

INTRODUCTION

This guidance document is concerned with the selection of medicinal products that are potentially useful for post-exposure prophylaxis and/or treatment of infectious diseases in the context of biological warfare. The guidance is the result of a consensus view reached between representatives from EU Member states during and after meetings held on 14 December 2001 and 12 February 2002 at the EMEA in London. It describes the therapies to be used in an emergency situation against agents that appear on the US Centre for Disease Control's (CDC) list of organisms and toxins that might be used as weapons of bioterrorism (categories A, B and C). The CDC's list of agents is based on considerations that include the possible modes of transmission, the ease of production, and the associated morbidity and mortality.

Following a known or suspected act of bioterrorism, it may take some time to confirm that an attack has occurred, to identify the pathogen, and to determine its antimicrobial susceptibility. Therefore, decisions regarding whether and when to commence therapy of exposed persons, and the choice of drug, must depend on the perceived risk. Such decisions can only be made on a case by case basis, and following urgent consultation (national and/or international) between governments and their expert advisers.

This document is not intended to provide comprehensive guidance on the management of patients or the public health measures that would be needed. The group agreed that the availability of medicinal products, and the legal, practical and logistic considerations that might influence the selection of products in individual Member states would not be considered in these recommendations.

The possible treatment options that have been suggested, have been selected under the provision that the pathogens listed have not been genetically engineered so as to be resistant to some or all of the potentially useful medicinal products.

The choice of first /second line drugs for treatment and/or prophylaxis and the dose and duration recommendations have been drawn from the literature (based on *in-vitro* activity and *in-vivo* data in animals and man) and from various national recommendations. Therefore, it must be pointed out that these recommendations should not be assumed to be based on randomised controlled clinical trials. Since the contraindications and warnings regarding the use of individual drugs may vary between Member states there is a recommendation that reference should be made to the prescribing information in each country.

Those agents on the CDC's list for which there is currently no drug treatment that can be recommended have been listed in the Annex.

It is envisaged that this guidance should be updated as appropriate to take into account new scientific knowledge.

As previously envisaged this guidance has been updated with information made available on nationally authorised vaccines and immunoglobulins that may be useful in the prevention of or post-exposure prophylaxis against certain pathogens.

The guidance document was first adopted by the scientific committee (CPMP) of the EMEA on 17 January 2002. The revised document was adopted by the CPMP on 21 February 2002, 21 March 2002 and 25 July 2002. **Thereafter a review followed in 2005, however no revisions were made at this time.**