

The Experience of a Drug Evaluation Committee at a University Hospital

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ABSTRACT

Introduction: The exponential development of innovative drugs poses challenges to healthcare systems in ensuring equitable access to new treatments. At the hospital level, Drug Evaluation Committees (DECs) in each institution analyze the evidence on the effectiveness, safety, and cost of new drugs and make recommendations tailored to their specific contexts. Our objective is to describe the DEC's activity at a university hospital.

Materials and Methods: This cross-sectional study was undertaken at a university hospital. The evaluations made between 2017 and 2023 were analyzed. We used descriptive statistics to quantify the number of evaluation requests received, the drugs incorporated, requesting departments, and the medications' ATC classification.

Results: The DEC began its activities in 2011 and is comprised of a team of 13 healthcare professionals. During the study period, 111 requests for drug inclusion were received, of which 90 (81.1%) were approved and incorporated into the institutional formulary. The Internal Medicine Department submitted 60 (54%) requests, 26 (23%) of those came from the Oncology Section.

Conclusions: The DEC plays a central role in incorporating new drugs into the institutional formulary, especially in critical areas such as Oncology, addressing the growing demand for evaluating innovative treatments. **Keywords:** Pharmacy and Therapeutics Committee, Technology Assessment, Pharmacy Service. Hospital Administration, Drug Committees.

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Experiencia del Comité de Evaluación de Medicamentos en un Hospital Universitario

RESUMEN

Introducción: el exponencial desarrollo de medicamentos innovadores plantea desafíos a los sistemas de salud para garantizar el acceso equitativo a los nuevos tratamientos. En el ámbito hospitalario, los Comités de Evaluación de Medicamentos (CEM) de cada institución analizan la evidencia sobre eficacia, seguridad y costo de los nuevos fármacos para emitir recomendaciones adaptadas a sus contextos específicos. Nuestro objetivo es describir la actividad del CEM en un Hospital Universitario.

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Material y métodos: estudio de corte transversal realizado en un Hospital Universitario. Se analizaron las evaluaciones efectuadas entre los años 2017 y 2023. Se utilizó estadística descriptiva para cuantificar el número de solicitudes de evaluación recibidas, medicamentos incorporados, servicios solicitantes y Clasificación Anatómica, Terapéutica, Química (ATC) de los fármacos.

Resultados: el CEM inició sus actividades en 2011 y está conformado por 13 profesionales de la salud. Durante el período en estudio, se recibieron 111 solicitudes para la incorporación de fármacos, de las cuales 90 (81%) fueron aprobadas e incluidas en el vademécum. El Servicio de Clínica Médica presentó 60 (54%) solicitudes, de las cuales 26 (23%) correspondieron a la Sección de Oncología.

Conclusiones: el CEM tiene un papel central en la incorporación de nuevos fármacos al vademécum institucional, especialmente en áreas críticas como Oncología, atendiendo a la creciente demanda de evaluación de tratamientos innovadores.

Palabras clave: Comité de Farmacia y Terapéutica, Evaluación de Tecnología, Servicio de Farmacia del Hospital, Administración del Hospital, Comités de Medicamentos.

INTRODUCTION

The exponential development of innovative drugs and those with greater technological complexity poses challenges for health systems in ensuring the population's access to new treatments. In this context, the design and implementation of strategies that promote the rational use of medicines are essential to ensure the sustainability of the system.¹

The introduction of these drugs into the market begins with regulatory approval and ends with the effective therapeutic application to a patient. Various organizations are involved in this process, making decisions at both macro levels—such as Ministries of Health, regulatory agencies, and health technology assessment bodies—and micro levels, like internal hospital committees or hospital pharmacotherapy committees.^{2,3}

There is evidence that the tools and information needed for decision-making in hospitals differ from those used by national-level health agencies.⁴ While national agencies are responsible for approving the commercialization of drugs, drug evaluation committees (DECs) assess and select the medicines that will make up the formulary of a given institution.. In turn, they issue specific usage recommendations based on rationality and efficiency criteria, tailored to the particular characteristics of each institution.⁴ These committees are composed of multidisciplinary teams of health professionals who must review the available evidence on the efficacy, safety, quality, and cost of the drugs being evaluated.^{5,6}

In Argentina, macro-level decisions regarding drug registration and recommendations for use are dictated by the Ministry of Health, the National Administration of Drugs, Food, and Medical Technology (ANMAT), and the National Commission for the Evaluation of Health Technologies and Clinical Excellence (CONETEC). “At the micro level, each organization makes its own decisions, and the specific models used by individual institutions have not been widely published or made known.”⁷

For this reason, to address the lack of documentation and contribute to the body of knowledge in this field, our purpose is to share the experience of the past six years of work by the Drug Evaluation Committee (DEC) of a university hospital in the Autonomous City of Buenos Aires, Argentina.

OBJECTIVES

Primary

1. To describe the functioning of the Drug Evaluation Committee (DEC) in a university hospital.

Secondary

- 2) To quantify the activity of the DEC in terms of:
 - a) Total number of drug evaluation requests received.
 - b) Number of drugs added to the hospital formulary following evaluation.
 - c) Medical departments and units that submitted drug evaluation requests.
 - d) Type of drug according to the Anatomical, Therapeutic and Chemical (ATC) classification.⁷

MATERIALS AND METHODS

The study took place at a university hospital in the Autonomous City of Buenos Aires, Argentina.

For the primary objective, we performed a descriptive analysis based on institutional procedure No. 045/11:

Drug and Biomedical Supplies Evaluation Committee, Version/Modification No.: 01/01, Effective Date: 9/23/2024*.

For the secondary objective, we carried out a retrospective observational study using rapid reports prepared by DEC members from January 2017 to December 2023.

The following variables were measured:

* Comunità - Hospital Italiano [Internet]. [cited 2024 Aug 13]. Available from: <https://intranet.hospitalitaliano.org.ar/normas-procedimientos>

- Number of requests evaluated: We recorded the total number of drug evaluation requests received during the study period.

- Number of approved and non-approved requests relative to the total number of requests received per year during the study period.

- Requesting department: the hospital department that submitted each request was identified and classified.

- Type of drug: each requested medication was categorized according to the ATC classification.⁷

Descriptive statistics were used for data analysis. Quantitative variables (number of requests, number of approved and non-approved requests) and qualitative variables (requesting department, type of drug) were summarized using absolute and relative frequencies (percentages).

ETHICAL CONSIDERATIONS

As this study is a review of evaluations without patient data or identifying information, approval from the Ethics Committee for Research Protocols was not necessary.

