SUBSIDIARY LEGISLATION 417.03

PATENTS (MEDICINAL PRODUCTS) REGULATIONS

1st January, 2003

LEGAL NOTICE 261 of 2002.

Citation.

1. The title of these regulations is the Patents (Medicinal Products) Regulations.

Interpretation.

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

Cap. 417.

"Act" means the Patents and Designs 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 in animals;

"patent" rneans 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.

Scope and applicability.

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.

Application for a certificate.

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

(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), 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.

Conditions for granting a certificate.

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

(*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.

Contents of application.

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

(*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 Govemment 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.

Publication of application.

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

(*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.

Grant of certificate.

8. (1) Where the application for a certificate meets the requirements established under these regulations the Comptroller shall grant a 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 sixty days from receipt of the notification mentioned in subregulation (3), 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 regulation 7(*a*) to (*e*) 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 regulation 7(*a*) to (*e*).

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

Effeccs of certificate.

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, subject to the same limitations and obligations.

Duration of licence.

10. The duration referred in regulation 9 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:

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

Expiry of the certificate.

11. The certificate shall lapse:

(*a*) at the end of the period provided for in regulation 10; 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.

Invalidity of the certificate.

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

(*a*) the provisions of regulation 5 have not been cornplied 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 the 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.

Notification of lapse or invalidity.

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

Procedure.

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

Transitory provision.

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 regulation 4(2) shall commence on the coming into force of these regulations.