

A.L. 231 ta' l-2008

**ATT DWAR IL-MEDIĊINI
(KAP. 458)**

**Regolamenti ta' l-2008 li jemendaw ir-Regolamenti
dwar l-Awtorizzazzjoni ghat-Tqeghid fis-Suq ta' Mediċini**

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 106 ta' l-Att dwar il-Mediċini, il-Ministru għall-Politika Soċjali għamel dawn ir-regolamenti li ġejjin:-

1. It-titolu ta' dawn ir-regolament hu Regolamenti ta' l-2008 li jemendaw ir-Regolamenti dwar l-Awtorizzazzjoni ghat-Tqeghid fis-Suq ta' Mediċini, u dawn għandhom jinqraw u jiftiehm u haġa wahda mar-Regolamenti ta' l-2007 dwar l-Awtorizzazzjoni ghat-Tqeghid fis-Suq ta' Mediċini, hawn iżjed 'il quddiem imsejha "ir-regolamenti prinċipali".

Titolu.

A.L. 324 ta' l-2007.

2. Ir-regolament 2 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

Jemenda r-regolament 2 tar-regolamenti prinċipali.

(a) is-subregolament (1) tiegħu għandu jiġi emendat kif ġej:

(i) minnufih wara t-tifsira "prodott mediċinali" għandha tiżdied din it-tifsira ġdida li ġejja:

"prodotti mediċinali ta' terapija avvanzata" tfisser prodott kif imfisser fl-Artiklu 2 tar-Regolament (KE) Nru 1394/2007 tal-Parlament Ewropew u tal-Kunsill datat it-13 ta' Novembru 2007 dwar prodotti mediċinali ta' terapija avvanzata;

(ii) it-tifsira "awtorizzazzjoni ghat-tqeghid fis-suq provviżorja" għandha tithassar; u

(b) fil-paragrafu (g) tas-sub regolament (2) tiegħu, minflok il-kliem "taht ir-responsabilità personali diretta tiegħu." għandhom jidhlu l-kliem "taht ir-responsabilità personali diretta tiegħu ;" u minnifh wara għandu jiżdied dan il-paragrafu ġdid li ġej:

"(h) kull prodott mediċinali ta' terapija avvanzata, kif imfisser fir-Regolament (KE) Nru 1394/2007, ippreparat fuq bażi ta' ebda rutina skond *standards* ta' kwalità speċifiċi, u li

jintuża f'Malta fi sptar li jkun taht ir-responsabbiltà professjonali esklużiva ta' tabib, sabiex dan ikun konformi ma ricetta individwali mahruġa minn tabib dwar prodott magħmul għal tal-apposta għal xi pazjent individwali. Il-manifattura ta' dawn il-prodotti għandha tkun awtorizzata mill-Awtorità dwar il-Liċenzjar f'Malta.”.

Jemenda
r-regolament 4
tar-regolamenti
prinċipali.

3. Is-subregolament (1) tar-regolament 4 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) fil-paragrafu (a) tiegħu, minnufih wara l-kliem “għal użu pedjatriku” għandhom jiżdiedu l-kliem “u r-Regolament (KE) Nru. 1394/2007 tal-Parlament Ewropew u tal-Kunsill tat-13 ta' Novembru 2007 dwar prodotti mediċinali ta' terapija avanzata”;

u

(b) il-paragrafu (g) tiegħu għandu jithassar u l-paragrafu (h) għandu jiġi enumerat mill-ġdid bħala l-paragrafu (g) tiegħu.

Jemenda
r-regolament 7
tar-regolamenti
prinċipali.

