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COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Transport of Dangerous Goods
(Twenty-third session, 30 June-4 July 2003, agenda item 4(c))

PACKAGINGS

Aerosols (UN 1950) and receptacles, small, containing gas (UN 2037), used for medicinal purposes

Transmitted by the expert from the United Kingdom

Background

1. The expert from the United Kingdom notes that pharmaceutical products are generally subject to the Model Regulations, although many are transported under the limited quantity provisions of Chapter 3.4. In manufacture such products must undergo extensive clinical trials and have to be produced under a system of Good Manufacturing Practice (GMP), which includes ISO9002 with additional requirements specifically aimed at pharmaceutical products. GMP is intended to ensure that products are consistently produced and controlled to quality standards. The World Health Organization (WHO) provides extensive guidance about such systems on its web site:

2. www.who.int/medicines/organization/qsm/activities/qualityassurance/gmp

These GMP systems are then adopted by national authorities such as those shown in the Annex to this document.

3. A number of aerosols and small receptacles are in existence that are manufactured and licensed under these GMP systems for pharmaceuticals. Most receptacles are less than 50ml in capacity and not covered by regulation in transport. However, recently some examples of larger aerosols and small receptacles have appeared on the pharmaceuticals market containing non-flammable gases. Under the current provisions in the Model Regulations, such aerosols and receptacles are required to be water bath tested in accordance with 6.2.4.1. Because the content is often heat sensitive and the water bath itself may contaminate the product, the hot water bath test may not be appropriate. This is because retaining sterile water in an open device such as the water bath can never be assured. The object of manufacture of pharmaceuticals under GMP is to avoid unintended contamination, which could cause damage to health or even death.

4. The expert from the United Kingdom proposes the Sub-Committee should consider that where aerosols or small receptacles, assigned to UN 1950 or UN 2037, are manufactured under the GMP system and licensed by the appropriate national medical health authority the hot water bath test may be waived.

Proposal

EITHER

Add a new Special Provision as follows:

SP3XX AEROSOLS, UN1950, or RECEPTACLES, SMALL CONTAINING GAS (GAS CARTRIDGES), UN 2037, containing pharmaceutical products and non flammable gas manufactured under the authority of a national medical administration and following the principles of Good Manufacturing Practice (GMP) laid down by the World Health Organization for this purpose may not be subject to the hot water bath test in 6.2.4.1, provided that adequate measures to test for leakage are incorporated into manufacturers' procedures, such as helium detection or water bathing a statistical sample from each production batch.

OR

Add a new 6.2.4.3 as follows:

Receptacles containing pharmaceutical products and non flammable gas manufactured under the authority of a national medical administration and following the principles of Good Manufacturing Practice (GMP) laid down by the World Health Organization for this purpose may not be subject to the hot water bath test in 6.2.4.1, provided adequate measures to test for leakage are incorporated into manufacturers' procedures, such as helium detection or water bathing a statistical sample from each production batch.

Annex

National Regulatory Authorities for Medicines

Therapeutic Goods Administration (TGA)
Commonwealth Department of Health and Family Services
PO Box 100 Woden
ACT 2606 Australia

Directorate General of Health Services
Drug Controller
General
Nirman Bhawan
New Delhi 110011
India

Pharmaceutical Inspectorate
Quartier Vésale
Bureau 305
Cité Administrative de l'Etat
B-1010 Brussels, Belgium

National Institute of Infectious Diseases
1-23-1 Toyama Shinjuku-ku
Tokyo 162
Japan

BioManguinhos, Brazil
Av Brasil 4365- Manguinhos
21045-900 Rio de Janiero/RJ
Brasil

Swiss Federal Office of Public Health
Schwarzenburgstrasse 165, 3097 Liebefeld
Bern, Switzerland

Bureau of Biologics and Radio-pharmaceuticals
Tunney's Pasture
Ottawa
Ontario K1AOL2
Canada

Medicines Control Agency
Department of Health
Market Towers, 1 Nine Elms Lane,
London SW8 5NQ
United Kingdom

Agence Française de Sécurité Sanitaire de Produits de Santé (AFSSAPS)
147, Boulevard Anatole
France 93285

National Institute for Biological Standards and Control
Blanche Lane, South Mimms
Potters Bar, Hertfordshire EN6 3 QG
United Kingdom

Paul Ehrlich Institut
Paul Ehrlich strasse 5l-59
Postfach 1740
D-63225 Langen, Germany

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike, Suite 2000
Rockville
MD 20852
USA

Ministerio della Sanità Dipartimennto per la Valutazione dei medicinali e la farmacovigilanza
Viale della Civilita Romana, 7
Roma, Italia