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Smallpox: WHO Executive Board passes the buck to the World Health Assembly

For the first time since 2011, the World Health Assembly (WHA) will undertake a substantive consideration of destruction of smallpox virus stocks when it meets in May 2014. At the meeting of the World Health Organization's Executive Board on 20-25 January 2014, a preliminary exchange of views revealed significant disagreement among Member States.

This despite a WHO public health expert committee concluding that no public health purpose remains to retain the virus stocks, held at WHO Repositories in the US and Russia. The committee says that sufficient sequences, diagnostics, and vaccines exist, and that anti-viral drug research is sufficiently advanced, so that the stocks can now be destroyed.

Some countries favored fixing a date of destruction of the virus, while others said doing so was premature. Some, particularly the US, appear to favor expansion of the research programme to address "new threats", a move that could indefinitely delay destruction of the stocks if taken on board by the WHA.

There is concern among experts that the US is attempting to raise fears about the "threat" of synthetic biology as a means to try to gain WHA approval to expand the research programme (and thus provide justification for virus retention), and that such an expansion could possibly include genetic engineering experiments, the subject of prior controversy at the WHA.

Please find below a report on the Executive Board's discussion on the issue.

With best wishes

Third World Network
131 Jalan Macalister
10400 Penang
Malaysia
Email: twnet@po.jaring.my
Website: http://www.biosafety-info.net/ and http://www.twn.my/
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Smallpox: WHO Executive Board passes the buck to the World Health Assembly

Austin, Texas, 28 Jan (Edward Hammond) – For the first time since 2011, the World Health Assembly will undertake a substantive consideration of destruction of smallpox virus stocks when it meets in May 2014.

At the meeting of the World Health Organization's Executive Board on 20-25 January 2014, a preliminary exchange of views revealed significant disagreement among Member States on the issue.

The research program on virus stocks of the eradicated disease, which since the 1980s have been held only at WHO repositories in Russia and the United States, is reaching its conclusion. The research was only authorized for public health purposes, and all Member States of the World Health Assembly have agreed to destroy the stocks once this is completed. According to a WHO's public health expert committee (the Advisory Group of Independent Experts (AGIES) to review the smallpox research program), no public health purpose remains to retain them. The AGIES says that sufficient sequences, diagnostics, and vaccines exist, and that anti-viral drug research is sufficiently advanced, so that the stocks can now be destroyed.

Another WHO oversight committee (the Advisory Committee on Variola Virus Research, ACVVR), which has less transparent operations and heavy representation from smallpox labs, somewhat disagrees. The ACVVR concludes that for most purposes, no need for smallpox virus remains, however, voting by a small majority late last year, it concluded that a narrow scientific rationale exists to retain stocks in order to finalize studies on anti-viral drugs. But in its bare majority ballot on anti-viral drugs, members from the United States cast over 25% of the vote, more than some entire WHO regions, such as Africa.

On the evening of 23 January, the WHO Executive Board took up the issue, and the exchange of views that took place suggests that discussions at the World Health Assembly will be difficult. Some countries favored fixing a date of destruction of the virus, while others said doing so was premature. Some, particularly the United States, appear to favor expansion of the research program to address what it terms "new threats", a move that could indefinitely delay destruction of the stocks if taken on board by the WHA.

China and Iran were clearest in calling for the WHA to set a destruction date for the virus. Iran recalled its statement from the 64th WHA calling for a destruction date and called for a mechanism to oversee destruction to be set up. China said that the research program had come a long way and that is was now time for use of live variola virus to stop and for strict and effective restrictions to be placed on artificial variola. China called for the process of destruction to begin, and for Member States to have equal footing in access to the results of the research program.

Most stridently opposed to destruction were, unsurprisingly, Russia and the United States. Russia noted the results of research conducted at the WHO Repository located within Russia and said these were of use to the international community. Russia said that it was working on antiviral drugs and that virus retention was justified and

necessary. Russia did not specifically address the conclusion of the AGIES that the research program no longer has a compelling public health purpose.

The United States said fixing a destruction date is premature, and drew particular attention to what it termed as "new threats" stemming from synthetic biology. The US considered that release of synthetic DNA could have "catastrophic" consequences, and supported the suggestion by Mexico (see below) that the WHO Director General form an expert group to report on variola virus and synthetic biology.

The United States has long held the position that it would agree to destroy the viruses in the WHO Repository in Atlanta once the WHA-authorized research program is completed. The US, observers noted, was now facing greater pressure to do so because of the conclusions of the AGIES that retaining the virus no longer has a public health purpose. Pressure is building on the US also because its outsized representation on the ACVVR appears to be the only reason why that Committee too did not vote to destroy the virus on every count.

Thus, there is concern among experts that the United States is attempting to raise fears about the "threat" of synthetic biology as a means to try to gain WHA approval to expand the research program (and thus provide justification for virus retention), and that such an expansion could possibly include genetic engineering experiments, the subject of prior controversy at the WHA. (This aspect of the Executive Board discussion will be addressed in greater detail in a future TWN article.)

Several other countries said that they could agree to continued retention of stocks, with varying degrees of enthusiasm. Brazil, Panama, Argentina, Australia, Japan, Lithuania, Albania, Saudi Arabia and Malaysia were among these. Most of these countries offered short statements with few details other than to note progress in the research program and the opinion that it is premature to destroy the stocks.

A few of these countries offered perplexing rationales for retention, such as an alleged need for more vaccines, despite the conclusion of both the AGIES and the ACVVR that sufficient vaccines exist. These include less "reactogenic" vaccines suitable for immunologically vulnerable populations and, of course, it was effective vaccines that have existed since the 1960s that led smallpox to be eradicated from the wild in the first place. Smallpox vaccines are not made from variola virus (which causes smallpox), but from Vaccinia, a related virus; hence live variola virus is not needed for vaccine production.

Canada's intervention was a mixed bag. On the one hand, Canada notably stated that no public health purpose remained for retention of the virus stocks. On the other, it said the stocks should be destroyed when "necessary measures" were in place. Among these, Canada mentioned that Member States should certify that they are free of variola virus, a suggestion that first came up at the 64th WHA, where it was proposed by the United States.

Specifics on this proposal are thin. Neither the United States nor Canada have addressed the fact that the WHO has already conducted a certification process. This took place in the 1970s and early 80s when, under WHO supervision, existing variola virus samples (at dozens of labs across the world) were either destroyed or deposited by Member States in WHO Repositories. (Originally five, now reduced to two.) The certification proposed by the US and now Canada thus duplicates work already done by WHO, and no specific rationale for re-certification has been proffered.

South Africa affirmed its commitment to prior WHA decisions that the virus stocks should be destroyed, and noted that variola DNA fragments found a few years ago in a South African lab would shortly be destroyed, in coordination with WHO.

Mexico and several other countries proposed that the WHO Director-General establish an expert group to report on variola virus and synthetic biology. The schedule and parameters of this group are unclear. The Director-General noted that she would try to obtain the resources for such an expert group which, presumably, would make a report to the WHA in May. It is unclear why this task could not be assigned to the existing AGIES committee, if necessary, supplemented by advisors.

Destruction of smallpox virus stocks will next be formally considered as a substantive agenda item at the 67th World Health Assembly, beginning on May 19, 2014 in Geneva.