AETSA

Guidelines for the incorporation of new drugs to a hospital formulary

GINF

# Version 3.0 2007

Pharmacy and therapeutics committee

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ hospital



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# APPLICATION QUESTIONNAIRE

## What is this questionnaire all about?

The present questionnaire is an instrument to be used to request the incorporation of a medicine to a hospital’s formulary.

Given that including a new drug into clinical practice has clinical, organizational and economic repercussions, any new incorporation must be preceded by an evidence-based evaluation. Although the hospital’s pharmacy and therapeutics committee will be responsible for the final evaluation, the requesting physician will be responsible for making available all the required data to the committee as they are the ones who possess all the relevant information on the medicine in question.

In that regard, these guidelines are meant to provide applicants with information on the data they must gather for the evaluation of the drug to be properly carried out. The role of the evaluators will be to help clinicians appropriately manage this instrument and to coordinate the different applications that may be filed for the same medicine by different hospitals.

These guidelines were developed based on the guidelines for the procurement of new technologies by the hospitals of Andalusia, known as the GANT guidelines, prepared by Andalusia’s healthcare technologies evaluation agency.

## How to fill in your application

1. This questionnaire has been designed as an internal hospital-based document to be filled out by the applicant and reviewed by the pharmacy committee. In the past, **some applications were filed by the manufacturer of the drug to be evaluated**. The manufacturer may be a variable source of information for the applicant, but it is the latter that should decide which information is clinically relevant and include it in their application.
2. The questionnaire should be filled out as fully and in as much detail as possible, using easily understandable language. A lack of information could prevent appropriate evaluation of your request.
3. The questionnaire was designed for evaluating an **example drug**, which means that some of the questions may not be relevant. Should this be the case, you may state it in the corresponding section(s).
4. Some of the **terms used** in the questionnaire may be ambiguous or subject to several interpretations. In case of doubt, please use the operational definition you deem most appropriate and make a clarification to that effect at the end. If you use abbreviations, please specify what they stand for the first time you employ them.
5. Some of the data requested may require a more detailed analysis or may not be available at the time of filling in the questionnaire. Please reflect it in an **annex**, suggesting, if possible, what can be done in order to obtain the unavailable information.
6. This document many me wholly of partially cited or reproduced, provided that the source is acknowledged. It should under no circumstances be modified.
7. The questionnaire will be available on the official website of Andalusia’s healthcare technologies evaluation agency.

# APPLICANT

Applicant’s details

Name and surname:

Department:

Job title:

The application is made:

* Individually
* After reaching a consensus with other members of your department
* After reaching a consensus with other members of the department and obtaining the approval of the head of the department

Please state if you have received external help to fill in this application:

* No
* Yes, from the members of the pharmacy and therapeutics committee
* Yes, from members of the pharmacy department
* Yes, from the manufacturing pharmaceutical company

If you answered in the affirmative, for which specific sections did you receive help?

**Declaration of situations that could entail a potential conflict of interests:**

1. Has the applicant participated in a clinical trial involving the drug to be evaluated?

* YES
* NO

2. Does the applicant hold any personal, commercial or professional relationship with the pharmaceutical company responsible for the drug to be evaluated?

* YES.
* NO

3. Is the applicant involved in any research project funded by the responsible pharmaceutical company?

* YES.
* NO

4. Do you consider that there is any other circumstance that may bias your professional judgement?

* YES
* NO

If your answer was in the affirmative, please specify.

**Date of the application: Signature:**

# A. DESCRIPTION OF THE DRUG AND ITS INDICATION

# THE DRUG

1. International nonproprietary name (INN), official name in Spain or generic name of the active ingredient.
2. Is the drug being marketed in Spain?

* YES.
* NO

Please state the dosage forms available and the pharmaceutical company that possesses the marketing license for Spain (If it is a foreign drug, please state the countries in which it is available)

1. Indication (s) for which incorporation of the drug to the hospital’s formulary is requested.
2. Officially approved indications in Spain. [[1]](#footnote-1)
3. The patients the new drug will be administered to are usually …

* ...Hospitalized patients
* ... Patients attending day hospital facilities/ patients treated at home
* ... Outpatients**[[2]](#footnote-2)**. In this case, is the drug a hospital-based drug?
* YES
* NO

1. Do you think that any other department, functional unit or medical specialty may be interested in using the new drug? If so, which? Do you think the pharmacy and therapeutics committee may contact anyone in particular to discuss the incorporation of the new drug to our hospital’s formulary?

# THE INDICATION

# Please provide a short description of the clinical problem for which you are applying for inclusion of the drug in the formulary (incidence and prevalence, staging, evolution, treatment subgroups, survival, quality of life, etc.).

