



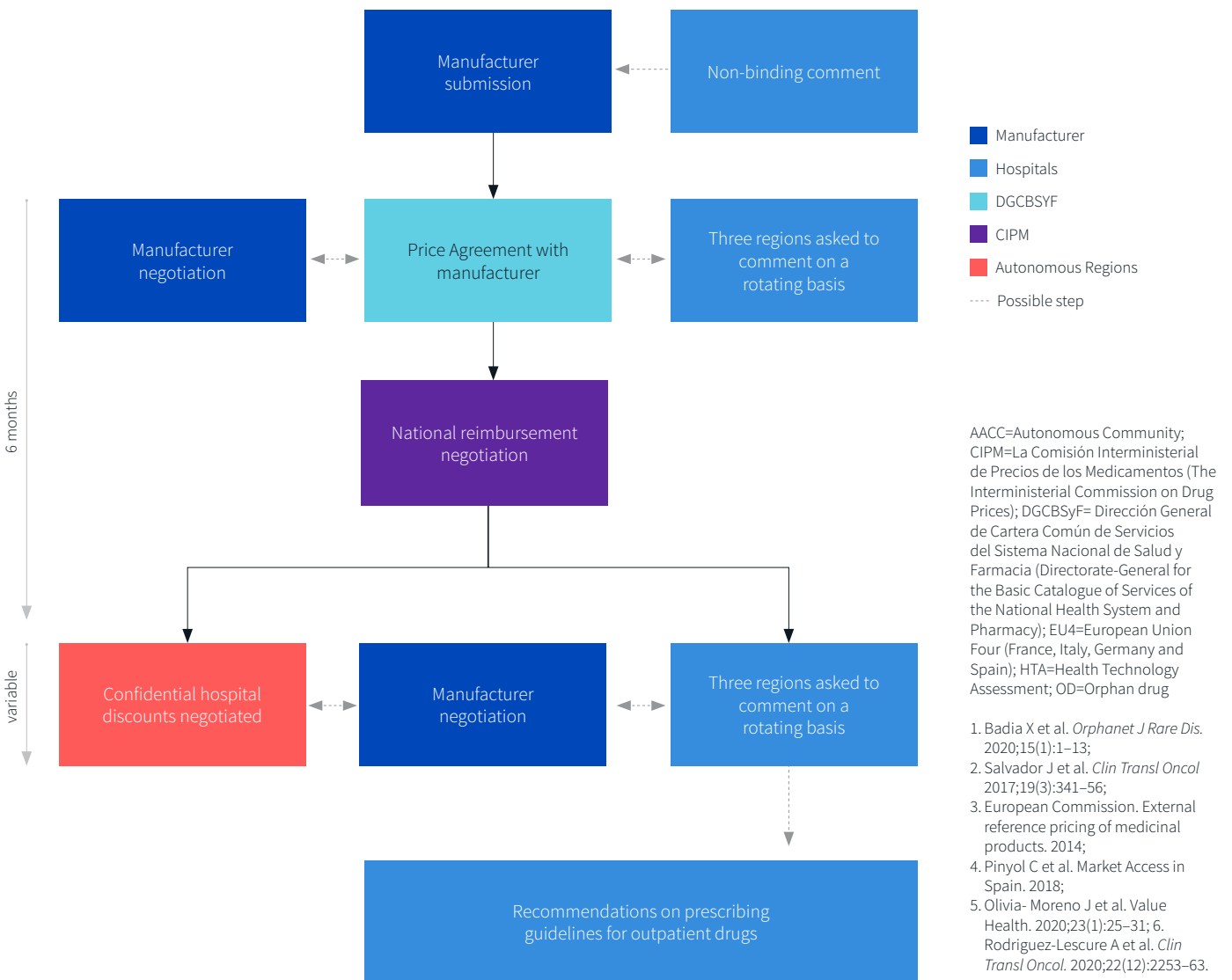
Pricing & Reimbursement in Spain

At a Glance

Although there is a national pricing and reimbursement process in Spain, the 17 autonomous regions and hospitals are in control of budgets and may further restrict access, leading to disparities in coverage by region.

