

Criteria for decision-making on medicines financing in Spain: How do we measure them and what relevance does each one have?

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Objectives

In Spain, the criteria for deciding whether a medicine is included in the basic package financed by the NHS were established in 2006 in a Law. However, **these criteria were not defined**, neither is it described how they should be measured.

Our aim is to **propose**, based on the opinion of a broad sample of experts, the **measurement instruments around which there is most consensus for measuring each of the criteria listed in the law**. We also explored the relative weight experts would give to each criterion, and whether they considered the list of criteria appropriate.

Methods

We administered a **survey to 1040 experts** from different stakeholder groups involved in **health economics, health technology assessment, and health technology development and commercialisation**.

Results

The 6 criteria used, and the measures suggested for each, are listed in **tables 1 and 2 below**. There is one criterion capturing different dimensions of social and therapeutic value, and cost-effectiveness (see Table 2). Relative weights given to each criterion, from 0 to 100 (all criteria adding up to 100), are listed in table 3 below.

Table 1	0% – 25%	26% - 50%	51% - 75%	76% - 100%
Severity	Severity instrument	DALY	QALY; Clinical units	/
Specific needs of certain groups	/	Pediatric populations; End of life	Rare diseases	Unmet need
Budget impact	Pharmaceutical expenditure 3-5 years horizon	/	/	Healthcare costs 3-5 years horizon
Available alternative	ATC4	ATC5	Therapeutic equivalence	/
Degree of innovation	/	MCDA	Checklist	/

Table 2	0% – 25%	26% - 50%	51% - 75%	76% - 100%
Therapeutic value	/	Clinical units; the French way (Actual benefit – SMR)	/	QALY
Cost-effectiveness	/	/	ICER	ICUR
Threshold (yes/no)	No	/	/	Yes
Threshold (expl/impl)	Implicit	/	/	Explicit
Threshold (‘exceptional’ situations)	No	/	/	Yes

Table 3	Weight (0 to 100)
Severity	21.54
Needs of certain groups	13.46
Value (social, therapeutic, incremental and ICER)	27.08
Budget impact	16.04
Available alternative	15.21
Degree of innovation	10.5

Conclusions

We believe that there is scope for **increasing the levels of transparency of the methodology** applied to support medicines funding decisions in Spain. The results provided in this study could provide a **solid starting point for a process of developing the criteria listed in the Medicines Act**, detailing the measurement instruments used to quantify each of them.