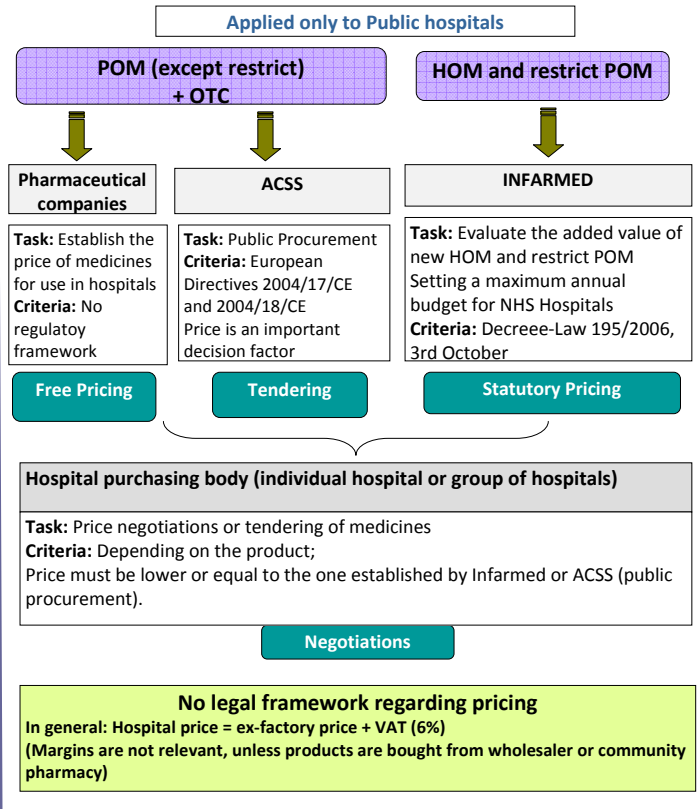
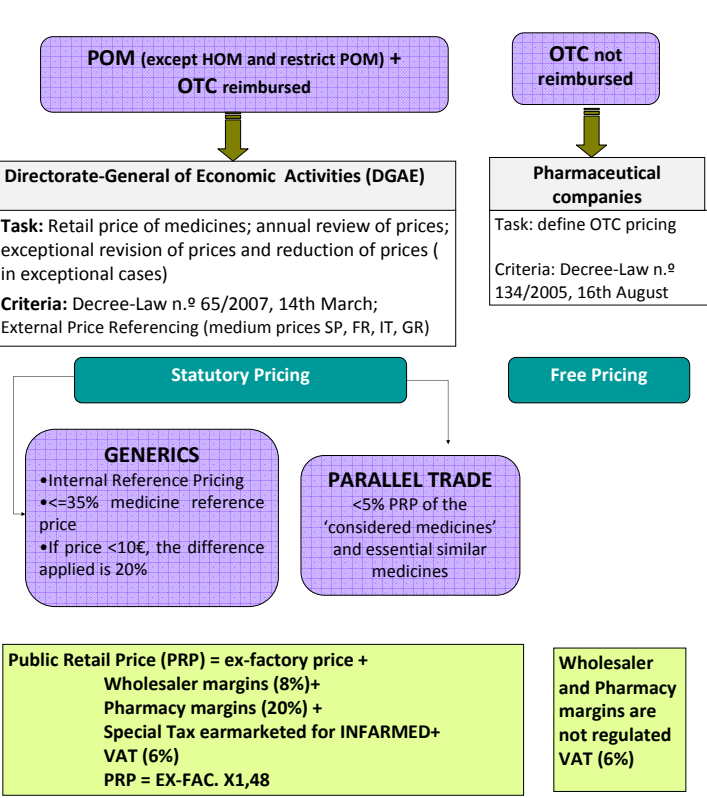


AUTHORISATION/  
CLASSIFICATION

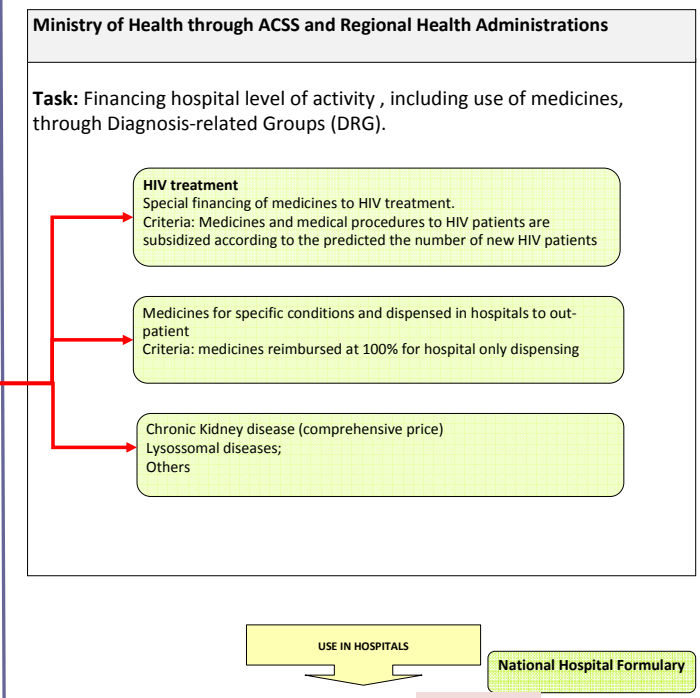
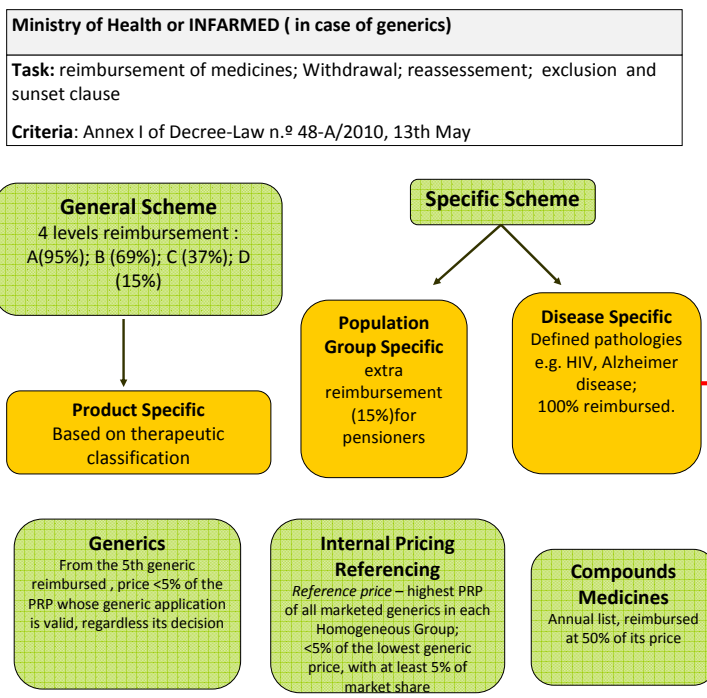
<b>European Medicines Agency (EMA) or National Medicines Agency (INFARMED)</b>
Task: decision on market authorisation
Criteria: Quality, safety, efficacy (Directive 2004/27/EC)
<b>National Medicines Agency (INFARMED)</b>
Task: decision on prescription and dispensing conditions
Criteria - Decree-Law No. 176/2006, 30th August; Directive n.º 2004/27/CE,
<b>INFARMED is also in charge of pharmacovigilance</b>

VIGILANCE

PRICING



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