

**Meeting of the States Parties to the Convention
on the Prohibition of the Development,
Production and Stockpiling of Bacteriological
(Biological) and Toxin Weapons and on Their
Destruction**

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Item 5 of the provisional agenda

**Standing agenda item: cooperation and assistance,
with a particular focus on strengthening cooperation
and assistance under Article X**

**Challenges and obstacles to developing international
cooperation, assistance and exchange**

**Background information document submitted by the Implementation
Support Unit**

Summary

The Seventh Review Conference decided that the 2012 to 2015 intersessional programme would include a Standing Agenda Item on cooperation and assistance, with a particular focus on strengthening cooperation and assistance under Article X. The Conference also decided that under this item, States Parties would consider, inter alia, "challenges and obstacles to developing international cooperation, assistance and exchange in the biological sciences and technology, including equipment and material, for peaceful purposes to their full potential, and possible means of overcoming these". Further to requests made by delegations in the course of consultations with the Chairman, this paper provides an overview of some of the specific challenges and obstacles to developing international cooperation, assistance and exchange that have been identified by States Parties and international organizations in the course of meetings of the Convention and in other relevant settings.

I. Introduction

1. In the final declarations of successive review conferences and in other documents, States Parties to the Convention have frequently referred, in various terms, to the need to overcome challenges and obstacles to developing international cooperation and, more broadly, to implementing Article X of the Convention. The Final Declaration of the

Seventh Review Conference, for example, while noting "existing bilateral, regional and multilateral assistance, cooperation and partnerships", recognized that "there still remain challenges to be overcome in developing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes"¹, but did not state what these challenges were. Similarly while a number of decisions and recommendations have been made for actions that are described as being for the purpose of overcoming challenges and obstacles², States Parties as a body do not appear to have ever attempted to identify, enumerate or specify exactly what these challenges and obstacles might be. Nevertheless, individual States Parties or groups of States Parties have at one time or another identified one or more specific challenges or obstacles. The Implementation Support Unit, in its annual reports to States Parties, has also identified challenges and obstacles encountered in the course of facilitating communication among States Parties and the exchange of requests for and offers of assistance in accordance with its mandate. In addition, some potentially relevant challenges and obstacles have been identified by international organizations not directly connected with the Convention.

2. This background paper collects specific challenges and obstacles that have been mentioned in BWC official documents (including ISU reports) since the start of the first intersessional programme in 2002, as well as some that have been mentioned by other organizations. It is an indicative rather than an exhaustive list, intended to illustrate the main kinds of challenges and obstacles that have been identified and to organise them thematically.

II. Challenges and obstacles identified in synthesis papers

3. Various challenges and obstacles to developing international cooperation, assistance and exchange were raised in presentations and discussions at the Meetings of Experts and thus were reflected in some way in the Chairman's *Synthesis of considerations, lessons, perspectives, recommendations, conclusions and proposals drawn from the presentations, statements, working papers and interventions on the topic under discussion at the Meeting of Experts* (commonly known as the "synthesis paper") which is produced by the Chairman following each Meeting of Experts as a resource for States Parties to draw upon in preparing for the subsequent Meeting of States Parties. For one reason or another, perhaps because States Parties prefer to frame their common understandings in terms of positive actions rather than lists of problems, these challenges and obstacles did not appear as such in the report of the corresponding Meeting of States Parties. They are reproduced here, noting that the synthesis papers are not agreed upon by States Parties and consequently have no status beyond reflecting the Chairman's synthesis of what one or more States Parties have said at the Meeting of Experts.

4. The synthesis paper of 2009, recognizing that "there remain challenges in developing international cooperation, assistance and exchange in biological sciences and technology for peaceful purposes to their full potential, and that many States Parties face considerable obstacles in building sufficient capacity for disease surveillance, detection, diagnosis and containment"³, listed the following specific problems as needing attention:

- (a) The lack of resources at the international level to deal with plant diseases;
- (b) The short-term and unpredictable nature of funding and available resources;

¹ BWC/CONF.VII/7, part II, paragraph 56.

