

Price Strategy Bulletin

New Spanish Medicines Law Contains Important P&R Changes

Introduction

The long awaited and much debated Law 29/2006 on Guarantees and the Rational Use of Medicines and Healthcare Products (*Ley de Garantías y Uso Nacional de los Medicamentos y Productos Sanitarios*) was published in Spain's *Boletín Oficial del Estado* on July 27, 2006.

While its primary purpose is twofold:

- to incorporate into Spanish legislation the new EU human medicines Directive 2004/27/EC, and
- to expand on how the various measures included in the Strategic Plan for Pharmaceutical Policy, published by the Ministry of Health at the end of 2004, are to be carried out,

the new law also revises the drug pricing rules, replacing 1990's *Ley de Medicamentos* and subsequent amendments.

Law 29/2006 extends to 113 articles over 44 pages. While the Law is already in force, certain provisions need additional statutes before they can take full effect. This brief review will relate only to the main P&R-related topics covered.

Pricing

New Products

The average price for the product in other EU countries will be considered in price-setting in Spain. It is not yet known which countries will be used as reference.

Another new concept is that a 'therapeutic utility' report, produced jointly by experts drawn from the Spanish Medicines Agency (AEMP) and the Inter-territorial Council of the National Healthcare System (CISNS) will factor into the agreed price. This marks the first official recognition of the role of the autonomous communities in price-setting by the national government in Madrid.

Non-reimbursed Products

Free pricing of these is maintained.

Price Revision

Products which have been commercialised for a period of over 10 years (or 11 years if a new therapeutic indication was authorized), but without generic competition in Spain, will have their prices reduced by 20%, provided that a generic version has been approved in another EU member state (except member states with transitional intellectual property regimes) with a price lower than that approved in Spain. Hospital-only products are to be treated similarly to those used in the ambulatory sector.

Prices can be reviewed if there is a health reason to do so, or as a consequence of a review of 'therapeutic utility', though price revision cannot take place more than once a year.

Reimbursement

Reimbursement by the SNS will be conditional on the level of innovation offered by the product, its therapeutic use, and the need to control public expenditure. The intention is that regions will participate in setting reimbursement conditions, though how this will occur has not yet been decided.

Reference Pricing

A fourth modification since reference pricing was first introduced in 2000 is introduced.

For multisource lines (containing the same active ingredient and administered by the same route) that have been available in Spain for at least 10 years, with at least one generic marketed, the reimbursement ceiling will be the average of the three lowest cost products in a group in terms of the drug's defined daily dose (DDD).

True bioequivalent generics (*especialidades farmacéuticas genéricas*; EFG) cannot have prices higher than the reference price. Originals and copy brands with prices higher by 30% or more than the reference price should either

- (a) reduce their prices to the reimbursement ceiling and enter into a reference price group, or

- (b) reduce their prices by 30% of the amount these are in excess of the reference price each year (until the reference price is reached, the brand will be excluded from a reference price group).

Products with a MSP below €2 are exempted from reference pricing, as are dosage form innovations showing 'therapeutic utility' for a period of five years from launch.

Pediatric formulations are treated separately from adult ones.

Generic Substitution

Community pharmacists are obliged to substitute the cheapest available equivalent - either an EFG or a copy brand with the same qualitative and quantitative composition, dosage form and pack size - if the prescribed product is priced higher than the reference price.

If the prescriber has used the INN, then the lowest cost equivalent product should be dispensed.

Rebates

Manufacturers are required to pay a sales-related rebate to the health service (SNS) every four months. For SNS sales at manufacturers' prices in the period up to €3 million the rebate is 1.5%. For sales in excess of €3 million the rebate is 2%. Companies that undertake certain types of biomedical research are eligible for a 35% reduction on the rebate.

Distribution

Distribution will be permitted by either wholesalers or marketing authorisation holders.

Discount Ban

Other than when justified by high volume orders or early payment terms, all discounts or the equivalent given by manufacturers to wholesalers and pharmacies are prohibited.

Traceability

Further backing is given to the existing obligation – not yet enforced - for manufacturers, wholesalers and pharmacies to implement batch tracking controls.

Labelling

There is no longer any requirement for the public price to appear on the pack labelling. This suggests the authorities are looking to revise prices, invariably downwards, more frequently.

e-Commerce

OTC medicines can in future be sold also by online pharmacies. This provision needs further development to be implemented.

Margins

Revised wholesale and pharmacy margins already came into effect on February 1st, 2006 under separate legislation.

Demand-side Controls

Prescribing by the INN will be actively promoted by national and regional authorities.

The structure of patient co-payment is unaffected. The standard rate is 40% (or 10% with a maximum of €2.64 for a chronic disease), while the elderly are exempt.

A form of prior authorization, known as the inspection visa (*visados*), has been used in certain regions for products that have second-line uses or multiple indications with different reimbursement conditions attached to each. After reviewing the patient's medical records a regional medical inspector can authorize the prescription to be dispensed. The new law also empowers the regions to participate in limiting prescribing and dispensing of individual products, but the final decision resides with the Ministry.

Nurses in particular were disappointed that initial proposals for supplementary prescribing by healthcare professionals were dropped. Doctors retain their prescribing monopoly under the new law.

Other

The so-called 'Bolar provision', to allow activities necessary for application for generic marketing authorization prior to patent expiry, is now included. However, generics cannot be placed on the Spanish market until 10 years have elapsed from the initial authorization of the reference product. A list of generics which could be sold in Spain during

the following five years will be published annually.

As a counterbalancing measure, there is now a 10 year period of data exclusivity (which may be extended by an additional year), during which the Spanish Medicines Agency cannot refer to originator's data when assessing the safety and efficacy of a generic applicant.

The full text of Law 29/2006 can be found at http://www.msc.es/normativa/docs/LEY29_2006GarantiasUsoRacionalmedicamentosyproductossanitarios.pdf.

Implications for Strategy Development

There is no doubt the new law is designed to boost Spain's sluggish generics' sector to the detriment of branded companies. At 7.5% by value and 13.8% by volume, generic penetration is less than half that found in some other major EU member states.

If a brand is more than 10 years old then a price cut will be forced on it in one of two ways. If it faces no generic competition it will be subject to a mandatory 20% price reduction. If it has generic competition already then the substance will be put in a reference price group and its price has to be cut to the reference price ceiling.

The industry association Farmaindustria expects annual losses of around €750 million, equivalent to a 7.5% fall in total pharmaceutical sales.

Perhaps one of the most challenging new developments facing industry will be to monitor, predict and hopefully influence policies impacting on P&R originating at the regional level. In the short term companies will need to understand the implications of enforced price cuts locally in Spain, and the potential impact on other countries within the EU.

PriceSpective is an international firm of pricing strategy experts, focused on providing strategic guidance in pricing and reimbursement to the pharmaceutical and biotechnology industries.

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