a situation, vaccine efficacy could be masked by the simultaneous rapid increase in disease incidence, making comparison to any baseline numbers irrelevant. For these reasons, an effective pharmacovigilance surveillance systems was urgently needed now to establish a meaningful baseline.

Importantly, the company had a highly reassuring message: availability of doses should not act to constrain proper trial design; enough vaccine doses would be available for clinical trials.

Phase 1 clinical trials, designed to select a well-tolerated and immunogenic dose, would deliver their most critical information by the last week of November. These trials would give the first indications of safety and the dose needed to trigger a relevant immune response

GSK announced plans to conduct phase 2 and 3 trials in parallel, in non-affected and affected countries, respectively.

Two phase 3 trials were proposed. One was a fully randomized clinical trial in Liberia with two arms: the GSK vaccine and a control vaccine, involving up to 12,000 persons and requiring around 6,000 doses to be administered over 3 to 4 months. The trial could be modified to include the NewLink Genetics vaccine, if available by then, and would thus begin as a three-arm study.

The second phase 3 trial was a cohort trial, with no use of placebo, targeted at health care workers in Sierra Leone. The trial could begin as early as mid-January 2015 with a plan to enrol up to 8,000 subjects and estimated vaccine needs of around 10,000 doses. If trials such as this one could be extended to all three countries, vaccination of all health care workers was considered feasible.

GSK's current and projected manufacturing capacity for purified bulk vaccine was estimated at 24,000 doses per month initially.
As more production lines are activated, totals will rise to 230,000 by April 2015, if they can be filled for release. The company projected that these monthly increases in production capacity will reach more than one million doses by the end of 2015.

The Canadian vaccine: straightforward manufacturing, high-yield, and scalable

The Canadian vaccine, which faces many of the same constraints as the GSK vaccine, was noted to have the advantage of a straightforward manufacturing and purification process. The production yield was high and vaccine production was considered scalable Two indications were currently under investigation: post-exposure prophylaxis and general use prophylaxis; post-exposure prophylaxis would require higher vaccine doses.

Like the GSK vaccine, the Canadian vaccine was a single-dose vaccine. However, side effects should be monitored very closely for a live attenuated vaccine. Even transient fever could be a significant drawback in countries where early diagnosis of multiple diseases, including Ebola, depended on detection of fever. This type of vaccine was also likely to face special regulatory challenges.

As reported, the vaccine's use in special populations, including children, pregnant women, and people with a compromised immune system, including people with HIV/AIDS, was under investigation.

NewLink's anticipated bulk vaccine manufacturing capacity from now to year-end varied, according to the dose selected, from 52,000 to 5.2 million doses. In the first quarter of 2015, these figures were expected to increase to from 125,000 to 12 million doses, again depending on the results of current phase 1 clinical trials. As vaccine roll-out could move very quickly, NewLink underscored the need to act quickly to get clinics, needles, staff, volunteers, and other provisions in place.

Johnson & Johnson: the prime boost vaccine concept

Officials from Johnson & Johnson updated participants on the company's Ad-MVA prime boost vaccine concept, with three vaccine regimens, being developed at its Ebola vaccine programme based in Denmark. Proof of concept had been obtained from a highly stringent study conducted in a non-human primate model. Clinical trials were expected to begin in human volunteers in early 2015. Again, the J&J vaccine encountered many of the same barriers, special problems, and potential needs faced by the GSK and Canadian vaccines

The company was using well-known technologies based on extensive experience in the development and manufacturing of vaccines for other infectious diseases, including tuberculosis, malaria, and HIV. For the Ebola vaccine, human cell lines were being used, and these cells were growing at high fidelity.
Production of an Ebola vaccine could be ramped up to reach around 30 million doses per year. Questions needing answers included the very low storage temperatures to ensure stability, the degree of protection, and the length of time that lasts. The company estimated that clinical trials could being in Africa in May of next year.

Additional vaccines under development
WHO alerted the group to several other vaccines, using different vectors and mechanisms of action, that are currently undergoing development at specific companies, including Protein Science, Inovio and in the Russian Federation. Participants noted that having multiple vaccines in various stages of development was a wise strategy that acknowledged many uncertainties about the power of any vaccine to protect. Some, possibly all, might fail.