² See for example the 2012 Report of the Meeting of States Parties, BWC/MSP/2012/5, paragraph 23.

³ BWC/MSP/2009/L.1, paragraph 2.

- (c) The shortfall of assistance to implement the requirements of the revised International Health Regulations (2005);
- (d) Insufficient focus on diseases that are prevalent in developing countries but are rarely present in developed countries;
- (e) Insufficient integration of the private sector and traditional medicine;
- (f) Weaknesses in infrastructure, human resources and the implementation of standard operating procedures in developing countries;
- (g) Difficulties in retaining skilled human resources and with day-to-day maintenance of core health capacity;
- (h) Lack of coordination among assistance providers both internationally and between different national departments;
- (i) Difficulties in sharing diagnostic samples and materials due to safety, security and transport regulations;
- (j) Difficulties in acquiring the necessary materials, equipment and technology;
- (k) The potential for non-proliferation provisions to hamper access to equipment, materials and scientific and technological knowledge for disease surveillance, mitigation and response.

5. The synthesis paper of 2010, recognizing that "developing effective measures for the provision of assistance and coordination with relevant organizations to respond to the use of a biological or toxin weapon is a complex task"⁴, listed the following challenges:

- (a) The lack of clear procedures for submitting requests for assistance or for responding to a case of alleged use of biological or toxin weapons;
- (b) The political aspects of situations in which there may be use or alleged use of biological or toxin weapons;
- (c) Lack of resources in the human and animal health fields, and most acutely in the area of plant health, particularly in developing countries;
- (d) The significant differences between responding to a natural outbreak of disease and an outbreak resulting from hostile use of a biological agent or toxin;
- (e) The time lag between recognising an outbreak of disease and establishing whether or not the outbreak was intentional;
- (f) The potentially complex and sensitive interface between an international public health response and international security issues;
- (g) An employer's duty of care when deploying staff to a potentially contaminated environment.

6. The 2010 synthesis paper also mentioned "legal, regulatory, and other barriers to effective multilateral cooperation, such as: inconsistent standards for forensic identification of agents; vaccine liability; and licensing for emergency use of medical countermeasures"⁵.

⁴ BWC/MSP/2010/L.1, paragraph 2.

⁵ BWC/MSP/2010/L.1, paragraph 3 (e).

III. Challenges and obstacles identified in working papers

7. Individual States Parties, or groups of States Parties, have also identified specific challenges and obstacles to developing international cooperation, assistance and exchange. These are summarised under the thematic headings below.

A. Restrictions and limitations on transfer and exchange

8. In a working paper submitted to the Seventh Review Conference⁶, the Islamic Republic of Iran cited the "imposition of undue restrictions and/or limitations on transfer of know-how, materials and equipment necessary for promoting capacity building in the fields of disease surveillance, detection, diagnosis, and containment of communicable diseases including production of vaccines and other biological materials". More specifically, in a working paper submitted to the 2009 Meeting of States Parties⁷, India stated that "denial of materials, equipment and technology for peaceful uses of biotechnology and bio-sciences including for disease surveillance and control continues to exist. Indian organizations face difficulties in accessing various items for research in the peaceful uses of biotechnology such as, viruses for preparation of antigens for developing diagnostic tests; equipment such as Positive Pressure Suits used in advanced containment laboratories; training opportunities for working in BSL3 and BSL4 labs; and collaborative R&D in the areas of vaccine development and therapeutics". A working paper submitted by Pakistan to the same meeting⁸ stated that "vaccination remains the most cost effective way to prevent infectious diseases, national capacity for research and development in vaccinology is to be enhanced significantly. The current vaccine production facilities at NIH need strengthening both in terms of technology and equipment for basic manufacturing along with development of human resources. Pakistan is facing difficulties in having an access to the stated technology and equipment which is hampering our efforts of equitable healthcare delivery".

