

**A.L. 437 ta' l-2004****ATT TA' l-2003 DWAR IL-MEDIĊINI  
(ATT NRU. III TA' l-2003)****Regolamenti ta' l-2004 dwar l-Importazzjoni Parallela  
ta' Prodotti Mediċinali**

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

1. It-titolu ta' dawn ir-regolamenti hu **Regolamenti ta' l-2004** Titolu  
dwar l-Importazzjoni Parallela ta' Prodotti Mediċinali.

2. Ghall-finijiet ta' dawn ir-regolamenti; Tifsir.

“l-Att” ifisser l-Att ta l-2003 dwar il-mediċini;

“distribuzzjoni parallela” tfisser l-importazzjoni minn Stat Membru ta' l-Unjoni Ewropea jew minn pajjiż fiż-żona Ekonomika Ewropea ta' prodott mediċinali awtorizzat bis-sistema ċentrali, minn importatur li jkun xi hadd differenti minn dak l-importatur awtorizzat u mahtur mid-detentur ta' l-awtorizzazzjoni ghall-kummerċ tal-prodott fis-suq f'Malta;

“importatur parallel” tfisser persuna li twettaq fl-attività ta' importazzjoni parallela;

“importazzjoni parallela” tfisser l-importazzjoni minn stat membru ta' l-Unjoni Ewropea jew minn pajjiż minn fiż-żona Ekonomika Ewropea ta' prodott mediċinali li jkun diġà awtorizzat li jitqiegħed fis-suq f'Malta, minn importatur li jkun xi hadd differenti minn dak l-importatur awtorizzat u mahtur mid-detentur ta' l-awtorizzazzjoni ghall-kummer tal-prodott fis-suq f'Malta;

“ippakkjar mill-ġdid” tinkludi t-tnehhija ta' '*Blister packs*' mill-pakkett oriġinali u t-tqegħid tagħhom f'pakkett esterjuri ġdid jew iż-żjieda ta' struzzjonijiet ġodda jew ta' informazzjoni ġdida dwar l-użu ġodda ta' oġġett jew it-twahhil ta' tikketti li jkunu jehlu minnhom nfushom.

“il-Kummissjoni” tfisser il-Kummissjoni ta' l-Unjoni Ewropea;

“pajjiż ta’ l-origini” tfisser dak ‘l-Istat Membru jew pajjiż fiż-żona Ekonomika Ewropea minn fejn il-prodott importat parallelament li jkun ġie mportat;

“prodott importat parallelament” tfisser prodott awtorizzat fi Stat Membru jew f’pajjiż fiż-żona Ekonomika Ewropea li jkun ġie mportat permezz ta’ mportazzjoni parallela;

“prodott fis-suq Malti” tfisser il-prodott mediċinali li jkollu awtorizzazzjoni għal tqeghid fis-suq u li miegħu jitqabbel il-prodott mediċinali importat parallelament;

“Stat Membru” tfisser Stat li hu membru ta’ l-Unjoni Ewropea.

Htieġa ta’ liċenza.

**3.** (1) L-ebda persuna ma tista’ timporta prodotti mediċinali parallelament kemm il-darba ma jkollhiex liċenza ta’ importazzjoni parallela għal kull prodott mediċinali, hawn iżjed ’il quddiem tkun imsejha l-liċenza.

(2) L-ebda persuna ma tista’ timporta prodotti mediċinali parallelament kemm il- darba ma jkollhiex:

(a) liċenza ta distribuzzjoni bl-ingrossa skond id-dispożizzjonijiet tar-Regolamenti dwar l-Importazzjoni u Distribuzzjoni ta’ Prodotti Mediċinali.

(b) liċenza ta’ mportazzjoni parallela mahruġa mill-Awtorità.

(3) Meta d-detentur ta’ l-liċenzja ta’ manifattura għall-ippakjar mill-ġdid ta’ prodotti importati parallelament ikun ukoll id-detentur ta’ liċenza ta’ importazzjoni parallela għall-istess prodott, huwa jkollu d-dritt li jiddistribwixxi bl-ingrossa l-prodott importat parallelament kif ippakjati mill-ġdid li dwaru tkun inharget il-liċenza ta’ manifattura.

