

SUBSIDIARY LEGISLATION 458.31

**AVAILABILITY OF MEDICINAL PRODUCTS
WITHIN THE GOVERNMENT HEALTH SERVICES
REGULATIONS**

6th March, 2009

LEGAL NOTICE 58 of 2009.

- 1.** The title of these regulations is the Availability of Medicinal Products within the Government Health Services Regulations. Title.
- 2.** (1) The primary objective of these regulations is the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost in Government Health Services. Scope.
- (2) These regulations shall apply where the holder of a marketing authorisation, hereinafter referred to as "the applicant", wishes to apply for the inclusion of a medicinal product on the list of medicinal products covered by the Government Health Services, hereinafter referred to as "the Government Formulary List".
- (3) These regulations shall be without any prejudice to the power of the Superintendent of Public Health to:
- (a) include any medicinal product in the Government Formulary List;
 - (b) apply pricing measures to any pending and new applications for the introduction of medicinal products.
- 3.** The Superintendent of Public Health shall be responsible for the implementation of these regulations and shall be assisted by the Government Formulary List Advisory Committee, hereinafter referred to as "the Committee". Responsibilities.
- 4.** (1) The Government Formulary List Advisory Committee shall consist of: The Committee.
- (a) a chairperson;
 - (b) two pharmacists who are also public officers;
 - (c) two clinicians from amongst the medical consultants who are public officers;
 - (d) a patient representative;
 - (e) a legal advisor who is a public officer;
 - (f) two economic advisors.
- (2) The Chairperson and the members of the Committee -
- (a) shall be appointed by the Minister responsible for health for a period of two years;
 - (b) may resign their office at any time by giving notice in

writing to the Minister.

(3) The Minister may at any time remove the Chairperson and, or any of the members of the Committee appointed according to sub-regulation (2), on grounds of disability to perform their functions, bankruptcy or neglect of duty.

(4) The quorum necessary for meetings of the Committee shall be the Chairperson and not less than half the other members:

Provided that the Committee may act notwithstanding any vacancy among its members.

(5) Before reaching a decision the Committee may consult any experts it deems necessary.

(6) The decisions of the Committee shall be taken by a majority of votes of members present at the meeting. The Chairperson shall have an original vote and, in the case of equality of votes, also a second or casting vote.

(7) The Superintendent of Public Health, the members of the Committee and any experts shall declare their interest, and the Minister shall have the right to refuse any committee members or experts on the basis of conflict of interest.

The Government
Formulary List.

5. (1) The Government Formulary List shall include a list of medicinal products by the International Non-proprietary Name (INN). The products in this list shall be classified according to the Anatomical Therapeutic Chemical (ATC) classification.

(2) The Government Formulary List shall not include proprietary names of products, unless in exceptional circumstances where patient safety is compromised.

(3) The Government Formulary List shall include conditions specific to coverage within the Government Health Services in terms of entitlement to free medicines, supply within the Government Health Services (primary and secondary care, use in specific clinics or hospitals), prescriber criteria and use within the Government Health Services (specific prescribers, conditions for prescribing, protocols, therapeutic guidelines or clinical guidelines).

Cap. 458.

(4) Products which are not classified as medicinal products in terms of the definition of the Medicines Act may be included on the Government Formulary List.

Application.

6. (1) An applicant may request that a medicinal product be included in the Government Formulary List. In such cases the applicant shall forward a separate application to the Superintendent of Public Health in accordance with the requirements laid down by the said Superintendent, as specified in the application form in Schedule I to these regulations.

(2) Any decision on the inclusion of a medicinal product on the Government Formulary List and the reference price to be paid for such product by the Government Health Services shall be taken through a single administrative procedure, which procedure shall

not exceed one hundred and eightydays from date of application.

(3) The applicant shall furnish the Superintendent of Public Health with adequate information. If the information supporting the application is inadequate, the time limit set in the preceding subparagraph shall be suspended and the applicant shall be notified of such detailed information as may be required.

7. Any decision not to include a medicinal product in the Government Formulary List shall be communicated to the applicant and it shall contain:

Decision not to include.

- (a) a statement of reasons based upon the criteria in Schedule II, including, if appropriate, any expert opinions or recommendations on which the decision is based;
- (b) information about the remedies available to the applicant under the laws in force and of the time limits allowed for applying such remedies.

