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

BWC/MSP/2004/MX/WP.7
15 July 2004

ENGLISH ONLY

Second Meeting
Geneva, 6-10 December 2004

Meeting of Experts
Geneva, 19-30 July 2004
Item 5 of the provisional agenda

Enhancing International Capabilities for Responding to and Mitigating the Effects of Outbreaks of Diseases - How to Overcome Legal Problems

Submitted by Germany

1. In most countries the use of drugs and vaccines for the treatment and prevention of diseases is strictly regulated by national laws. Such use is normally confined to those products specifically approved for this purpose by national licensing authorities. National laws and regulations also generally prohibit the importation of non-licensed drugs and vaccines and for all such products require an openly declared expiration date.

2. Any list of potential biological warfare agents includes numerous micro-organisms and toxins for which licensed drugs and vaccines are, for a variety of reasons, unavailable. Since infections and intoxications caused by most biological warfare agents are in the category of relatively rare events, pharmaceutical companies may have little interest in conducting research into diseases caused by such agents. In addition, the small number of patients suffering from such diseases makes it more or less impossible to run the mandatory clinical trials of new drugs without which they cannot be licensed for the treatment of these diseases. Similar problems exist with the development and licensing of new vaccines, where testing for side-effects using high numbers of volunteers is required.

3. A recent case serves to illustrate these difficulties. When the debate started on protecting populations against possible bioterrorist attacks with *Variola virus*, the causative agent of smallpox, it became clear that in most countries the vaccinia-vaccine used to innoculate people against smallpox was no longer licensed by national authorities. The reason was simple: once WHO announced the eradication of smallpox in the eighties, most countries stopped vaccinating against the disease and many saw no reason to maintain a license for the vaccine, which had always been - and still is - controversial on account of its side-effects. At the same time the development of a new smallpox vaccine known as MVA, which in Germany was already being tested on over 100,000 vaccinees, was stopped. As a result, countries planning to stockpile the old vaccinia-vaccine in order to be better prepared for possible bioterrorist attacks using variola

have been compelled either to revive old licenses - even though it is questionable whether the old vaccine could meet today's stringent licensing requirements - or to find other ways to legalize the use of this vaccine in cases of emergency.

4. MVA is now back on the agenda as a substitute for the old vaccine, but whether it can be placed on the market sufficiently soon under normal licensing procedures is another question.

5. Another example: Ciprofloxacin, better known under the trademark CIPROBAY, was not specifically authorized in Germany for the treatment of anthrax when the anthrax attacks occurred in the United States in autumn 2001. A few weeks later and as a result of these attacks, the drug was licensed in Germany also for the treatment of anthrax.

6. Attacks using biological warfare agents may take place at any time, whether or not drugs and vaccines meeting all the scientific and legal requirements of a regular licensing process are available. Preparedness for such events therefore also means taking steps to legalize the importation, storage and use of non-licensed drugs to deal with emergency situations where no authorized products are available.

7. Accordingly, Germany issued on 17 June 2003 an Ordinance allowing exemptions from the German *Drug Law* (Arzneimittelgesetz) and from the *EU Council Regulation (EEC) 2309/93 of 22 July 1993 laying down community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.* The Ordinance allows the importation, storage and use of non-licensed drugs and vaccines where the use of such products is necessary for civil defence and disaster relief purposes or for operations of the Federal Armed Forces, the Federal Border Police or the Mobile Police Force.

8. As already indicated, the Ordinance provides for products to be exempted from import restrictions as well as the requirement of an openly declared expiration date if the products concerned are under scheduled quality control management. Establishing a proper legal basis for the use of non-licensed drugs and vaccines in emergency situations will avoid the need for lengthy discussions on the legal status of drugs and vaccines offered for help during as well as after international relief operations. For this reason legalizing the import and use of non-licensed drugs by any state would be a valuable contribution to enhancing international capabilities and preparedness for responding to and mitigating the effects of outbreaks of diseases.

9. The full texts of the Ordinance as well as the *Drug Law* and the *EU Council Regulation (EEC) 2309/93 of 22 July 1993 laying down community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Product* are available on the CD-ROM prepared by the Federal Foreign Office as background information for participants at the BTWC Meeting of Experts in July 2004.

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