Applikazzjoni għal hrug ta’ liċenza.

**4.** (1) Applikazzjoni sabiex tinhareġ liċenza għall-importazzjoni parallela għandha ssir lill-Awtorità dwar il-Liċenzi u għandu jkun fiha dik l-informazzjoni, dawk id-dokumenti u kull materjal iehor skond id-dispożizzjonijiet ta’ dawn ir-regolamenti.

(2) Applikazzjoni bhal dik imsemmija fis-subregolament (1) għandha tindika:

(a) l-isem, l-indirizz u d-dettalji ta’ persuna nformata li jista’ jsir kuntatt magħha tad-detentur tal-liċenza ta’ l-importazzjoni parallela proposta;

(b) l-isem u l-indirizz ta' l-applikant, jekk dan ikun differenti minn dak tad-detentur tal-liċenza;

(ċ) l-istil fil-kummer tad-detentur tal-liċenza ta' importazzjoni parallela fuq it-tikketti u l-fuljetti tat-tgharif;

(d) l-isem, il-forma farmaewtika, kull sustanza attiva, id-doża, dettalji tad-daqs tal-pakkett, id-detentur ta' l-awtorizzazzjoni għall-kummer, u n-numru ta' l-awtorizzazzjoni għall-kummer tal-prodott mediċinali li dwaru tkun qegħda ssir applikazzjoni għal-liċenza ta' importazzjoni parallela;

(e) l-isem, il-forma farmaewtika, doża, dettalji ta' l-isem u l-indirizz ta' d-detentur ta' l-awtorizzazzjoni għall-kummerċ u n-numru tal-awtorizzazzjoni għall-kummerċ tal-prodott fis-suq Malti;

(f) kopja tal-liċenza ta distribuzzjoni bl-ingrossa u jekk il-prodott importat parallelament ikun se jiġi ppakkjat mill-ġdid, kopja tal-liċenza tal-manifattur; iżda jekk id-detentur tal-liċenza tal-manifattur ikun responsabbli kemm għall-ippakkjar mill-ġdid kemm għad-distribuzzjoni bl-ingrossa tal-prodott importat parallelament, f'dak il-każ tkun mehtieġa biss kopja tal-liċenza tal-manifattur mehtieġa; u

(g) il-bażi li fuqha l-applikant jkun qed ivanta prezunzjoni ta' similarità essenzjali bejn il-prodott lokali u dak importat.

(3) L-Awtorità għandha tipproċessa applikazzjoni għal-liċenzja ta' importazzjoni parallela fi żmien hamsa u erbgħin gurnata minn meta l-applikazzjoni tiġi validata. Dak il-perjodu jiġi sospiż f'dawk il każijiet meta l-applikant jiġi mitlub li jagħti aktar informazzjoni.

**5. (1)** Liċenza għall-importazzjoni parallela tinghata biss għall-prodotti mportati parallelament li jkunu jissodisfaw dawn il-kriterji li ġejjin: Għoti ta' liċenzi.

(a) il-prodott fis-suq Malti għandu jkollu awtorizzazzjoni valida għal tqeghid fis-suq f'Malta;

(b) il-prodott importat parallelament għandu jiġi mportat minn Stat Membru jew minn pajjiż fiż-żona Ekonomika Ewropea u għandu jkollu awtorizzazzjoni valida għal tqeghid fis-suq f'dak il-pajjiż;

(ċ) il-prodott importat parallelament għandu jkollu l-istess forma farmaewtika u jkun l-istess bhal, jew ma jkollu

ebda differenza terapewtika sinifikanti minn, il-prodott tas-suq Malti.

(2) Liċenza għall-importazzjoni parallela ma tibqax valida f'każ li l-awtorizzazzjoni għall-kummer tiġi rtirata minhabba raġunijiet direttament relatati mal-protezzjoni tas-saħha pubblika.

