

**A.L. 465 ta' l-2004****ATT TA' L-2003 DWAR IL-MEDIĊINI  
(ATT III TA' L-2003)****Regolamenti ta' l-2004 li jemendaw ir-Regolamenti dwar  
il-Mediċini (Awtorizzazzjoni ghat-Tqeghid fis-Suq)**

BIS-SAHHA tas-setghat moghtija mill-artikolu 106 ta' l-Att ta' l-2003 dwar il-Mediċini, il-Ministru tas-Sahha, l-Anzjani u Kura fil-Komunità ghamel ir-regolamenti li ġejjin:-

1. (a) It-titolu ta' dawn ir-regolamenti huwa Regolamenti ta' l-2004 li jemendaw ir-Regolamenti dwar Mediċini (Awtorizzazzjoni ghat-Tqeghid fis-Suq), u ghandhom jinqraw u jiftiehmha waħda mar-Regolamenti ta' l-2004 dwar il-Mediċini (Awtorizzazzjoni ghat-Tqeghid fis-Suq), hawnhekk iżjed 'il quddiem imsejhin "ir-regolamenti prinċipali".

Titolu u skop.

A. L. 387 ta' l-2004.

(b) L-iskop ta' dawn ir-regolamenti huwa li tiġi trasposta d-Direttiva 93/41/KEE.

2. Wara regolament 24 ghandu jżied regolament ġdid:-

Iżid ir-regolament 26 ġdid mar-regolamenti prinċipali.

"Applikazzjonijiet qabel l-1 ta' Jannar, 1995.

"26. Applikazzjonijiet għall-awtorizzazzjoni ghat-tqeghid fis-suq li jkunu ġew imghoddija lill-Kumitat tal-Prodotti Mediċinali Proprjetarji qabel l-1 ta' Jannar, 1995 skond l-Artikolu 2 tad-Direttiva 87/22/KEE u li dwarhom il-Kumitat konċernat ma tax opinjoni sa l-1 ta' Jannar, 1995, ghandhom jiġu kkunsidrati skond Regolament (KEE) numru 2309/93."

**L.N. 465 of 2004**

**MEDICINES ACT, 2003  
(ACT III OF 2003)**

**Medicines (Marketing Authorisation) (Amendment) Regulations,  
2004**

IN exercise of the powers conferred by article 106 of the Medicines Act, the Minister of Health, the Elderly and Community Care has made the following regulations:-

1. (a) The title of these regulations is Medicines (Marketing Authorisation) (Amendment) Regulations, 2004 and they shall be read and construed as one with the Medicines (Marketing Authorisation) Regulations, 2004, hereinafter referred to as “the principal regulations”. Title and scope  
L.N. 387 of 2004.

(b) The scope of these regulations is to transpose Directive 93/41/EEC.

2. Immediately after regulation 25 of the principal regulations there shall be added the following new regulation: Adds regulations 26 to the principal regulations.

“Applications made before 1<sup>st</sup> January, 1995.

“26. Applications for marketing authorisations which have been referred to the Committee for Proprietary Medicinal Products before the 1<sup>st</sup> January, 1995 in accordance with Article 2 of Directive 87/22/EEC and in respect of which the Committee concerned has not given an opinion by the 1<sup>st</sup> January, 1995, shall be considered in accordance with regulation (EEC) No 2309/93.”.