1. What drugs (or other alternative therapies) are currently being used to treat the indication (or indications) to which the new drug will be applied? Does your department have a written document with the clinical practice guidelines to be followed for pharmacological treatment of that indication? If so, please enclose a copy.
2. Please state your opinion on the potential advantages of the new drug as compared with the currently available alternatives:

* Higher effectiveness
* Greater safety
* Boosts adherence/compliance
* Facilitates administration: dosing / route of administration
* Other

# B. EFFICACY AND SAFETY

1. Provide a list of the clinical trials your application is based on. Please include **only** high-quality trials conducted for the indication for which you are requesting the inclusion of the drug in the hospital’s formulary. **Use one table for each one of the trials selected.** Please, enclose a copy of each trial.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Author and year** | | | | | | | |
| Study design | | | | | | | |
| Randomized ⁬ Yes ⁬ No  Open-label ⁬ Yes ⁬ No  Placebo-controlled ⁬ Yes ⁬ No  ITT analysis ⁬ Yes ⁬ No | Baseline patient characteristics: | | | | Number of patients:  % lost to follow-up:  Duration of the study: | | |
| Treatment of the experimental group | | Treatment of the control group | | | | | |
| Efficacy and safety results | | | | | | | |
| **Endpoints evaluated in the study**  (mark as appropriate) | | **Result of EXPERIMENTAL group** | **Result of CONTROL group** | | | **Absolute difference** | **p** |
| Main efficacy endpoint | |  |  | | |  |  |
| Other efficacy endpoints | |  |  | | |  |  |
| Other efficacy endpoints | |  |  | | |  |  |
| Main safety endpoint | |  |  | | |  |  |
| **Other complications / adverse reactions** | |  |  | | |  |  |
| **Applicability / relevance of results** | | | | | | | |
| * Is the control drug the best therapeutic alternative available? * Are dosing, regimen and length of treatment appropriate? Are they used in clinical practice for the control drug? * Are the patients in the study similar to those in your clinical practice? | | | | * Do you consider the analyzed endpoints clinically relevant? * Are the results clinically relevant? | | | |

1. Are there studies other than clinical trials that you would like to include? If so, are they …

* Meta analyses
* Systematic reviews
* Clinical practice guidelines (by official agencies)
* Observational studies
* Evaluations by official agencies
* Others

Please state the reference, a brief summary and the reason why you consider that the study should be considered for the evaluation process.

# C. EFFECTIVENESS AND APPLICABILITY

1. Do you think that the conclusions of the previously stated clinical trials may be applicable to our hospital’s everyday practice? [[3]](#footnote-3)

* YES
* NO

1. Is there in your opinion a particular group of patients who may derive a particular benefit from the drug to be evaluated?
2. How could you implement treatment with the drug to be evaluated if it were included in the hospital’s formulary? [[4]](#footnote-4)

# E. ECONOMIC EVALUATION

1. Is there any economic evaluation (cost-effectiveness, cost-utility) study for this drug? Please state the relevant literature reference below and enclose a copy of the article.

* Yes
* No

|  |
| --- |
| REFERENCE |
| 1. |
| 2. |

1. Please specify if the new drug, for the proposed indication and within the scope of your specialty …

* May fully replace the current standard of care
* May partially replace the current standard of care (some subgroups of patients will benefit from the new drug while others will have to remain on the current standard of care)
* May be added to the standard treatment for the overwhelming majority of patients
* May be added to the standard treatment for some subgroups of patients

15. Should the current standard of care not be completely replaced by the new drug, or should the new drug be applied only in certain groups of patients, what proportion of patients do you think would use the new drug?

1. What is the current prevalence and incidence of the clinical problem for which you are requesting for the new drug to be included in our formulary?

**PREVALENCE** (total number of patients CURRENTLY eligible to receive the new drug in our hospital):

**INCIDENCE** (nr. of new patients/year):

1. Please fill in the following table:[[5]](#footnote-5)

|  |  |  |
| --- | --- | --- |
|  | Treatment cost | Difference with respect to the standard of care |
| Standard of care |  | ---------------------- |
| New drug |  |  |

1. Will the introduction of the new drug result in a change in the use of concomitant treatments? If so, explain how.

* Yes
* No

1. What would be the potential repercussions of introducing the drug on the treatment of non-hospitalized patients (primary care, outpatient clinic, etc.)?
2. State what saving could be made, if any, as a result of the adoption of the new drug:

* Savings in medicines
* Savings in hospital stays
* Savings in other healthcare services
* Non-healthcare-related savings

# Evaluation of applications

The committee shall evaluate all applications according to the procedure described on this page. The committee’s decision will be issued in the form contained on the following page.