Perjodu ta' validità u t-tiġdid.

**6.** Liċenza għall-importazzjoni parallela tiġi mghotija għal perjodu ta' hames snin. L-applikazzjoni biex tiġgedded il-liċenzja għall-importazzjoni parallela għandha tiġi ppreżentata lill-Awtorità dwar il-Liċenzi mhux aktar tard minn tlett xhur qabel ma tiskadi l-liċenza ta' qabel.

Dmirijiet ta' importanza parallela.

**7.** Huwa d-dmir ta' importatur parallel li:

(a) jiżgura li jkun hemm sistema ta' verifika ċara dwar kif jimxi il-prodott mediċinali minghand id-distributur awtorizzat jew il-manifattur fil-pajjiż minn ta' l-orijini;

(b) jippreżenta lill-Awtorità dwar il-Liċenzi dikjarazzjoni li l-fornatur tiegħu jkun ser iżommu nformat dwar dak kollu reletat mal-Farmakoviġilanza;

(c) jipprovdi, f'każ ta' ippakkjar mill-ġdid ta' prodott mediċinali, dikjarazzjoni bil-miktub li tkun tikkonferma li d-detentur ta' l-awtorizzazzjoni għall-kummer tal-prodott oriġinali imqiegħed fis-suq f'Malta jkun ġie avżat dwar li prodott ippakkjat mill-ġdid ikun se jitqiegħed fis-suq f'Malta, xahar qabel ma tiġi ppreżentata l-applikazzjoni lill-Awtorità dwar il-Mediċini. Kopja ta' l-ittra li tintbagħat lid-detentur ta' l-awtorizzazzjoni għall-kummer għandha wkoll tiġi ppreżentata flimkien ma' l-applikazzjoni għal liċenza ta' importazzjoni parallela;

(d) jiżgura, fil-każ ta' prodotti ppakkjati mill-ġdid, li n-numru tal-liċenza ta' l-importazzjoni parallela assenjat mill-Awtorità dwar il-Liċenzi jkun jidher fuq l-ippakkettjar fuq barra tal-prodott mediċinali. F'każ li l-prodott mediċinali li jkollu liċenza ta' importazzjoni parallela ikun wiehed identiku mal-prodott fis-suq Malti, għandhom japplikaw għal-istess kondizzjonijiet ta' enumerazzjoni bħal ma japplikaw għal prodott fis-suq Malti.

Records li għandhom jinżammu.

**8.** (1) Għandu impurtatur parallel dejjem iżomm *records* ta' l-orijini, l-kwantitajiet importati, u n-numri tal-lott tal-prodotti mediċinali mportati parallelament.

(2) Meta hekk tintalab dik l-informazzjoni msemmija fis-subregolament (1) ta' dan ir-regolament għanda tiġi ppreżentata lill-Awtorità dwar il-Liċenzi minghajr ebda' dewmien.

**L.N. 437 of 2004**

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

**Parallel Importation of Medicinal Products 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 Parallel Importation of Medicinal Products Regulations, 2004. Title.

**2.** For the purpose of these regulations- Interpretation.

“the Act” means the Medicines Act, 2003

“the Commission” means the Commission of the European Union;

“Maltese-market product” means the medicinal product for which a marketing authorisation has been granted with which the parallel imported medicinal product is compared;

“Member State” means a State which is a member of the European Union;

“parallel distribution” means the importation from a Member State or a country within the European Economic Area of a centrally authorised medicinal product, by an importer who is someone other than the importer authorised and appointed by the marketing authorisation holder of the product on the Maltese market;

“parallel importation” means the importation from a Member State or a country within the European Economic Area of a medicinal product which is already authorised on the Maltese market, by an importer who is someone other than the importer authorised and appointed by the marketing authorisation holder of the product on the Maltese market;

“parallel importer” means a person engaged in the activities of parallel importation;

“parallel imported product” means a product authorised in a Member State or a country within the European Economic Area imported by parallel importation;

“repackaging” includes the removal of blister packs from the original packaging and their insertion into new external packaging or addition of new user instructions or information or the fixing of self-stick labels;

“source country” means the Member State country from which the parallel imported product is imported.