Design of protocols for phase 2 and phase 3 clinical trials

If the vaccines are determined to be safe, tens of thousands of doses could be used in West African trials beginning in January of next year to test their efficacy. Randomized controlled trials remain the "gold standard", but many agreed on the appropriateness of using stepped-wedge designs as well.

As outlined in a background paper and in the presentation by GlaxoSmithKine, the US, through its National Institutes of Health and Centers for Disease Control and Prevention (CDC), had undertaken a coordinated and concurrent approach to two phase 3 evaluations. One would be a randomized, controlled trial. The second would be a cluster randomized, stepped-wedge trial. CDC was moving ahead to plan the stepped-wedge trial. The US National Institutes of Health has taken the lead in planning the randomized, controlled trial

As noted by US agencies, selection of a country for the trials must balance questions of feasibility, security, infrastructure for logistical support, and the status of the outbreak. Site selection criteria within affected countries were reported to include an ability to identify and enrol a sufficient study population, the quality of surveillance for disease in health care workers, and the ease of vaccine cold chain logistics, ideally within a four-hour drive from the study site, with secure vaccine storage.

The US further acknowledged that the stepped-wedge trial, although less resource intensive, would require substantial resource, logistical, and personnel support to limit the impact on the existing health care infrastructure. As announced, a field assessment of conditions in Sierra Leone was planned to take place in late October and the first week of November.

Experts from the three countries took a leading role in assessing the readiness, preparedness, and most urgent needs for international support in countries targeted for early administration of vaccines.

Priority uses of vaccines when supplies are limited

Participants generally agreed that health care workers, including burial teams and facility cleaners as well as medical and laboratory staff, should have first call on vaccines, especially now when supplies are strictly limited. In the three countries, the targeting of health care workers was thought to be reasonably acceptable to the general public, who can understand that those who put their lives at risk deserve to be protected first.

Apart from vaccination of frontline health workers, participants discussed the use of “ring vaccination” to surround and contain new foci of infection, also following the importation of cases into new countries. The strategy of ring vaccination was fine-tuned during the WHO campaign to eradicate smallpox, and proved highly effective in limiting further spread of the virus and eventually eradicating it. However, as some pointed out, ring vaccination would work well only in the presence of highly effective contact tracing, which was not presently the case in the three most severely affected countries.

Impediments to vaccine uptake in the three countries, including suspicions of “Western” medicine and vaccines in general, and a high risk of security incidents, were frankly assessed. As participants again stressed, formidable

logistical challenges will need to be overcome, including the fact that some vaccines need to be frozen at very low temperatures to avoid concerns about shelf-life and stability. Several ways of overcoming these challenges were presented and discussed.

In evaluating the priority use of vaccines, participants noted that risk-benefit analyses would be strongly influenced by the different conditions in heavily affected countries, neighbouring countries, countries experiencing low transmission, countries with just a few imported cases, and countries that are currently free of Ebola virus disease.

Regulatory requirements

The overarching sense of urgency was shared by regulatory authorities, who recognized the need to act fast to accelerate the availability of vaccines, again voicing the view that safe and effective vaccines, in sufficient quantities, could have a major impact on the outbreaks. To enable rapid access to vaccines, the authorities argued for special considerations that go beyond the traditional approaches to product assessment and approval. However, they stressed that regulatory requirements and decisions must always be based on good science; scientific standards could not be compromised.

European and US regulatory authorities, working in close collaboration with vaccine companies, proposed expedited licensing and registration pathways for the most advanced candidate vaccines. Ways to harmonize regulatory requirements among the various agencies were also discussed. To speed up approval, industry proposed that regulatory authorities might send staff to oversee industry's own testing procedures.