RESULTS

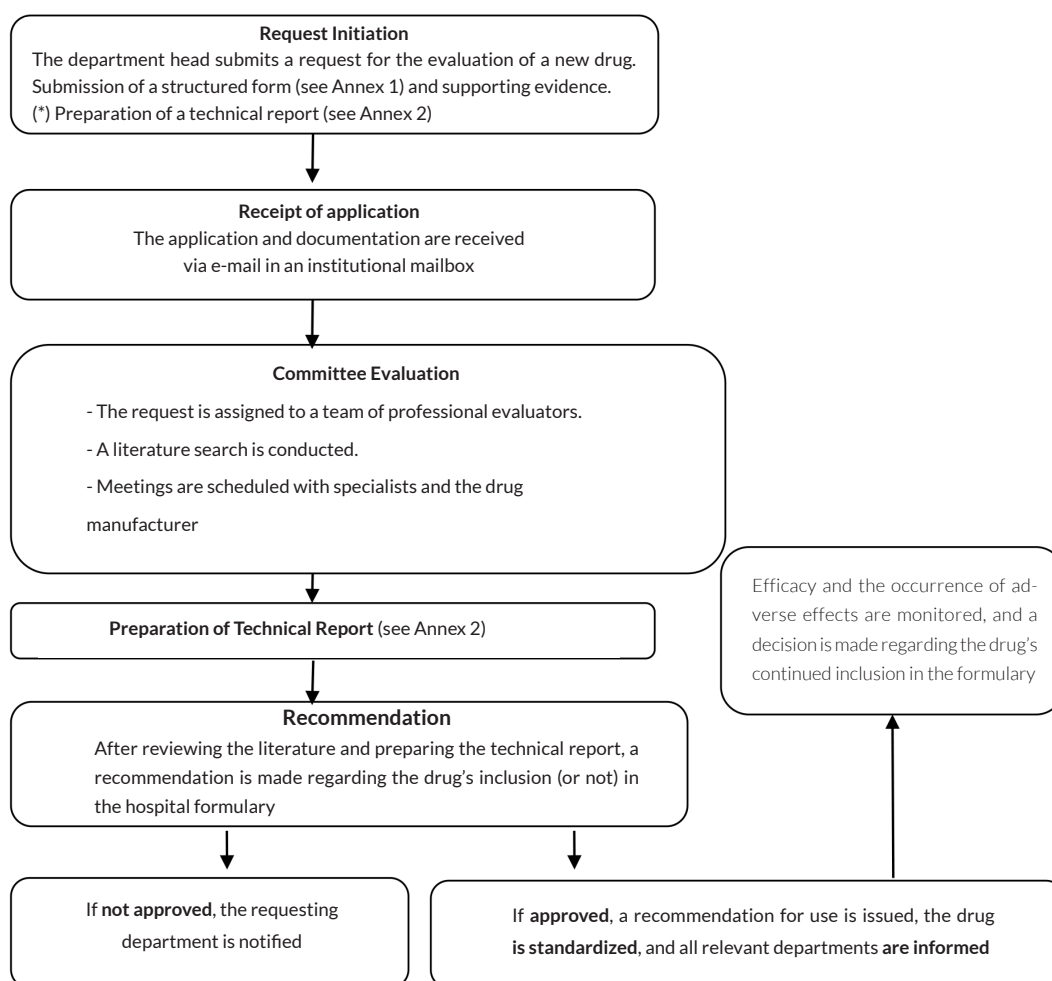
The Hospital's Drug Evaluation Committee (DEC) reports to the Medical Directorate, which appoints its members. It began operating in 2011, at which time it was composed of a physician, a pharmacist, and an administrative staff member. It is currently made up of 13 healthcare professionals, including pharmacists and physicians. A description of its operations appears in Figure 1.

During the study period from 2017 to 2023, 111 drug incorporation requests were received, of which 90 (81%) were approved and added to the hospital formulary.

Fifty requests were received in 2022–2023, comprising 45% of all requests during the study period. Figure 2 illustrates the total number of requests and the number of requests approved and denied for inclusion in the hospital formulary, categorized by year.

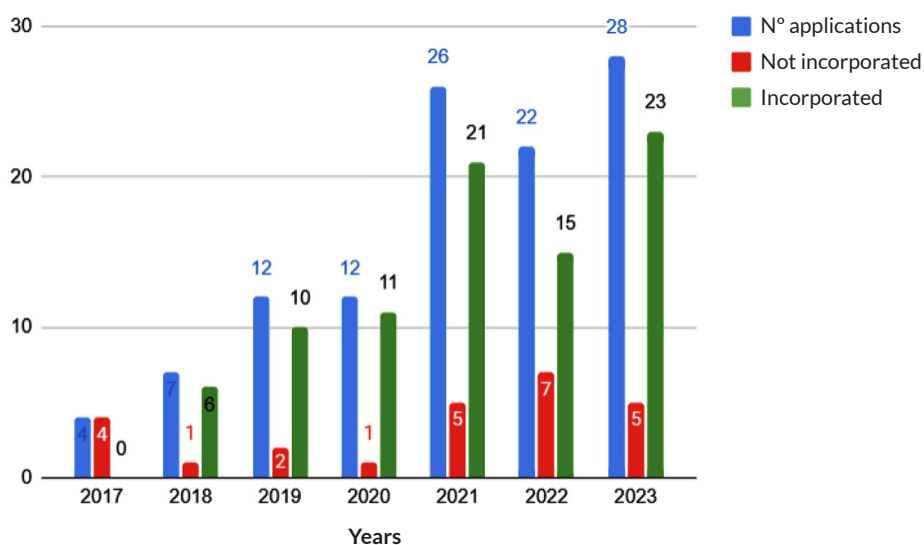
The hospital departments that submitted drug evaluation requests from 2017 to 2023 are listed in table 1.

