

DIPARTIMENT TAS-SAHHA

"PALAZZO CASTELLANIA"
15, TRIQ IL-MERCANTI
IL-BELT



DIPARTMENT OF HEALTH

"PALAZZO CASTELLANIA"
15, MERCHANTS STREET
VALLETTA

Our Ref:
Your Ref:

Telephone 224071

DHMS 2959/93/JF
DH Circular No. 128/98

23 September 1998

To: Licensed Wholesale Dealers in Pharmaceutical Products

CERTIFICATES OF A PHARMACEUTICAL PRODUCT

Reference is made to DH Circulars No. 149/94, 194/95, 22/97 and 31/97 on Certificates of a Pharmaceutical Product.

Your attention is being drawn once again to the fact that a number of certificates are being refused by the Medicines Regulatory Affairs Unit and the Port Health Office because they do not conform with all the requirements of the previous DH Circulars. Wholesale dealers should not request Free Sale Certificates but should insist on Certificates of a Pharmaceutical Product issued in a format recommended by the WHO.

The following requirements are being communicated for your information and are in addition to the requirements of the previous circulars.

Amendments to certificates

Any amendments made to certificates must bear the stamp of the issuing authority and, where possible, the signature of the person authorised to sign on behalf of the authority next to the amendment.

Amounts of active ingredients per unit dose

Amounts of active ingredients which are expressed as percentages are not acceptable unless the amounts are expressed in terms of weight and/or volume, that is, % w/v, % w/w, % v/w or % v/v.

In the case of products that are presented as solutions, for example, solution for injection, oral liquids, etc., the active ingredients should be expressed in terms of a specified volume, for example, the volume of water for injections.

Dosage forms

The dosage form of injectable products should be appropriately described to identify the form clearly. A distinction is to be made between solutions, suspensions and emulsions for injection and powders for reconstitution for injection. The use of the terms “injectable” or “injection” which are not qualified by the form of injection are not acceptable.

The use of the term “enema” is not acceptable unless qualified by the form, e.g. solution for enema, suspension for enema, powder for rectal solution, etc.

In the case of medicinal products that are presented as sachets, the use of the term “sachet” is not acceptable as a description of the dosage form since the term describes the type of immediate packaging. The contents of the sachet should be more accurately described, e.g. powder for reconstitution, gel, etc.

Belgium

The Pharmaceutical Inspectorate of Belgium has started issuing Certificates of a Pharmaceutical Product in the format recommended by the WHO at the fiftieth WHA. Certificates issued as from 15 October 1998 that are not in this format will not be accepted.

Spain

The Direccion General de Farmacia y Productos Sanitarios of the Ministerio de Sanidad y Consumo has started issuing Certificates of a Pharmaceutical Product conforming to the WHO format. Certificates issued as from 15 October 1998 that are not in the WHO format will not be accepted.

Switzerland

The International Office for the Control of Medicines (IOCM) issues Certificates of a Pharmaceutical Product for medicines that are manufactured for export only but which have been officially appraised, analysed and registered according to the same rules as for products placed on the market in Switzerland. The products concerned are granted a product licence.

These certificates issued by the IOCM are to be henceforth submitted to the Medicines Regulatory Affairs Unit and the Port Health Office for consideration. Wholesale dealers who are in possession of such certificates which have not expired are requested to resubmit them for reconsideration even if they were previously refused. The Department of Health reserves the right to refuse those certificates which do not comply with the requirements of the Department and the WHO Certification Scheme.

United Kingdom

On 1 April 1998, the Medicines Control Agency started issuing Certificates of a Pharmaceutical Product conforming to the WHO format. Export certificates in the older style are no longer being issued by the MCA.

Certificates for medicinal products classified as food items


Products such as vitamin preparations that are classified as medicinal products in Malta may not be covered by certificates issued from the same authorities as for other medicinal products. In such cases a certificate may often be issued by a separate department or Ministry which is responsible for the control of food items in the country where the product is sold.

The certificate must include a statement attesting that the product is on sale in the country of the issuing authority. In addition, when the following information is not listed in the certificate, it should be included in a schedule prepared by the manufacturer under the headings:

- *Name of product and pharmaceutical form*
- *Active ingredien(s) and amount(s) per unit dose*
- *Name and address of manufacturer.*

No such certificate is acceptable unless it complies with these requirements.

Further information on certificates may be obtained from the Medicines Regulatory Affairs Unit of the Government Pharmaceutical Services (telephone: 242066; fax: 251132, 243316).



J.M. CACHIA
a/Chief Government Medical Officer