Urgent measures to improve readiness for clinical trials and vaccines

The need for community engagement, mobilization, and preparedness to appreciate and accept the protective power of vaccines received considerable attention. All agreed: work with communities must start now. Participants also discussed several practical problems with vaccination programmes under the real conditions seen in West African countries. Communities – and also medical staff – will need to understand that vaccines may not provide 100% protection, that the immune response is unlikely to begin immediately, that a booster dose might be needed, and that the emphasis on rigorous personal hygiene and protective measures will need to continue.

As MSF pointed out, vaccination programmes often draw crowds, and this could introduce its own set of problems. As others noted, transportation over treacherous roads, irregular electrical supplies, and the beginning now, after the rainy season ended, of extremely hot weather add to the already formidable logistical challenges. Needs identified included a very rapid

building of basic public health infrastructures, also for managing the logistical demands of clinical trials and vaccine delivery, storage, and distribution, eventually in mass vaccination campaigns.

Coordination and alignment among multiple partners

Participants pointed to the need for find innovative ways of securing the accelerated and coordinated engagement of multiple partners that have a role to play in bringing safe and effective vaccines to those in greatest need. Urgent priorities included the streamlining and harmonization of regulatory requirements and finding mechanisms for aligning and coordinating what a representative from industry called a “blizzard” of activities, requests, and sometime competing demands.

In other words, the tremendous good will being shown by multiple partners, while most welcome, needed to be harnessed and channelled with greater efficiency. Participants identified another signal of good will and solidarity with the people of West Africa: the high number and rapid enrolment of volunteers, in the US and Europe, to participate in phase 1 clinical trials.

Speakers from the three most severely affected countries, including some whose economies have virtually collapsed, repeatedly emphasized the need for international support in rebuilding fundamental public health infrastructures. One asked if all the various studies and investigations currently under way or planned might be coordinated and consolidated into a single sub-regional research project. As noted, the countries are small and the distances between capital cities are not great.

In the overarching spirit of urgency, several recommendations were made for using existing mechanisms, such as WHO’s Strategic Advisory Group of Experts, or SAGE, on immunization. SAGE was considered especially important as a source of advice on strategies for Ebola vaccine rollout. Many other existing mechanisms and forthcoming meetings were identified that could work to coordinate regulatory authorities, harmonize their requirements, and maintain vigilance for vaccine safety.

Determination to finish the job

Vaccine companies expressed awareness that a vaccine might not, in the end, be needed. At the same time, they affirmed their absolute determination to see current R&D efforts, clinical trials, and regulatory approval through to completion. Several reasons were given.

First, a booster vaccine may prove essential. Second, as some – perhaps even all – vaccines may fail, the more products in the pipeline, the greater the safety margin. Third, even if the number of new cases were to drop significantly, a vaccine would still be needed to stamp out the disease

completely, with full confidence. Fourth, the current event will not be the last outbreak of Ebola virus disease to bring misery, panic, and social and economic upheaval to Africa; a stockpile of fully approved vaccines will improve preparedness. Finally, the numerous innovations now being pioneered will hold the world in good stead when the next new epidemic-prone virus inevitably emerges.

Next steps: the rush of urgent activities demands strong leadership from WHO in its coordinating and convening roles

WHO was asked to take forward work in several areas with the utmost urgency. The Director-General agreed to do so. She announced plans to clear her agenda for the coming weeks and stated that she would immediately put together a senior team to advise the Organization on ways to coordinate and expedite multiple lines of work.

Small, lean working groups would be formed, within days, to work out immediate practical needs, in the three countries, for basic public health infrastructures as well as for the implementation of clinical trials. Some of the problems identified would be put to industry, which has a good track record of finding solutions in crisis situations.

Dr Chan also made specific requests. She asked US agencies to provide detailed descriptions of protocols for the forthcoming randomized controlled and stepped-wedge clinical trials. She asked for more coordinated and enabling work, in close collaboration with industry, among US, European, and other regulatory authorities.

Finally, she asked industry to use its “critical paths” analysis to pinpoint the precise decisions needed from others in order to support expedited plans.

On its part, WHO was asked to maintain a global portfolio of additional candidate vaccines as these emerge from ongoing investigations at government-sponsored research institutes and in the laboratories of R&D-based pharmaceutical companies.