8. (1) Any decision to exclude a medicinal product from the Government Formulary List, shall contain a statement of reasons based on objective and verifiable criteria. Such decision including, if appropriate, any expert opinions or recommendations on which the decisions are based, shall be communicated to the person who is responsible therefore.

Decision to exclude specific medicinal products.

(2) Any such person as may be responsible shall also be informed of the remedies available to him under the laws in force and the time-limits allowed for applying such remedies.

9. Any decision to exclude a category of medicinal products from the Government Formulary List shall contain a statement of reasons based on objective and verifiable criteria and be published in an appropriate publication to be determined by the Superintendent of Public Health.

Decision to exclude a category of medicinal products.

10. (1) Any decision made under regulations 7, 8 and 9 may be appealed from before the Government Formulary List Appeals Committee, hereinafter referred as "the Appeals Committee".

Appeals from decisions.

(2) The Appeals Committee shall be composed of the following members, who shall not be public officers:

- (a) a Chairman nominated by the Minister responsible for health from among legal practitioners;
- (b) a medical practitioner;
- (c) a pharmacist.

(3) All members of the Appeals Committee shall be so appointed for a term of three years and may be re-appointed for a further term or terms.

(4) The Appeals Committee shall, upon an application to that effect by the person concerned, meet to hear and decide upon a decision reached by the Government Formulary List Advisory Committee.

(5) An appeal to the Appeals Committee shall be filed within the peremptory term of twenty days from such a decision.

(6) The Appeals Committee shall regulate its own procedure and levy such fees as may be prescribed.

(7) In exercise of its function under this regulation, the Appeals Committee may appoint experts to relate on any matter before it.

(8) The decisions of the Appeals Committee shall be in writing and shall be deemed final and conclusive and shall not be subject to review by the ordinary courts of law except on points of law.

Price increase.

11. (1) Without prejudice to regulation 14, the following provisions shall apply if an increase in the price of a medicinal product is permitted only after prior approval has been obtained from the Superintendent of Public Health acting on the advice of the Committee.

(2) The Superintendent of Public Health shall ensure that a decision is adopted on an application submitted, in accordance with the requirements laid down under Schedule III, by the holder of a marketing authorization to increase the price of a medicinal product and that this is communicated to the applicant within ninety days of its receipt.

(3) The applicant shall furnish the Superintendent of Public Health with adequate information, including details of those events intervening since the price of the medicinal product was last determined, which in his opinion justify the price increase requested.

(4) If the information supporting the application is inadequate, the Superintendent of Public Health shall forthwith notify the applicant of what detailed additional information is required and take their final decision within ninety days of receipt of this additional information.

(5) In case of an exceptional number of applications, the period may be extended once only for a further period of sixty days. The applicant shall be notified of such extension before the expiry of the period.

(6) In the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to apply in full the requested price increase.

Statement of reasons.

12. Should the Superintendent of Public Health decide not to permit the whole or part of the price increase requested, the decision shall contain a statement of reasons based on objective and verifiable criteria and the applicant shall be informed of the remedies available to him under the laws in force and the time limits allowed to apply for such remedies.

Price renegotiation.

13. (1) The Minister responsible for health may request that the price being charged by the holder of the marketing authorization be reviewed according to the exigencies of the Government Health Services.

(2) The Minister responsible for health shall furnish the holder of the marketing authorization with adequate information which, in his opinion, justifies the review in the price being charged to the Government Health Services.

(3) The holder of the marketing authorization shall within ninety days from date of request referred to in sub-regulation (2) provide a reasoned decision to the request made by the Minister responsible for health.

14. (1) In the event of a price freeze imposed on all medicinal products or on certain categories of medicinal products by the Minister responsible for finance in consultation with the Minister responsible for health, the Minister responsible for finance shall carry out a review, at least once a year, to ascertain whether the macro-economic conditions justify that the freeze be continued unchanged. Within ninety days of the start of this review, the Minister responsible for finance shall announce what increases or decreases in prices are being made, if any.

Price freeze.

(2) In exceptional cases, a person who is the holder of a marketing authorization for a medicinal product may apply for a derogation from a price freeze if this is justified by particular reasons. The application shall contain an adequate statement of these reasons.

(3) The Superintendent of Public Health shall ensure that a reasoned decision on any such application is adopted and communicated to the applicant within ninety days. If the information supporting the application is inadequate, the Superintendent of Public Health shall forthwith notify the applicant of what detailed additional information is required and take his final decision within ninety days of receipt of this additional information.

