

A.L. 26 ta' l-2006**ATT TA' L-2003 DWAR IL-MEDIĊINI
(ATT NRU. III TA' L-2003)****Regolamenti ta' l-2006 dwar Drittijiet li tiġbor l-Awtorità
Dwar il-Mediċini**

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 106 ta' l-Att ta' l-2003 dwar il-Mediċini, il-Ministru tas-Sahha, Anzjani u Kura fil-Komunità, wara konsultazzjoni ma' l-Awtorità dwar il-liċenzjar, u bi ftehim mal-Prim Ministru u Ministru tal-Finanzi, għamel ir-regolamenti li ġejjin:-

1. (1) It-titolu ta' dawn ir-regolamenti hu **Regolamenti ta' l-2006** dwar Drittijiet li tiġbor l-Awtorità dwar il-Mediċini. Titolu.

2. Għall-finijiet ta' dawn ir-regolamenti – Tifsir.

“Id-Direttiva 2001/83/KE” tfisser Direttiva 2001/83/KE tal-Parlament Ewropew u tal-Kunsill tas-6 ta' Novembru 2001, dwar il-Kodiċi Komunitarju dwar prodotti mediċinali għall-użu mill-bniedem, u l-emendi relattivi kif emendat bid-Direttiva 2004/27/KE u d-Direttiva 2004/24/KE;

“liċenza kwalifikata” hija liċenza mogħtija lil prodott biex dan jitqiegħed fis-suq mingħajr awtorizzazzjoni għat-tqegħid fis-suq, kif speċifikat fl-Att ta' l-2003 dwar il-Mediċini u l-leġislazzjoni sussidjarja;

3. Għandhom jithallsu lill-Awtorità dwar il-Mediċini, dwar liċenza kwalifikata u attivitajiet relatati, il-hlasijiet li jidhru fl-Iskeda li tinsab ma' dawn ir-regolamenti: Drittijiet.

Izda dawn id-drittijiet ma' jkoprux hlasijiet li jkun hemm bżonn li jithallsu lill-awtoritajiet kompetenti ohra għal xi dokumenti u, jew rapport li jkunu meħtieġa mill-Awtorità dwar il-Mediċini għall-hruġ finali ta' dawn il-liċenzi jew għal deċiżjonijiet. Dawk l-ispejjeż addizzjonali mħallsa mill-Awtorità dwar il-Mediċini għandhom jiġu mitluba separatament.

SKEDA

Liċenza (Liċenza Kwalifikata) biex jitqiegħed fis-suq prodott mingħajr awtorizzazzjoni għat-tqegħid fis-suq għal kull prodott (skond Artiklu 126(a) tad-Direttiva 2001/83/KE), skond l-għamla farmaċewtika/doża	Lm
Liċenza kwalifikata (Riċevuta u validazzjoni ta' l-applikazzjoni)	50
Hruġ ta' liċenza	150
Notifika ta' varjazzjoni approvata	10
Tiġdid annwali tal-liċenza	50

L.N. 26 of 2006

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

Medicines Authority (Fees) Regulations, 2006

IN exercise of the powers conferred by article 106 of the Medicines Act, 2003, the Minister of Health, Elderly and Community Care after consultation with the Licensing Authority and with the concurrence of the Prime Minister and Minister of Finance, has made the following regulations:—

1. (1) The title of these regulations is the Medicines Authority (Fees) Regulations, 2006. Title.

2. For the purposes of these regulations – Interpretation.

“Directive 2001/83/EC” shall mean Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, and its amendments as amended by Directive 2004/27/EC and Directive 2004/24/EC;

“qualified licence” is a licence granted to a product to be placed on the market without a marketing authorisation as specified in the Medicines Act, 2003 and any regulations made thereunder;

3. There shall be paid to the Medicines Authority, in respect of a qualified licence and related activities, fees as specified in the Schedule to these regulations. Fees.

Provided that these fees do not include any fees charged by other competent authorities in relation to any documentation and, or, reports required by the Medicines Authority for final issue licences or decisions. Such additional expenses incurred by the Medicines Authority shall be charged separately.

SCHEDULE

Licence for placing on the market of products without a marketing authorisation (Qualified Licence) per product (Article 126(a) of Directive 2001/83/EC) per pharmaceutical form/strength	Lm
Qualified licence (Receipt and validation of application)	50
Issue of licence	150
Notification of approved variation	10
Annual renewal of licence	50