9. In a working paper submitted to the Sixth Review Conference⁹, the Islamic Republic of Iran noted that "any limitation on biological experts, particularly on those from developing States Parties, that may hamper their education or their participation in the relevant seminars and training programs as well as their access to the relevant information sources is contrary to the letter and spirit of the Convention", but did not explicitly state that such limitations currently exist.

10. In a working paper submitted to the 2012 Meeting of Experts¹⁰, Cuba stated it was facing obstacles to the implementation of the Convention due to the "economic, commercial and financial embargo imposed by the Government of the United States of America against Cuba", citing in particular restrictions on the acquisition by Cuban hospitals and research institutes of medicines, laboratory reagents, vaccines, diagnostics and equipment.

⁶ BWC/CONF.VII/WP.29.

⁷ BWC/MSP/2009/WP.8.

⁸ BWC/MSP/2009/WP.9.

⁹ BWC/CONF.VI/WP.24.

¹⁰ BWC/MSP/2012/MX/WP.7 (Spanish only)

B. Inadequacy of institutional mechanisms

11. In a working paper submitted to the Sixth Review Conference¹¹, the Islamic Republic of Iran cited the "inadequacy of the existing institutional mechanisms for promoting international cooperation". In a working paper submitted to 2009 Meeting of States Parties¹², the Group of the Non-aligned Movement and Other States stated that the Convention "lacks an appropriate mechanism that would allow States Parties to facilitate the broadest possible transfer and exchange materials and scientific and technological information regarding the use of bacteriological (biological) and toxin agents for peaceful purposes, as well as exercise the right to participate in these exchanges".

C. Difficulty of assessing needs

12. In a working paper submitted to the 2009 Meeting of States Parties¹³, Japan (on behalf of the JACKSNNZ informal group) stated that providing effective assistance "necessitates that donor countries understand clearly the differing circumstances and needs of the recipient states". In a working paper submitted to the same meeting¹⁴, Sweden (on behalf of the European Union) cited the "identification of specific needs of individual States Parties".

13. In a working paper submitted to the 2012 Meeting of Experts¹⁵, the United Kingdom reported on an international conference on *Safe and Secure Materials: Matching Resources to Reality* held at the Centre on Global Health Security and International Security at Chatham House¹⁶. The conference identified a number of issues related to assessing the needs of developing countries with respect to improving capacity in biosafety and biosecurity. These included the following:

"(a) Legislation often promotes highly secure physical containment with new buildings, high-tech security systems and personnel training, which are associated with high costs. However, some developing nations may not have the necessary resources, infrastructure and regulatory capacity to construct and operate such facilities. Furthermore, there is no point in specifying high-tech, high-maintenance equipment if it cannot then be adequately maintained through its life.

(b) Perception of risk is a key factor. There is a need to counter the provision of 'over-regulated' or 'over-engineered' solutions that are unsuitable for developing countries due, for example, to cost or lack of local availability of resources such as building materials and electricity supply. Much work is required to develop realistic operating protocols, and in matching risks to resources. A single uniform international standard may not be appropriate for all developing countries. However, there is also a need to address the possible perception that this could result in an unethical approach of providing lower quality or higher risk solutions than those applied in developed countries.

(c) Project funding is usually short-term, but effective capacity building requires long term commitment from funders. It is important to take account of whole-life costs, including running costs and maintenance as well as initial capital investment.

¹¹ BWC/CONF.VI/WP.24

¹² BWC/MSP/2009/WP.2

¹³ BWC/MSP/2009/WP.3

¹⁴ BWC/MSP/2009/WP.6

¹⁵ BWC/MSP/2012/MX/WP.2

¹⁶ <http://www.chathamhouse.org/sites/default/files/public/Research/Global%20Health/170512summary.pdf>

(d) Engineering and technology are not the whole picture. The need for training, and local solutions to its provision must not be forgotten – including consideration of how people learn and perceive risk. It is also important to address the attitudes of policy makers and managers. Effective biorisk management is thus a key issue."

