

A.L. 378 ta' l-2004

**ATT TA' L-2003 DWAR IL-MEDIĊINI,
(ATT. NRU. III TA' L-2003)**

**Regolamenti ta' l-2004 li jemendaw ir-Regolamenti dwar
l-Importazzjoni u d-Distribuzzjoni bl-Ingrossa ta'
Prodotti Mediċinali**

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 106 ta' l-Att ta' l-2003 dwar il-Mediċini, il-Ministru tas-Saħħa, l-Anzjani u Kura fil-Kommunità għamel ir-regolamenti li ġejjin:-

1. It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2004 li jemendaw ir-Regolamenti ta' l-2004 dwar l-Importazzjoni u d-Distribuzzjoni bl-Ingrossa ta' Prodotti Mediċinali, u għandhom jinqraw u jiftiehmu haġa waħda mar-Regolamenti ta' l-2004 dwar l-Importazzjoni u d-Distribuzzjoni bl-Ingrossa ta' Prodotti Mediċinali, hawnhekk iżjed 'il quddiem imsejha "ir-regolamenti prinċipali" .

Titolu.

A.L. 154 ta' l-2004.

2. Fir-regolament 2 tar-regolamenti prinċipali, wara d-definizzjoni "persuna responsabbli" għandu jidhol dan li ġej:

Jemenda r-regolament 2 tar-regolamenti prinċipali.

“ “prodott mediċinali” tfisser prodott mediċinali li tkun inħarġitlu awtorizzazzjoni għal tqegħid fis-suq mill-awtorità kompetenti ta' Stat Membru jew konformement mar-Regolament (EC) 726/2004;”

3. (1) Ir-regolament 7 kollu kif inhu bħalissa tar-regolamenti prinċipali għandu jiġi enumerat mill-ġdid bħala subregolament (1) tar-regolament.

Jemenda r-regolament 7 tar-regolamenti prinċipali.

(2) Minnufih wara s-subregolament (1) kif enumerat mill-ġdid, għandu jidhol dan li ġej:-

“(2) Kull bejjiegh bl-ingrossa għandu jiżgura li ssir provvista kif imiss u kontinwa ta' prodotti mediċinali lil spiżeriji u persuni li jkunu awtorizzati jissuplixxu prodotti mediċinali biex dawn ikunu jissodisfaw il-htigijiet tal-pazjenti.

(3) Iktar minn hekk, il-bejjiegh bl-ingrossa ghandu, ghal kull prodott li jkun qed jiddistribwixxi jaghti lill-Awtorità kopja awtentikata ta' awtorizzazzjoni ghal tqeghid fis-suq valida f'Malta, flimkien ma ittra ta' aċċess, it-tnejn mahruġin mid-detentur ta' l-awtorizzazzjoni ghal tqeghid fis-suq, u li jkunu jaghtu lill-bejjiegh bl-ingrossa d-dritt li juża dik l-awtorizzazzjoni ghal tqeghid fis-suq:

Iżda bejjiegh bl-ingrossa jista' jiġġestixxi d-distribuzzjoni bl-ingrossa ta' prodotti mediċinali li dwarhom ma jkunux gew imghoddija lill-Awtorità kopja awtentikata ta' awtorizzazzjoni ghal tqeghid fis-suq valida f'Malta u ittra ta' aċċess, jekk biss huwa jkollu fil-pussess tiegħu liċenza ta' importazzjoni parallela mahruġa skond il-liġi li jkun hemm fis-sehħ f' dak iż-żmien.” .

Iżid ir-regolament 11 ġdid mar-regolamenti prinċipali.

4. Minnufih wara r-regolament 10 tar-regolamenti prinċipali ghandu jidhol dan ir-regolament ġdid numru 11 kif ġej:

“Dmirijiet ta' kull distributtur li ma jkunx id-detentur ta' l-awtorizzazzjoni ghal tqeghid fis-suq.

11. Ikun id-dmir ta' kull distributtur, li ma jkunx id-detentur ta' awtorizzazzjoni ghal tqeghid fis-suq, li jimporta prodott minn Stat Membru iehor, li jawża lid-detentur ta' l-awtorizzazzjoni ghal tqeghid fis-suq u lill-Awtorità bl-intenzjoni li jkollu li jimporta dak il-prodott. Fil-każ ta' prodotti li ma tkunx inhargitilhom awtorizzazzjoni skond Regolament (EC) Nru. 726/2004, l-avviż lill-Awtorità ghandu jkun minghajr preġudizzju ghal proċeduri addizzjonali kif provdut dwarhom il-liġi li jkun hemm fis-sehħ f' dak iż-żmien.” .

L.N. 378 of 2004

**MEDICINES ACT, 2003
(ACT NO. III OF 2003)**

**Importation and Wholesale Distribution of Medicinal Products
(Amendment) Regulations, 2004**

IN exercise of the powers conferred by article 106 of the Medicines Act, 2003, the Minister of Health, the Elderly and Community Care, has made the following regulations:–

1. The title of these regulations is the Importation and Wholesale Distribution of Medicinal Products (Amendment) Regulations, 2004 and they shall be read and construed as one with the Importation and Wholesale Distribution of Medicinal Products Regulations, 2004 hereinafter referred to as “the principal regulations”.

Title.

L.N. 154 of 2004.

2. In regulation 2 of the principal regulations, after the definition “imported medicinal products” there shall be inserted the following:

Amends regulation 2 of the principal regulations.

“ “medicinal product” means a medicinal product in respect of which a marketing authorization has been issued by the competent authority of a Member State or pursuant to Regulation (EC) No 726/2004;”.

3. (1) The present whole regulation 7 of the principal regulations shall be renumbered as sub-regulation (1) thereof.

Amends regulation 7 of the principal regulations.

(2) Immediately after sub-regulation (1) as renumbered, there shall be inserted the following:-

“(2) Every wholesale dealer shall ensure that an appropriate and continuous supply of medicinal products is furnished to pharmacies and persons authorized to supply medicinal products in order to satisfy the needs of patients.”

(3) In addition, the wholesale dealer shall, in respect of each product he is distributing, furnish to the Authority an authenticated copy of a valid marketing authorization in Malta, together with a letter of access, both issued by the marketing authorization holder, granting the wholesale dealer the right of use of such marketing authorization:

Provided that a wholesale dealer may only engage in the wholesale distribution of medicinal products in respect of which no such authenticated copy of a valid marketing authorization in Malta and letter of access have been forwarded to the Authority, if he is in possession of a parallel import licence issued in terms of the law in force at the time.”.

Adds new regulation 11 to the principal regulations.

4. Immediately after regulation 10 of the principal regulations there shall be inserted the following new regulation 11:

“Duty of any distributor not being the marketing authorization holder. 11. It shall be the duty of any distributor, not being the marketing authorization holder, who imports a product from another Member State to notify the marketing authorization holder and the Authority of his intention to import such product. In the case of products which have not been granted an authorization in terms of Regulation (EC) No726/2004, the notification to the Authority shall be without prejudice to additional procedures provided for by the law in force at the time.”.