(4) Should the derogation be granted, the Superintendent of Public Health shall forthwith publish an announcement in the Gazette of the price increase allowed.

(5) Should there be an exceptional number of applications, the period may be extended once only for a further period of sixty days. The applicant shall be notified of such extension before the expiry of the initial period.

15. Nothing in these regulations shall preclude the Superintendent of Public Health from applying any controls and conditions in the case of the procurement and supply of any medicinal product that is covered by the Government Health Services.

Superintendent of
Public Health may
apply controls.

SCHEDULE I

Regulation 6(1)

Ref. No.

Form T01

Application to the Superintendent of Public Health for the consideration of a medicinal product to be covered by the Government Formulary List as per the Government Health Services (Medicinal Products) Regulations, 2009.

This application is to be filled in clearly and completely, otherwise it will be returned and will not be considered. The time lines for the decision specified in the legislation apply once the application is validated and accepted.

1. Details of Applicant

1.1 *Name of Marketing Authorisation Holder*

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1.2 *Address*

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1.3 *Telephone number*

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2. Details of Medicinal Product

2.1 *Product Name*

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2.2 *Active Ingredient*

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2.3 *Pharmaceutical form*

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2.4 *Strength*

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2.5 Method and Route of Administration

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2.6 Proposed pack size/s to be placed on the Government Formulary List

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2.7 Indications for which the product is being requested [indications should be covered by locally approved Summary of Product Characteristics (SPC)].

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2.8 Posology / Dosage regimen (as covered by SPC)

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2.9 Duration of treatment course (where applicable)

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2.10 Pharmacotherapeutic Group:

ATC Code
Pharmacotherapeutic Group

3. Authorisation Status

3.1 Authorisation of the medicinal product in Malta (tick where applicable)

3.1.1

Authorisation in accordance with procedures laid down in Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended.

3.1.2

National Marketing Authorisation [also includes products approved through the Mutual Recognition Procedure (MRP) and the Decentralised Procedure (DCP)]

3.2 Authorisation Number

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3.3 Date of issue of Authorisation

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3.4 <i>Expiry Date of Authorisation</i>

4. Costing

4.1 <i>Estimated Unit Cost</i> Euro .
Include any further information on specific conditons and incentives

4.2 <i>Total Cost per Patient (Annually or per Treatment Course)</i> Euro .
(Please explain how this figure was reached)

4.3 <i>The estimated number of patients who would require the medicinal product (state how this information was derived).</i>

4.4 <i>Pharmaco-economic evaluation of the medicinal product (this is not mandatory and the Superintendent of Public Health reserves the right to perform his evaluation)</i>

4.5 <i>Price being charged to other Member States within the EU for the same medicinal product (the Superintendent of Public Health reserves the right to perform his evaluation)</i>

5. Further Information regarding the Medicinal Product

5.1 <i>Reasons for requesting the medicinal product to be considered for coverage by the Government Formulary List</i>

5.2 *Comparison of this medicinal product to similar or alternative medicinal products or other treatments available on the market*

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5.3 *Comparison of this medicinal product to other medicines on the Government Formulary List in terms of:*

- | |
|---|
| • Innovation |
| • Therapeutic effectiveness/improvement |
| • Cost and economic evaluation |
| • Cost-effectiveness |
| • Safety |
| • Efficacy |
| • Impact on quality of life |
| • Availability and versatility of medicinal product |
| • Other |

List any information about the product which is being attached:

Approved SPC
Authenticated copy of Marketing Authorisation
Literature to substantiate any information given

I, hereby confirm:

- i) That to the best of my knowledge and belief, all the particulars I have given in this application form and all the documentation submitted, are correct and complete.
- ii) I am fully aware that the list of medicines available within the Government Health Services is by ATC classification and that the medicinal product will be considered by its active ingredient and not as a proprietary/branded product.
- iii) I am aware of the criteria that apply through the legislation (Social Security Act, Cap. 318, article 23; Availability of Medicinal Products within the Government Health Services Regulations, 2009.).

.....
Signature of Applicant

.....
Name in BLOCK LETTERS

Date

In the case where the applicant, for the purpose of this application, would like to nominate a person authorised to:

- a) communicate/sign on his behalf or
- b) act fully on his behalf,

there shall be provided details of the nominee and the type of authorisation available.