D. Lack of coordination

14. In a working paper submitted to the 2009 Meeting of States Parties¹⁷, Sweden (on behalf of the European Union) cited the need for coordination of assistance from States Parties and international organisations and stated that the "identification of all activities of assistance from a State Party with relevance for an integrated approach within the area of disease surveillance and disease mitigation provides a significant challenge due to the vast number of initiatives by a wide range of Government departments and agencies, research funding bodies, the private sector and other organisations". Sweden also noted that the "extensive efforts" that would be required to collect the comprehensive information necessary to improve coordination posed a further challenge.

IV. Challenges and obstacles identified by the Implementation Support Unit

15. In its annual reports to States Parties, the ISU has identified problems with facilitating cooperation and assistance among States Parties in accordance with its mandate. In its 2007 report¹⁸, the ISU stated that it had received "very few requests for, or offers of, assistance with national implementation or CBMs. It was therefore unable to do much to fulfil the important aspects of its mandate concerning the facilitation of communication among States Parties and the exchange of requests for and offers of assistance". In its 2008 report¹⁹, the ISU noted some improvement but stated that "problems remain with the operation of the ISU as a clearing-house for requests for and offers of assistance, for the reasons identified in the 2007 ISU report ... in general, few requests are made, and the rate of response to those few requests is low".

16. In its 2010 report²⁰, the ISU stated that it was operating "at the very limits of its current capacity of three full-time staff, and in 2010 had to decline a number of invitations to relevant workshops and other activities due to lack of available personnel. Opportunities for outreach and clearing-house activities also had to be postponed or cut back. The ISU's activities are further constrained by a lack of dedicated administrative support".

V. Challenges and obstacles identified by other organizations

17. While organizations operating in similar areas to the BWC, such as the Organisation for the Prohibition of Chemical Weapons and the International Atomic Energy Agency, may have encountered, identified and perhaps analysed challenges and obstacles to developing international cooperation, assistance and exchange for peaceful purposes, it is beyond the scope of this paper to examine and determine which if any of these challenges and obstacles might also apply to the BWC, that is, to developing international cooperation,

¹⁷ BWC/MSP/2009/WP.6

¹⁸ BWC/MSP/2007/3

¹⁹ BWC/MSP/2008/3

²⁰ BWC/MSP/2010/2

assistance and exchange in the biological sciences and technology, including equipment and material. BWC States Parties might consider the value of inviting these organizations to share their experiences concerning the development of international cooperation, assistance and exchange at a Meeting of Experts, so that States Parties can discuss and assess their relevance for the BWC.

18. A recent joint publication by the World Health Organization, World Intellectual Property Organization and World Trade Organization, *Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade*²¹, does seem to be directly relevant. This study examines the interplay between public health, trade and intellectual property, and how these policy domains affect medical innovation and access to medical technologies. It identifies and examines a number of problems and challenges, including:

(a) Access and availability: patients are unable to obtain medicines and medical technologies. The study argues that there is rarely a single, isolated reason for this.

(b) The selection and use of medicines rationally; whether patients and public health services can afford them; sustainable financing; reliable health and supply systems; the regulation of medicines to ensure they are of a high quality, without obstructing innovation and access.

(c) The intellectual property system's rules, the way rights such as patents or trademarks are obtained and managed, the way policy options and flexibilities are applied.

(d) International trade and its rules, and the way they are applied, can determine whether medicines are available, and what prices patients have to pay – for example through duties charged on imported products. Competition policy is part of this: it can promote innovation, and improve access to medicines.

(e) The impact of the steadily growing number of bilateral or regional free trade agreements: this has not yet been systematically analysed, particularly for public health.

²¹ Available at http://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm