



Superintendence of Public Health Sovrintendenza tas-Sahha Pubblika

Ministry for Health, the Elderly and Community Care

5th January 2012

Responsible Persons
Wholesale dealers

Dear Sir/Madam,

Re: Advanced therapy medicinal product as defined in Regulation (EC) No 1394/2007 and used in Malta.

An advanced-therapy medicinal product (ATMPs) is a medicinal product for human use that could be based on gene therapy, somatic-cell therapy or tissue engineering.

In line with Regulation (EC) No 1394/2007, as from the 30th December 2011, all advanced therapy medicinal products that are industrially manufactured need a marketing authorisation through the centralised procedure and issued by the European Commission. This requirement also applies to products which have been on the market with a national marketing authorisation issued before 30 December 2008. Those medicinal products without a marketing authorisation issued in line with Regulation (EC) No 1394/2007 can not be placed on the Maltese market. Examples of advanced therapy medicinal products can be identified on http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000301.jsp&mid=WC0b01ac05800862c0.

Advanced therapy medicinal products that are prepared /manufactured in Malta on a non-routine basis and used in Malta in a hospital under the exclusive professional responsibility of a medical practitioner in line with a medical prescription for an individual patient also need an authorisation. The manufacturing of these products shall be authorised by the Licensing Authority in Malta.

Medicinal products that are prepared on a non-routine basis according to specific quality standards, and imported/distributed in Malta in a hospital under the exclusive professional responsibility of a medical practitioner, require a marketing authorisation issued in line with Regulation (EC) No 1394/2007 and without such a marketing authorisation, these medicinal products can not be placed on the Maltese Market or used in a local hospital.

In line with the statutory obligation to apply the provisions of LN 324 of 2007 "The Medicines Marketing Authorisation Regulations" Regulation 2, (2) sub paragraph (h), you are requested to declare if you are distributing any advanced therapy medicinal product by 20th January 2012. This information is to be sent to

Dr John Joseph Borg
Post-Licensing Director
203, Level 3,
Medicines Authority
Rue D'Argens
Gzira, GZR 1368

Dr Ray Busuttil
Licensing Authority