.....
Signature of Applicant

.....
Name in BLOCK LETTERS

Date

.....
Signature of Nominee

.....
Name in BLOCK LETTERS

Date

For office use only: Application received on/...../.....

SCHEDULE II

Regulation 7(a)

The Criteria which are taken into account by the Superintendent of Public Health, the Committee and any experts with which they consult in deciding whether or not to include a medicinal product on the Government Formulary List.

- The registration status of the medicinal product in Malta.
- Entitlement to free medicines as specified in the Social Security Act, Cap. 318, article 23 and the Fifth Schedule Part II to the same Act regarding Diseases and Conditions in respect of which Free Medical Aid may be accorded, as well as medicinal products required for the provision of care within Government Institutions. A medicinal product or a category of medicinal products to treat conditions which fall outside the scope of the Government Health Services may be entirely excluded from the Government Formulary List.
- Diagnostic and other requirements for the prescription, use and monitoring of the medicinal product particularly if additional costs are incurred. The possibility for monitoring the use of the medicinal product and the outcome of treatment. The fact that patients were started on treatment or were part of a clinical trial does not affect the decision for inclusion of a medicinal product on the Government Formulary List.
- The value, extent and relevance of the information and evidence available about the medicinal product particularly in terms of innovation, therapeutic effectiveness and improvement, safety, efficacy, impact on quality of life, availability and versatility of medicinal

product, cost-effectiveness, comparison to other available medicines and other treatment modalities.

- Cost and economic evaluation such as the conditions for the supply, prescription, use and monitoring of the medicinal product, affordability by the national health services and the social and epidemiological impact shall be taken into account in determining the coverage of a medicinal product by the Government Health Services.

The Superintendent of Public Health, the Committee and any experts with which they consult in deciding whether or not to include a medicinal product on the Government Formulary List reserve the right to take into account other criteria as they may deem necessary.

SCHEDULE III

Regulation 11(2)

Ref. No.

Form T02

Application to the Superintendent of Public Health for the consideration of a price for a medicinal product included on the Government Formulary List as per the Government Health Services (Medicinal Products) Regulations, 2009.

This application is to be filled in clearly and completely, otherwise it will be returned and will not be considered. The time lines for the decision specified in the legislation apply once the application is validated and accepted.

1. Details of Applicant

1.1 Name of Marketing Authorisation Holder

--

1.2 Address

--

1.3 Telephone number

--

2. Costing

2.1 Present Price of Unit Cost to Government

Euro

Include any further information on specific conditions and incentives

--

2.2 Total Cost per Patient (Annually or per Treatment Course)

Euro

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(Please explain how this figure was reached)

2.3 *The estimated number of patients who would require the medicinal product (state how this information was derived).*

2.4 *Pharmaco-economic evaluation of the medicinal product (this is not mandatory and the Superintendent of Public Health reserves the right to perform his evaluation)*

2.5 *Price being charged to other Member States within the EU for the same medicinal product (the Superintendent of Public Health reserves the right to perform his evaluation)*

3. Reasons for requesting price increase of the Medicinal Product

3.1 *Reasons for requesting price increase of the medicinal product included in the Government Formulary List*

3.2 *Comparison of this medicinal product to similar or alternative medicinal products or other treatments available on the market*

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3.3 *Comparison of this medicinal product to other medicines on the Government Formulary List in terms of:*

- | |
|---|
| • Innovation |
| • Therapeutic effectiveness/improvement |
| • Cost and economic evaluation |
| • Cost-effectiveness |
| • Safety |
| • Efficacy |
| • Impact on quality of life |
| • Availability and versatility of medicinal product |
| • Other |

List any information about the product which is being attached:

Approved SPC
Authenticated copy of Marketing Authorisation
Literature to substantiate any information given

I, hereby confirm:

- i) That to the best of my knowledge and belief, all the particulars I have given in this application form and all the documentation submitted, are correct and complete.
- ii) I am fully aware that the list of medicines available within the Government Health Services is by ATC classification and that the medicinal product will be considered by its active ingredient and not as a proprietary/branded product.
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Signature of Applicant

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Name in BLOCK LETTERS

Date

In the case where the applicant, for the purpose of this application, would like to nominate a person authorised to:

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- b) act fully on his behalf,

there shall be provided details of the nominee and the type of authorisation available.

.....

Signature of Applicant

.....

Name in BLOCK LETTERS

Date

.....

Signature of Nominee

.....

Name in BLOCK LETTERS

Date

For office use only: Application received on/...../.....