New drug incorporation requests by ATC classification can be seen in Figure 3.⁸



* Randomized clinical trials, systematic reviews, ANMAT approval, and the drug's package insert as primary sources of information.
Source: Figure produced by the authors.

Figure 1. Description of the functioning of the Drug Evaluation Committee.



Source: Graph produced by the authors.

Figure 2. Total number of applications, not incorporated and incorporated by year.

Table 1. Medical departments that requested drug evaluations.

Medical Departments	Number of Requests n = 111
Internal Medicine	60 (54)
Oncology Section n (%)	26 (23)
Hematology Section n (%)	13 (12)
Infectious Diseases Section n (%)	9 (8)
Dermatology Section n (%)	6 (5)
General Internal Medicine Section n (%)	2 (2)
Rheumatology Section n (%)	2 (2)
Hepatology Section n (%)	1 (1)
Allergy Section n (%)	1 (1)
Neurology n (%)	15 (14)
Pulmonology n (%)	8 (7)
Gynecology n (%)	6 (5)
Cardiology n (%)	6 (5)
Endocrinology, Metabolism, and Nuclear Medicine n (%)	6 (5)
Gastroenterology n (%)	3 (3)
Nephrology n (%)	3 (3)
Urology n (%)	2 (2)
Psychiatry n (%)	1 (1)
Ophthalmology n (%)	1 (1)

Source: Table produced by the authors. *No. of requests*

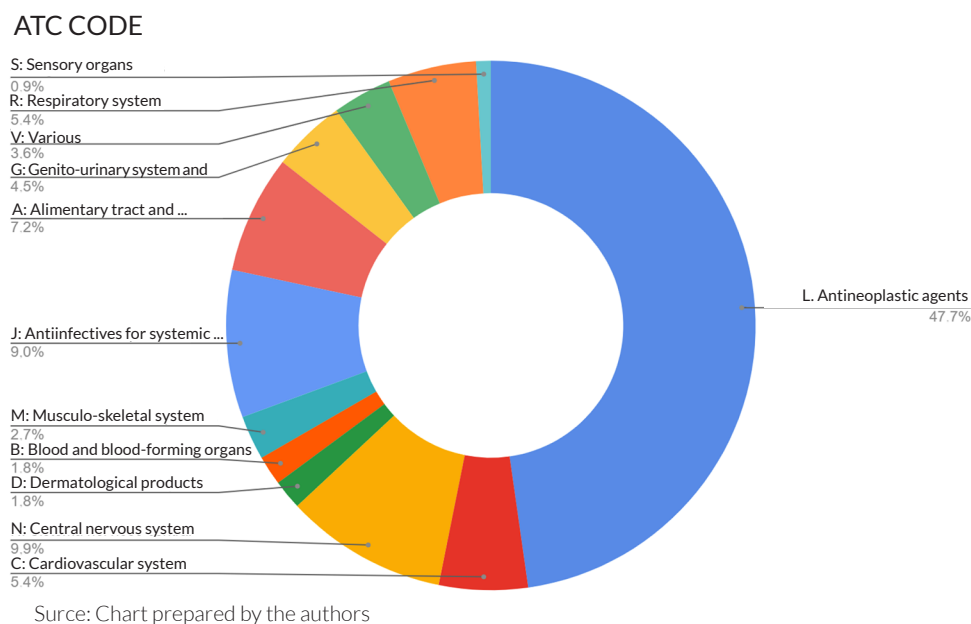


Figure 3. Requests for drugs by ATC classification.