4. Il-paragrafu (a) tas-subregolament (1) tar-regolament 7 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) fis-subregolament (1) tiegħu, minflok il-kliem minn “l-Artikolu 6 tad-Direttiva 2001/83/KE” sal-kliem “f'Malta jew fil-Komunità.” għandhom jidhru l-kliem “Regolament 4(1) għal mhux inqas minn tmien snin f'xi Stat Membru jew fil-Komunità. Prodott mediċinali ġeneriku li jkun awtorizzat konformement ma' din id-disposizzjoni m'għandux jitqiegħed fis-suq sakemm jgħaddu għaxar snin minn l-ewwel awtorizzazzjoni tal-prodott ta' referenza.”;

(b) minnufih wara s-subparagrafu (i) tiegħu, għandu jiżdied dan il-proviso li ġej:

“Iżda l-perjodu ta' għaxar snin hawn qabel imsemmi għandu jiġi estiż għal mhux iżjed minn hdax-il sena jekk, matul l-ewwel tmien snin minn dawk l-għaxar snin, id-detentur ta' l-awtorizzazzjoni għat-tqegħid fis-suq jikseb xi awtorizzazzjoni wahda jew aktar għal xi indikazzjoni terapewtika li, meta tkun qegħda ssirilha l-valutazzjoni xjentifika qabel l-awtorizzazzjoni tagħha, tiġi kkunsidrati bħala li jkollha benefiċċju kliniku sinifikanti kif paragonat ma' terapiji eżistenti.”; u

(ċ) fit-tieni proviso mas-subparagrafu (ii) tiegħu, fit-tifsira “prodott mediċinali ta' referenza” minflok il-kliem “bir-regolament 4,” għandhom jidhru l-kliem “bir-regolament 4(1),”.

L.N. 231 of 2008

**MEDICINES ACT
(CAP. 458)**

**Medicines (Marketing Authorisation) (Amendment) Regulations,
2008**

IN exercise of the powers conferred by article 106 of the Medicines Act, the Minister for Social Policy has made the following regulations:-

1. The title of these regulations is the Medicines (Marketing Authorisation) (Amendment) Regulations, 2008 and they shall be read and construed as one with the Medicines (Marketing Authorisation) Regulations, 2007 hereinafter referred to as “the principal regulations”.

Title.

L.N. 324 of 2007.

2. Regulation 2 of the principal regulations shall be amended as follows:

Amends regulation 2 of the principal regulations.

(a) sub-regulation (1) thereof shall be amended as follows:

(i) immediately after the definition “abuse of medicinal products” there shall be inserted the following new definition:

“advanced therapy medicinal product” means a product as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products;”;

(ii) the definition “provisional marketing authorisation” shall be deleted; and

(b) in paragraph (g) of sub-regulation (2) thereof, for the words “direct personal responsibility.” there shall be substituted the words “direct personal responsibility;” and immediately thereafter there shall be added the following new paragraph:

“(h) any advanced therapy medicinal product, as defined in Regulation (EC) No 1394/2007, which is prepared on a non-routine basis according to specific quality standards, and used in Malta in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient. The

manufacturing of these products shall be authorised by the Licensing Authority in Malta.”.

Amends regulation
4 of
the principal
regulations.

3. Sub-regulation (1) of regulation 4 of the principal regulations shall be amended as follows:

(a) in paragraph (a) thereof, immediately after the words “for paediatric use” there shall be added the words “and Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of the 13th November 2007 on advanced therapy medicinal products”; and

(b) paragraph (g) thereof shall be deleted and paragraph (h) shall be renumbered as paragraph (g) thereof.

Amends regulation
7 of
the principal
regulations.

4. Paragraph (a) of sub-regulation (1) of regulation 7 of the principal regulations shall be amended as follows:

(a) in sub-paragraph (i) thereof, for the words from “Article 6 of Directive 2001/83/EC” to the words “in Malta or in the Community.” there shall be substituted the words “Regulation 4(1) for not less than eight years in a Member State or in the Community. A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.”;

(b) immediately after sub-paragraph (i) thereof, there shall be added the following proviso:

“Provided that the said ten-year period shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.”; and

(c) in the second proviso to sub-paragraph (ii) thereof, in the definition “reference medicinal product” for the words “under regulation 4,” there shall be substituted the words “under regulation 4(1),”.