Following national reimbursement, manufacturers may have to negotiate with each region and hospital, delaying market access.

Pricing and Reimbursement Process

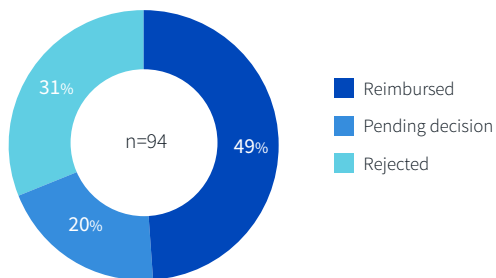


Key Considerations

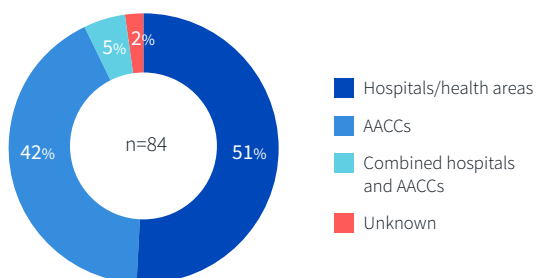
- Providing the regions with a non-binding comment as input into the pricing and reimbursement process is intended to make them more collegiate, and likely to accept national decisions (and add the drug to their formularies).
- Prices are negotiated with the DGCBSyF, which employs internal and external reference pricing*.
- National reimbursement decisions are usually positive, since reaching this stage means an agreed price will have been negotiated between the manufacturer and the DGCBSyF.
- Spain has some of the highest OD prices in the EU4; however, achieving positive reimbursement can be challenging; less than 50% of EMA-approved ODs were reimbursed in the past decade.
- Regions and hospitals may then conduct their own assessments, including local HTAs, and decide whether to include drug on formulary or apply restrictions.
- Autonomous region recommendations are not mandatory, as prescribing is not indication specific.
- National pricing and reimbursement process can take substantially longer than six months, and regional/hospital negotiations further delay patient access.

In Practice

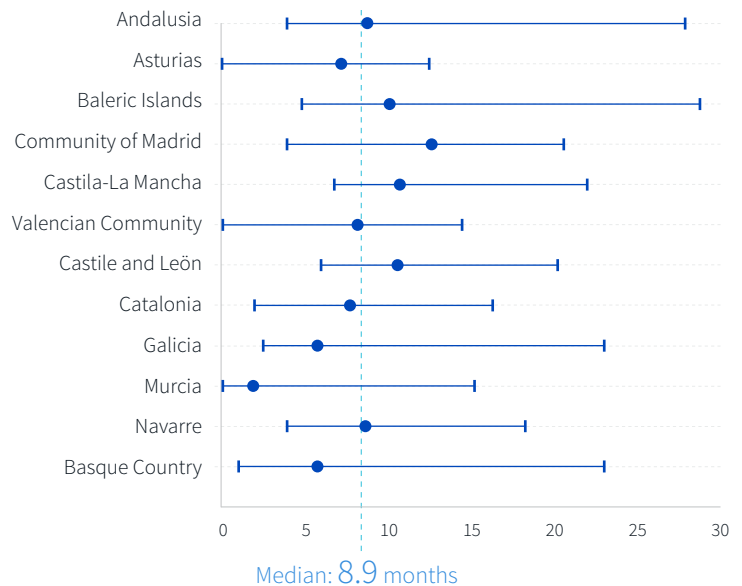
Reimbursement status of ODs approved by European Commission between 2003–2009



Decision-makers affecting hospital-based access to oncologics**



Time from P&R fixation to regional access for oncologics† (months)



Delays have varied considerably between oncologics, with a median delay of 4.5 months for palbociclib versus 15 months for nivolumab.

*Spain references the lowest price in Austria, Belgium, Cyprus, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, the Netherlands, Portugal, Slovenia and Slovakia; **Pembrolizumab, atezolizumab, nivolumab, ribociclib, palbociclib, dabrafenib + trametinib, cobimetinib + vemurafenib, and olaparib; †AACCs with less than five responses for time delay were removed from the analysis.



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