Licence  
requirement.

**3.** (1) No person shall engage in the parallel importation of medicinal product unless he is in possession of a parallel import licence in respect of each medicinal product, hereinafter referred to as the licence.

(2) No person shall engage in the parallel importation of medicinal products unless such a person is in possession of:

(a) wholesale dealer’s licence in accordance with the provisions of the Importation and Wholesale Distribution of Medicinal Products Regulations, and

(b) parallel import licence issued by the Authority.

(3) When the holder of the manufacturing licence for repackaging of a parallel imported product is also the holder of the parallel import licence in respect of the product, he shall have the right to distribute by wholesale the repackaged parallel imported product in respect of which the manufacturing licence has been issued.

Application for  
granting of a  
licence.

**4.** (1) Any application for the granting of a parallel import licence shall be made to the Licensing Authority and shall contain such information, documents any other material in accordance with the provisions of this regulation.

(2) Such application as is mentioned in sub-regulation (1) shall indicate the following:

(a) name, address and contact person of the proposed parallel import licence holder;

(b) name and address of the applicant, if different from that of the licence holder;

(c) parallel import licence holder's trading style on labels and leaflets;

(d) name, pharmaceutical form, any active ingredient, strength, pack size details, marketing authorisation holder, marketing authorisation number of the medicinal product for which a parallel import licence is being applied for;

(e) name, pharmaceutical form, strength, name and address of the marketing authorisation holder and marketing authorisation number of the Maltese-market product;

(f) copy of the wholesale dealer's licence and, if the parallel imported product is to be repackaged, of the manufacturer's licence; provided that if the holder of the manufacturer's licence is responsible for both repackaging and distribution of the parallel imported product, then only a copy of the manufacturer's licence shall be required; and

(g) basis on which the applicant makes a presumption of essential similarity between the local and imported product.

(3) The Authority shall process an application for a parallel import license within forty-five working days of validation of the application. Such period shall be suspended in those cases where the applicant is requested to furnish additional data.

**5.** (1) A parallel import licence shall only be granted for parallel imported products that fulfill the following criteria: Granting for a licence.

(a) Maltese-market product shall have a valid marketing authorisation in Malta;

(b) parallel imported product shall be imported from a Member State or a country of the European Economic Area and it must have a valid marketing authorisation in that country;

(c) parallel imported product shall have the same pharmaceutical form and be identical to, or have no significant therapeutic difference from, the Maltese-market product.

(2) A parallel import licence shall cease to be valid if the marketing authorisation is withdrawn for reasons directly related to the protection of public health.

Validity and renewal.

**6.** A parallel import licence is granted for a period of five years. An application for the renewal of the parallel import licence shall be submitted to the Licensing Authority no later than three months before expiry of the previous licence.

Duties of parallel importer.

**7.** It shall be the duty of a parallel importer to:

(a) ensure that there is a clear audit trail from the authorised distributor or manufacturer in the source country;

(b) submit to the Licensing Authority a declaration that the supplier is going to keep him informed of any Pharmacovigilance issues;

(c) provide, in the case of repackaging of a medicinal product, a written declaration stating that the marketing authorisation holder of the original product marketed in Malta has been notified about the repackaged product being put on sale in Malta, one month prior to submitting the application to the Medicines Authority. A copy of the letter sent to the marketing authorisation holder shall also be submitted together with the application for a parallel import licence;

(d) ensure, in the case of repackaged products, that the parallel import licence number assigned by the Licensing Authority is present on the outer packaging of the medicinal products. In the case where the medicinal product with the parallel import licence is identical to the Maltese market product, the same requirements for numbering apply as for the Maltese market product.

Keeping of records.

**8.** (1) A parallel importer shall at all times keep records of the origin, imported quantities, and batch numbers of the parallel imported medicinal products.

(2) Upon request, such information as is referred to in sub-regulation (1) hereof shall be submitted to the Licensing Authority without delay.