The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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EMEA/CPMP Guidance document on use of medicinal products for treatment and prophylaxis of biological agents that might be used as weapons of bioterrorism

At the request of the European Commission, Enterprise DG, the Pharmaceuticals Unit, the EMEA and its Scientific Committee, the Committee for Proprietary Medicinal Products (CPMP) produced a guidance document on the use of medicinal products for treatment and prophylaxis of biological agents, that might be used as weapons of bioterrorism. The first version of the guidance, produced on 16th January 2002, considered those agents in Category A of the US Centre for Disease Control's (CDC) list of agents that might be used for the purposes of bioterrorism. On 21 February 2002 and 21 March 2002 the document was extended to cover agents in categories B and C of the CDC's list. On 25 July 2002 the document was extended to include information on nationally authorised vaccines and immunoglobulins for the prevention or post-exposure prophylaxis of some infections.

This document is not intended to be a comprehensive guideline on the management of patients and the public health measures that would be necessary in the case of such an attack. The document is confined to the possible drugs and regimens that might be useful in the case of an attack with each agent listed. It should be noted that there are differences between Member States in the content of the Summaries of Product Characteristics (SPC) for many of the drugs that have been suggested for treatment and/or prophylaxis. In fact, few of the drugs mentioned are authorised for the treatment and/or prophylaxis of the specific diseases mentioned. In addition, the licensing status and the actual availability of some of the drugs suggested varies between EU Member states. All these factors may well influence drugs that would actually be used in the case of an attack. Moreover some medicines, including anti-toxins, may have to be obtained through special access mechanisms in individual Member States. Therefore, prescribers should always consult existing national guidance and expertise, and should always refer to the national prescribing information regarding each of the medicinal products suggested.

This guidance document will be updated on a regular basis as appropriate.
The document is also available on the website of the European Commission: http://pharmacos.eudra.org

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7. Botulism

8. Brucellosis

9. Q fever

10. Glanders and Melioidosis

11. Other infectious diseases (Psittacosis, Epidemic Typhus (*Rickettsia prowazekii),* Multidrug-resistant tuberculosis, Shigellosis, Salmonellosis, Cholera)

12. ANNEX (Biological agents for which currently no specific treatment can be recommended)