Current Barriers and Strategies for Optimizing Access to Onco-Hematological Drug Combinations in Spain: Multidisciplinary Delphi Consensus

HPR135



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Introduction.

Combination therapies have become the standard treatment in onco-hematology due to their greater efficacy compared to monotherapy¹. However, current evaluation, pricing, and reimbursement (P&R) mechanisms are not well-suited for these therapies, as they are typically designed for monotherapies involving a single patented drug².

In general, combination therapies in onco-hematology consist of multiple innovative drugs produced by different laboratories, and they typically have multiple indications²⁻³. Then, these combination therapies face significant barriers, resulting in reduced reimbursement and greater delays in P&R decisions for these combinations compared to drugs used in monotherapy¹⁻³. With the expected increase in combination therapies over the next five years, it is essential to review current evaluation frameworks to enhance patient access to onco-hematological combination treatments.

Results.

Sociodemographic and professional characteristics

PARTICIPATION: 27 participants



Participant profiles

45%	n=12	Hospital pharmacist*	
37%	n=10	Hematologist/Oncologist**	
11%	n=3	Patient representatives	
7%	n=2	Decision-maker	

*3 of them (11%) were part of the Pharmacy Commission at the local/regional level **4 of them (15%) were part of Pharmacy Comission at the local/regional level

Strategies

Consider the eu HTA as a harmonizing agent for the positioning of new combined onco-hematological therapies across Europe (77.8%).

Availability and definition of a specific evaluation framework including:

- Justified reimbursement resolution (100%*)
- Clear and defined criteria in the P&R process (96.3%*)
- Economic evaluation criteria should reflect real-world disease management and patient care (92.6%)
- Replicating the pharmacotherapy committee model for evaluating these therapies, involving the key stakeholders from the beginning (92.6%*)
- Specific evaluation framework (85.2%*)
- Multi-party negotiations (88.9%*)
- Set different pricing according to use in monotherapy, combination or according to indication (81.5%)
- Establish criteria for evaluating the clinical value of each drug in combined onco-hematological therapies based on evidence from trials and comparisons (81.5%)

Objective.

This study aims to identify current barriers and propose strategies to optimize access to onco-hematological drug combinations

Methods.

- A national two-round Delphi study was conducted, addressed to key stakeholders involved in the evaluation of onco-hematological therapies in Spain (hematologists/oncologists, hospital pharmacists, decision-makers, and patient representatives).
- The questionnaire was developed based on a **literature review** and advice from a **multidisciplinary expert committee** (including two hospital pharmacists, a hematologist, a decisionmaker, and a representative from the Spanish Cancer Patient Group).
- The questionnaire consisted of 32 questions divided into two

Barriers				
	A lack of clarity and detail in the P&R criteria (85.2%)		A lack of clarity and detail in the justification of the resolution (85.2%)	
Б О	The absence of an active role of the patient in the evaluation of these therapies (81.5%)		The inability to implement a price per indication (77.8%)	

- A methodology to assess the clinical value and pricing of each component in combination therapy (77.8%*)

Outcomes-based value attribution framework:

- Collect health outcomes through electronic systems (96.3%*)
- Establish a single integrated information system (92.6%*)
- Facilitate tools to autonomous communities and hospitals to present the scientific evidence they generate (85.2%*)

Promote healthcare professional training on drug evaluation (92.6%)

National consensus on pharmacotherapeutic protocols and guidelines (85.2%*)**

Provide clinicians with options beyond expanded use for optimal treatment from reimbursement request to decision (77.8%)

euHTA: european Health Technology Assessment, P&R: Price & Reimbursement. % of consensus from desirability/recommendation perspective. *Consensus statements in the first round.

**Unique strategy that achieved consensus from both perspectives (desirability/recommendation [85.2%] and feasibility [77.8%]).

Conclusion.

Adapting the evaluation framework for onco-hematological drug combinations in Spain is essential. To achieve this, the following key strategies are proposed:

sections: 1. Barriers to access, and 2. Strategies/actions to improve access to onco-hematological combination therapies in Spain.

The degree of agreement was evaluated using a 7-point Likert scale (1 = "strongly disagree" to 7 = "strongly agree"), withconsensus defined as \geq 75% agreement (6-7) or disagreement (1-2). Barriers were presented only in the first round. Strategies were subjected to consensus from two perspectives: desirability/recommendation and feasibility.

Define evaluation and P&R criteria and methodology, ensure joint participation of manufacturing laboratories in negotiations, and consider the possibility of setting prices based on usage (monotherapy/combination or indication)

Promote value-based decision-making

Develop national-level pharmacotherapeutic guidelines and pharmacoclinical protocols

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ACKNOLEDGEMENTS: The study was funded by Sanofi and coordinated in collaboration with Outcomes'10.

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