The drugs evaluated and incorporated into the hospital formulary are listed in **Appendix 3**.

DISCUSSION

In our study, we describe the composition of the Medication Evaluation Committee (MEC) within the integrated network of a university hospital, which structurally fulfills some of the components identified by the Hospital-Based Health Technology Assessment (HB-HTA) study subgroup.

Following the models proposed by this HB-HTA subgroup, our committee aligns with the description of an internal committee consisting of a multidisciplinary group of healthcare professionals from within the organization who do not hold exclusive roles within the committee.

In Argentina, various institutions have working groups or committees dedicated to health technology assessment. However, we did not identify any published literature describing the structure or outcomes of those assessments.

A strength of the MEC's work is that each drug is critically evaluated and analyzed based on the available scientific evidence, including a corresponding assessment of its budgetary impact. That enables appropriate management of medication use based on safety and efficacy criteria, under continuous monitoring.

Among the challenges faced by this type of committee is that the partial dedication of its members limits the amount of time they can allocate to these activities. Another characteristic of our MEC is that its recommendations apply only to the hospital network (its various sites and

peripheral centers) and are not extended to or shared with other healthcare organizations. That represents a limitation in resource efficiency, as it contributes to unnecessary duplication of efforts in evidence evaluation and analysis⁴.

Regarding the quantification of the activities of the PTC (Pharmacotherapeutic Technical Committee), it is important to establish a national frame of reference. In Argentina, CONETEC is the agency responsible for conducting evaluations and issuing technical recommendations on the adoption, disinvestment, usage, financing, and coverage of health technologies.⁹ These CONETEC recommendations are incorporated into the body of evidence that supports the PTC's final report and tailored to the specific needs of the hospital.¹⁰

In our study, we observed that the highest proportion of drugs evaluated fell under the ATC classification of antineoplastic and immunomodulating agents (classification L), representing 47.7% of all evaluations. For the same period, CONETEC reports show this category accounts for 42% of evaluations. These results are similar and reflect a shared trend in the assessment of this type of medication.

Our findings show that in the 2022–2023 biennium, the PTC received an increased number of requests, representing 45% of the total submitted throughout the entire study period (2017–2023). The Oncology Section recorded the highest number of requests, consistent with the growing availability of new cancer therapies on the market. A review article on new oncology indications approved by the U.S. Food and Drug Administration (FDA) reports an annual approval rate of 56 new drugs

between 2017 and 2022, compared to previous years when the approval rate was considerably lower.¹¹ This increase in evaluations of cancer therapies may be due to the rapid development of new treatments and the growing demand from clinical teams to access them. Oncology is a high-pressure care area with significant clinical impact, which drives an increase in requests to the PTC to assess evidence and support their inclusion.

In this discussion, we focused on the points for which reference data are available, although such data remain limited at the regional level. This limitation underscores the need to continue generating and sharing information to support the development of evidence-based decision-making strategies within the hospital setting.

CONCLUSIONS

The rational use of medicines is a cross-cutting challenge at all levels of healthcare, and the presence of a hospital-based Pharmacy and Therapeutics Committee (PTC) is the key to promoting more efficient use of available resources, tailored to the context and specific needs of each institution. Our study presents the experience accumulated over six years of PTC operations, documenting its structure, work methodology, and number of evaluations. By making its activities visible and quantifiable, this work contributes to regional knowledge, offering a reference model for health management in other contexts.

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ANNEX 1. Request form for the evaluation of new drugs

