



SPAIN

Recent and planned developments in pharmaceutical policies 2014

Policies related to high cost medicines

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| D E V E L O P M E N T S | Changes in pricing | Changes in reimbursement |
| | <p><i>Royal Decree 177/2014, 21st mar:</i> <i>Regulates the reference pricing system, maximum prices, minor prices, voluntary decreases, updating mechanisms, information systems (NHS and public information)</i></p> <ul style="list-style-type: none"> • <i>New Reference Pricing Groups (RPG) without generic, more than 10 years in the market</i> • <i>Availability guarantees: comparators should be in the market</i> • <i>RPG Minimum threshold</i> • <i>Certain groups weighted by consume to moderate price decrease</i> • <i>Legal basis to collect consume data for hospital only use medicines</i> <p><i>Order 1225/2014, 10th july updating the RPG in the NHS: 195 new groups are included (total 426 RPG), 29 new RPG for Hospital use medicines (total 98), includes for the first time groups for large packs (137 RPG)</i></p> <p><i>Ongoing price reviews for certain groups selected by consume data and high prices in relation to european countries: AIDS, hepatitis C, inhalers, antidiabetics</i></p> | <p><i>Therapeutic positioning reports issued by the Spanish Agency of Medicines in collaboration with Autonomous Communities since 2013 have been further developed in 2014</i></p> |
| | Other changes | |
| | <p><i>New generation of biosimilars ej infliximab have been approved for reimbursement, information/education activities have taken place regarding biosimilars</i></p> | |
| S P E C I A L T O P I C | High cost medicines | |
| | <p><i>High cost and/or medicines with high uncertainty are subject to new pricing and reimbursement models increased since 2012:</i></p> <ul style="list-style-type: none"> • <i>Application of mechanisms (visa) to verify adjustment to approved indications and conditions of use</i> • <i>Requirement to submit sales and number of patients under treatment after a defined period of time leading to a possible price review</i> • <i>Discounts to the NHS</i> • <i>Expenditure capping</i> • <i>Patient registries</i> • <i>Patient eligibility</i> <p><i>These procedures will be further developed in future legislation</i></p> | |