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Guidelines for the incorporation of new drugs to the Virgen del Rocio Hospital formulary

(GINF)

# VERSION 1.4

* This document was prepared jointly by the pharmacy committee of the Virgen del Rocio University Hospital and Andalusia’s Healthcare Technology Evaluation Agency

Pharmacy and Therapeutics Committee of the Virgen del Rocio University Hospital

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**PROPOSAL FOR THE INCORPORAION OF MNEW MEDICINES TO THE VIRGEN DEL ROCIO UNIVERSITY HOSPITAL’S FORMULARY**

# 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 the Virgen del Rocio University 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 the requesting physician 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. Should you require any clarification, please contact:

* The members of the pharmacy and therapeutics committee (December 2004):
  + Javier Bautista (Pharmacy);
  + Javier Dapena (Pediatrics);
  + Francisco Domínguez Abascal (Gastrointestinal diseases);
  + Ildefonso Espigado (Hematology);
  + Miguel Angel Gómez (Surgery)
  + Antonio Hevia (Pharmacology);
  + Rafael Hinojosa (Critical care)
  + Ángeles Martínez (Ginecology)
  + Bernardo Santos (Pharmacy).
  + José Manuel Varela (Internal medicine);
* The pharmacy department, who will be available to answer your questions or even to fill in the form with you (please get in touch with Dr. Santos: at extension 82091).

1. The questionnaire is available both in paper and electronically on the hospital’s intranet. Should you use the paper version, you may find that the space provided in some of the sections is too small. In that case, please provide the additional information in the form of annexes.
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.

#### 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

Date of the application: Signature:

# A. DESCRIPTION OF THE DRUG AND ITS INDICATION

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

* Yes. Please state the dosage forms available and the pharmaceutical company that possesses the marketing license for Spain.
* NO. Please state the dosage forms available, the pharmaceutical companies licensed to market the drug abroad, and the countries where the medicine is available.

1. Indication (s) for which incorporation of the drug to the hospital’s formulary is requested. **[[2]](#footnote-2)**.
2. Officially approved indications in Spain. Remember that approved indications are stated in the drug’s SmPC, which must always be enclosed to any commercial materials. If the drug is only available abroad, please state the approved indications in its country of origin.
3. Patients for whom the drug is requested are usually ...

* ... Hospitalized patients
* ... Patients attending day hospital facilities/ patients treated at home
* ... Outpatients**[[3]](#footnote-3)**. In this case, is the drug a hospital-based drug?
* YES
* NO

Please be advised that the information on whether the drug is hospital-based or not is included in its SmPC.

1. What drugs and what regimens are currently being used to treat the indication (or indications) for which the new drug is being requested? 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 (efficacy, safety, economic, organizational, etc.) advantages of the new drug as compared with the currently available alternatives.
3. 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?

# B. EVIDENCE WITH RESPECT TO EFFICACY, EFFECTIVENESS AND SAFETY

# EFFICACY AND SAFETY

The pharmacy and therapeutics committee is responsible for selecting the safest and most efficacious drugs based on the best evidence available in the literature, i.e., controlled clinical trials or meta analyses of clinical trials, vis-à-vis the standard of care.

Exceptionally, clinical trials will be accepted where the control group receive placebo (drugs for indications not covered by previous drugs) or studies other than clinical trials (evaluation of safety problems, for example). The following questions will nevertheless refer only to ***controlled clinical trials where the new drug is compared to the standard of care***. If you wish to include trials carried out with a different design, you will be required to demonstrate the relevance of the evidence they contribute.

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.

*Please enclose a copy of each of the trials listed.*

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| **1st AUTHOR** | **REFERENCE** |
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Example:

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| Kaufmann | Kaufmann M, Bajetta E, Dirix LY, Fein LE, Jones SE, Zilembo N, et al. Exemestano is superior to megestrol acetate after tamoxifen failure in postmenopausal women with advance breast cancer. Results of a phase III randomized double-blind trial. The Exemestane Study Group. J Clin Oncol 2000;18(7): 1399-411 |

9.- Please use the table below to provide a short summary of the evidence contributed by each one of the trials listed above.

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| **AutHor,**  **year** | **Treatment** | | **Results** | | | | |
| **Regimen experimental group** | **Regimen control group** | **Main endpoints** | **Result experimental group** | **Result control group** | **Absolute risk difference/ relative risk** | **Complications/ adverse reactions** |
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1. Are there any other studies that do not meet the previously stated requirements, i.e., non-controlled clinical trials, trials for indications other than the one the drug is requested for), but which you wish to include anyway? Please state the citation, a brief summary and the reason why you deem the study to be important for the evaluation process.
2. Is there a study that compares the new drug with other therapeutic alternatives, such as a systematic review, a decision-making analysis or a meta-analysis? If so, please state the relevant details below and enclose a copy.

* YES
* NO

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| **1st AUTHOR** | **REFERENCE** |
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# EFFECTIVENESS AND APPLICABILITY

1. This section includes a few questions regarding the applicability of the previously stated studies:
   1. Do you think that the benchmark used is the best therapeutic alternative available?

* YES NO
  1. Do you think that the dose, duration of treatment, etc. used in the studies are the best therapeutic alternative available?
* YES NO.
  1. Is the regimen used for the evaluated drug the same as the one proposed for its clinical use in our hospital?
* YES NO
  1. Do you consider the main endpoint clinically relevant and methodologically appropriate?
* YES NO
  1. Do you think that the differences observed between the two treatments can constitute a real advantage for the patient (regardless of whether statistical significance was obtained)?

1. Do you think that the results of the previously stated clinical trials may be applicable to our hospital’s clinical practice? 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.?

# E. ECONOMIC EVALUATION

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

1. Please estimate the number of patients/year where the drug would be used in our hospital. Absence of this information would prevent an assessment of the new drug’s economic impact for the hospital.
2. 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

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| **1st AUTHOR** | **REFERENCE** |
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1. Total cost of treatment with the new drug (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).
2. Cost of the standard therapy. Absolute cost differences
3. Estimation of potential savings to be made.

# 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. Contradictions between the answers to questions 3 and 4 will result in the application being included in **Category A-2**
3. If the indication for which the application was filed is treated in an ambulatory way and the drug is not hospital-based (question 5), then the application will be included under **Category A-3**
4. 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**.
5. 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**.
6. 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. All studies must be comparable in terms of their methodology, studied population, endpoints, 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.

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 the indication for which the drug was requested is not an approved indication in Spain.**

**A-3** **- IT MAY NOT BE INCLUDED IN THE FORMULARY because it is indicated for a condition that does not need to 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 profile* than 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.**

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**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 ef*ficacy 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 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.- SE INCLUYE EN LA GFT *with* specific recommendations.**

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

1. One-off usage of a drug not marketed in Spain (available only for compassionate use or marketed only abroad) for a specific patient may help address a specific clinical problem. In this case, contact should be established urgently with the hospital’s pharmacy department so that the drug can be administered to the patient as early as possible.

   Nevertheless, ***the pharmacy and foreign and compassionate drugs committee must in all cases evaluate these applications, particularly when they are made repetitively or when they involve large groups of patients***. The application must be processed through the GINF format. [↑](#footnote-ref-1)
2. Please remember that the use of a drug for indications not officially approved in Spain (even if the medicine may be marketed in the country) is considered an experimental use and must take place within a **clinical trial** or by filing a **compassionate use** request. As regards foreign medicines, import licenses can only be granted when the indications approved in the country of origin are the same as those prescribed by our hospital. [↑](#footnote-ref-2)
3. 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-3)