Application to the Committee for the Evaluation of Medicines and Biomedical Devices	
Date of request: __/__/__	
Applicant Information	
Applicant's name _____	
Department/Management Area _____	
Professional category _____	
Contact information _____	
Type of update	
Inclusion	Exclusion
Description of the medication or supply	
Generic name of the active ingredient (or combination): _____	
Brand name: _____	
Manufacturer: _____	
Contact information: _____	
Inclusion	
Effectiveness and applicability	
Indication for use (therapeutic action): _____	
Recommended dosage (adults/pediatrics): _____	
Recommended duration of treatment: _____	
Therapeutic advantages over currently used products: _____	
Supporting documentation	
Documentation must be submitted electronically to: evaluacion.medicamentos@hospitalitaliano.org.ar	
Product registration (ANMAT)	
Manufacturer registration (if new)	
Best available scientific evidence	
Meta-analyses / Systematic reviews Randomized controlled trials Uncontrolled scientific evidence Manufacturer information	
Main outcomes	
Economic aspects	
Estimated monthly use: _____	
Exclusion	
Reason for the exclusion request: _____	

_____ Signature and stamp of the applicant	

ANNEX 2. Structure of the Technical Report used by the MEC

Requesting service: Medication name: Manufacturer: Pharmaceutical form: Therapeutic indications: Dosage: Mechanism of action: Context: Clinical efficacy: Safety: Regulatory agency approvals: Agency evaluations: Clinical practice guidelines: Hospital cost estimate: Meeting with requesting service: Meeting with manufacturer: Committee recommendations and conclusions: Bibliography: Date: / /
The undersigned hereby acknowledge receipt of the conclusions and recommendations presented in this document by the Committee for the Evaluation of Medicines regarding the drug requested by the section/service:
Signature of the members of the Medicines Committee:

ANNEX 3. Evaluated drugs incorporated into the hospital formulary

Category		Drugs
A	Alimentary tract and metabolism	Empagliflozin, teneligliptin, insulin aspart (new formulation), ne-tupitant/palonosetron, semaglutide, dulaglutide, linaclotide, metreleptin
B	Blood and blood-forming organs	Luspatercept, selexipag
C	Cardiovascular system	Inclisiran, macitentan, tolvaptan, evolocumab, pitavastatin, alirocumab
D	Dermatological products	Abrocitinib, dupilumab
G	Genitourinary system and sex hormones	Mifepristone, levonorgestrel 19.5 mg (IUD), silodosin, ulipristal acetate, etonogestrel/ethinylestradiol
J	Antiinfectives for systemic use	mipenem/cilastatin/relebactam, remdesivir, sofosbuvir/velpatasvir, doravirine/lamivudine/tenofovir, bictegravir/emtricitabine/tenofovir, letermovir, darunavir/cobicistat/emtricitabine/tenofovir, elvitegravir/cobicistat/emtricitabine/tenofovir, isavuconazole, meningococcal group B vaccine
L	Antineoplastic and immunomodulating agents	Enfortumab vedotin, deucravacitinib, sotorasib, neratinib, fedratinib, zanubrutinib, nintedanib, liposomal irinotecan, upadacitinib, atezolizumab, encorafenib, erdafitinib, isatuximab, tepotinib, dacomitinib, entrectinib, polatuzumab, interferon gamma, thiotepa, pembrolizumab, lorlatinib, niraparib, satralizumab, ofatumumab, ozanimod, mifamurtide, naxitamab, abemaciclib, ramucirumab, siponimod, risankizumab, guselkumab, avelumab, baricitinib, alpelisib, apalutamide, bosutinib, cabozantinib, acalabrutinib, lenvatinib, vismodegib, trifluridine/tipiracil, ponatinib, ixekizumab, apremilast, ixazomib, durvalumab, venetoclax, osimertinib, vedolizumab, ribociclib, olaparib, obinutuzumab.
M	Musculoskeletal system	Risdiplam, romosozumab, vosoritide
N	Nervous system	Rimegepant, apomorphine, dextromethorphan/quinidine, dimethyl fumarate, tafamidis, fremanezumab, pimavanserin, erenumab, paliperidone, brivaracetam, eslicarbazepine
R	Respiratory system	Elexacaftor/tezacaftor/ivacaftor, glycopyrronium/formoterol, benralizumab, tezacaftor/ivacaftor, ivacaftor, ivacaftor/lumacaftor
S	Sensory organs	Latanoprostene bunod
V	Various	Sodium zirconium cyclosilicate, patiomer, idarucizumab, radium