

L.N. 261 of 2002

**PATENTS ACT
(CAP. 417)**

Patents (Medicinal Products) Regulations, 2002

IN exercise of the powers conferred by article 59 of the Patents Act, the Minister for Economic Services has made the following regulations: -

1. (1) The title of these regulations is the Patents (Medicinal Products) Regulations, 2002. *Citation and commencement*

(2) These regulations shall come into force on the 1st day of January 2003.

2. In these regulations, unless the context otherwise requires:- *Interpretation*

"Act" means the Patents Act;

"certificate" means a supplementary protection certificate issued by the Comptroller for the purposes of these regulations;

"Comptroller" means the Comptroller of Industrial Property;

"medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or animals;

"patent" means a patent as defined in the Act, in relation to a product;

"product" means the active ingredient or combination of active ingredients of a medicinal product and includes the process to obtain such product or an application of such product;

3. These regulations shall apply to any product protected by a patent and which is subject, prior to being placed on the market as a medicinal product, to an authorisation procedure. *Scope and applicability*

4. (1) Any person who has obtained a market authorisation in relation to a product may apply for a certificate to the Comptroller. *Application for a certificate*

(2) The application for such certificate shall be lodged within six months from

the date on which the market authorisation has been granted.

(3) Notwithstanding the provisions of subregulation (2) of this regulation, where the authorisation to place the product on the market is granted before the patent is granted, the application for a certificate shall be lodged within six months from the date on which the patent is granted.

5. A certificate shall be granted if on the date of the application:

*Conditions for
granting a
certificate*

- (a) the product is protected by a patent;
- (b) an authorisation to place the product on the market as a medicinal product has been granted and is in force;
- (c) the said authorisation is the first authorisation to place the product on the market as a medicinal product; and
- (d) the product has not already been granted a certificate.

6. An application for a certificate shall contain the following information:-

*Contents of
application*

- (a) the name and address of the applicant;
- (b) if the applicant is being represented by an agent the name and address of such agent;
- (c) the registration number of the patent and the title of the invention;
- (d) the date and the number if any, of the first authorisation to place the product on the market:

Provided that if such authorisation has been previously granted by an authority outside Malta with which the Government of Malta has reciprocal or international agreement on supplementary protection certificates, the date, the number if any, and the country where the authorisation has been first granted;

- (e) a copy of the market authorisation together with a summary of the product characteristics and in the case that the first market authorisation has been granted by an authority outside Malta as aforesaid also a copy of that authorisation together with a summary of the product characteristics.

7. The Comptroller shall, on receipt of an application for a certificate, issue a notice in the Gazette containing the following information:-

*Publication of
application*

- (a) the name and address of the applicant; ,
- (b) the registration number of the patent;
- (c) the title of the patented invention;

(d) the date and the number, if any, of the market authorisation and the product identified in that authorisation;

(e) if applicable, the date and the number if any, of the first authorisation to place the product on the market if the first authorisation has been granted by an authority outside Malta.

8. (1) Where the application for a certificate meets the requirements established under these regulations the Comptroller shall grant a certificate.

Grant of certificate

(2) A certificate shall only be granted to the proprietor of the patent.

(3) Where in the opinion of the Comptroller the application does not fully comply with the requirements established under these regulations he shall notify the applicant accordingly which notification shall contain the reasons why the application is non-compliant.

(4) The applicant may, within 60 days from receipt of the notification mentioned in sub-regulation (3) above, rectify his position to the satisfaction of the Comptroller, failing which the Comptroller shall reject the application.

(5) The Comptroller shall, on the granting of a certificate issue a notice in the Gazette containing the information listed under paragraphs (a) to (e) of regulation 7 of these regulations together with the date of granting and the date of expiry of the certificate.

(6) If an application has been rejected, the Comptroller shall issue a notice to this effect in the Gazette. Such notice shall contain the information listed under paragraphs (a) to (e) of regulation 7 of these regulations.

(7) Any fee paid for an application which has been rejected under this regulation shall be forfeited.

9. Where a certificate has been granted under these regulations, the protection conferred by the patent in relation to the product shall continue to apply for the duration established under regulation 10 of these regulations, subject to the same limitations and obligations.

Effects of certificate

10. The duration referred in regulation 9 above shall commence at the expiry of the term of the patent and shall continue to have effect for that period equal to the period elapsed between the first day of the sixth year following the date of the application for a patent and the date of the first authorisation to place the product on the market in Malta or in any other country with which the Government of Malta has reciprocal or international agreements on supplementary protection certificates:

Duration of licence

Provided that the period lapsed as aforesaid shall in no case exceed five years.

11. (1) The certificate shall lapse:

Expiry of the certificate

(a) at the end of the period provided for in regulation 10 above; or

(b) if the certificate-holder surrenders it; or

(c) if any fee due is not duly paid; or

(d) if the market authorisation in relation to the product has been withdrawn.

12. (1) The certificate shall be invalid if:

*Invalidity of
the certificate*

(a) the provisions of regulation 5 of these regulations have not been complied with; or

(b) the patent has lapsed before the expiry of its term; or

(c) the patent is revoked or limited to the extent that product for which the certificate was granted would no longer be protected by the claims of the patent or, after the patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

(2) Any person may submit an application to the Comptroller for a declaration of invalidity of a certificate.

13. If the certificate lapses as is referred to in paragraphs (b), (c) and (d) of regulation 11 of these regulations or is invalid as is referred to in regulation 12 of these regulations the Comptroller shall notify such event in the Gazette.

*Notification of
lapse or
invalidity*

14. In the absence of procedural provisions in these regulations, the procedural provisions applicable under the principal Act in relation to a patent shall, to the extent that they may be applicable, apply to a certificate.

Procedure

15. Any product which, on the date of coming into force of these regulations, is protected by a patent and for which the first authorisation to place it on the market in Malta as a medicinal product was obtained may be granted a certificate. In such a case the six month period referred to in subregulation 4(2) of these regulations shall commence on the coming into force of these regulations.

Transitory