1. A complete absence of data, or an absence of data in the essential sections of the form (questions 4, 5, 6, 7, 9, 12 and 13) may lead to the rejection of the application and its inclusion in **Category A-1.** At its own discretion, in certain circumstances the committee may ask the applicant to provide further information or make the necessary changes to ensure that the application meets the basic requirements and can be reexamined.
2. If the indication for which the application is made can be treated on an outpatient basis, and the drug is not a hospital-based medication (question 5), **and patients do not need to be admitted to receive it,** the application will be included under **Category A-2**
3. If the answers related to efficacy, effectiveness and safety (section B) are not accompanied by the required clinical trials, or if the clinical trials submitted are associated with significant methodological problems or a lack of clinically significant results, they the application will be included under **Category B-1**.
4. If the answers related to efficacy, effectiveness and safety (section B) are substantiated by high-quality clinical trials where clinically significant results indicate that the new drug is associated with a poorer efficacy/safety profile than the currently available therapeutic alternative in the hospital, the application will be included under **Category B-2**.
5. If the answers related to efficacy, effectiveness and safety (section B) are not accompanied by any criteria suggesting any differences between the new drug and its alternatives and if there is no difference in their cost-effectiveness profile, the new drug may be considered therapeutically equivalent to the existing therapies and the application may be included under **Category C.** This decision may respond to one of two circumstances:

* The applicant has submitted clinical trials comparing the new drug with its alternative where both medicines have shown to be therapeutically equivalent; or
* Clinically significant data have been obtained by parallel studies of each alternative vis-à-vis a third comparator. Al studies must be comparable in terms of their methodology, studied population and other characteristics.

Market conditions and the implications of including (or not) the new equivalent alternative in the hospital’s formulary may lead to the drug being included in **Category C-1 or Category C-2.**

1. If the new drug has been **subjected to clinical trials demonstrating** that its efficacy, effectiveness and safety profile present with significant clinical advantages over the currently available therapeutic alternative in the hospital, or that is has a clearly favorable cost-efficiency profile, it will be included in the formulary. The previously used drug may or may not be removed.
2. Inclusion in **categories D** or **E** will depend on the need to prevent adverse events and ensure that the management of the drugs will be entrusted only to the most experienced clinicians and that only the patient subgroups for whom the drug has been tested are treated with it. **Other circumstances requiring specific restrictions may also apply.**

Considering the previously stated criteria, the pharmacy and therapeutics committee will include the evaluated drug in one of the following categories and reflect its decision in the minutes of the corresponding meeting.

**A.- THE DRUG MAY NOT BE INCLUDED IN THE HOSPITAL’S FORMULARY because some of the basic requirements have not been met.**

**A-1. - IT MAY NOT BE INCLUDED IN THE FORMULARY because the information contained in the application is insufficient.**

**A-2. - IT MAY NOT BE INCLUDED IN THE FORMULARY because it is indicated for a condition that need not be treated in hospital or the outpatient clinic.**

**B-1. THE DRUG MAY NOT BE INCLUDED IN THE HOSPITAL’S FORMULARY because there is insufficient evidence that it is associated with a better efficacy/safety profilethan the standard of care provided in the hospital.**

**B-2.- THE DRUG MAY NOT BE INLCUDED IN THE HOSPITAL’S FORMULARY because, according to the existing evidence, it is associated with a poorer efficacy/safety profile tan the standard of care provided in the hospital.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**C-1. The medicine’s efficacy and safety profile is comparable to that of the existing alternatives for the proposed indications. In addition, no evidence is provided that the drug results in any improvement regarding cost-effectiveness or the organization and management of care.**

**For these reasons, it MAY NOT BE INCLUDED IN THE HOSPITAL’S FORMULARY.**

**C-2.- The medicine’s efficacy and safety profile is comparableto that of the existing alternatives for the proposed indications. In addition, no evidence is provided that the drug results in a higher *cost-effectiveness ratio*. However, is incorporation to the hospital’s procurement processes could result in organizational advantages*.***

**For these reasons, the drug MAY BE INCLUDED IN THE HOSPITAL’S FORMULARY AS A THERAPEUTIC EQUIVALENT to the existing options. The specific drug to be administered will depend on the result of each public tender.**

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**D-1. The drug MAY BE INCLUDED IN THE HOSPITAL’s FORMULARY with specific recommendations.**

**D-2. The drug MAY BE INCLUDED IN THE HOSPITAL’S FORMULARY with specific recommendations and with the commitment to reexamine it after a certain period of time to be determined by the committee.**

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**E. SE INCLUYE EN LA GFT sin recomendaciones específicas.**

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1. 1 Approved indications are stated in the drug’s SmPC. If the drug is only available abroad, please list its approved indications in the country of origin. [↑](#footnote-ref-1)
2. Please note that drugs used only for outpatients are not included in the formulary. Drugs legally classified as HOSPITAL-BASED drugs are the exception to this rule. [↑](#footnote-ref-2)
3. 3 That is, could there be any circumstance that may interfere with the effectiveness of the treatment, such as the availability of diagnostic tests or patient support programs; the existence of clinical or social differences between our patients and those analyzed in the reported clinical trials; effects of the learning curve, etc.? [↑](#footnote-ref-3)
4. 4 For example, line of treatment proposed, clinical conditions to be met by candidates, salvage treatment, etc. [↑](#footnote-ref-4)
5. if it is a chronic drug, please specify its monthly cost and if the duration of treatment is highly variable please specify the cost per day); in case of chemotherapy indicate the cost of a full treatment. [↑](#footnote-ref-5)