THE SPANISH INTERMINISTERIAL MEDICINAL PRODUCTS PRICING COMMITTEE (CIPM): THE MINISTRY OF HEALTH (MoH) EXPANDS PUBLIC INFORMATION ON PRICING AGREEMENTS AND REIMBURSEMENT CONDITIONS

July 4th 2019

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The Spanish Interministerial Medicinal Products Pricing Committee (CIPM): The Ministry of Health (MoH) expands public information on pricing agreements and reimbursement conditions

(Original article link: here)

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The MoH continues to make progress in the transparency of its decisions within the CIPM. Months ago, it incorporated the notified price information and last month included justifications for its decisions, based on Article 92 of Royal Legislative Decree (RLD) 1/2015 approving the revised text of the Law on Guarantees and Rational Use of Medicines (*Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios*).

a) Gravity, duration and sequelae of the different pathologies for which they are indicated.

b) Specific needs of certain groups.

c) Therapeutic and social value of the medicinal product and its incremental clinical benefit, taking into account its cost-effectiveness ratio.

d) Rationalisation of public spending for pharmaceutical benefit and budget impact in the National Health System.

e) Existence of medicinal products or other therapeutic alternatives for the same conditions at a lower price or lower treatment cost.

f) Degree of innovation of the medicinal product.

In the informative note, released on July 4th, includes the agreements of the CIPM meeting which took place last May 30th, the **MoH has incorporated broader information on the authorised indication, the conditions of prescription and dispensation for each medicine, as well as any singular measures determined for each case. It also incorporates a colour code (green and red) to help visualisation of agreed approvals and rejections.**

Special singular measures

It is also possible now to know some other conditions attached to the financing agreement, such as the **revision in time of the price agreed based on actual sales**. This is the case of some medicines such as Semglee® (insulin glargine), Mylan's biosimilar, which has been **authorised following the ordinary procedure and which must be monitored and its expenditure controlled through Seguimed** (a computer application that manages data related to product transactions between laboratories, warehouses and pharmacies), requiring **the manufacturer periodically records the required sales information in the system.**

In the case of Veltassa® (patiromer sorbitex calcium), its prescription has been limited to certain medical specialists, and limited to patients with certain conditions of heart failure and other clinical conditions. In addition, an annual review of actual sales and appoved prices is established, after which, the CIPM warns that a **price reduction will be made if sales are not within the established, agreed parameters.**

The MoH establishes from now on a **monitorisation of actual sales in order to inform annual review of prices**, so manufacturers **must register in Seguimed and provide the required information about sales to the NHS.**

As far as Imfinzi® (durvalumab), the CIPM has partially accepted AstraZeneca's allegations and accepts the inclusion of the drug in the pharmaceutical provision, although it restricts its financing, **'on the basis of available evidence and in accordance with the NHS Therapeutic Positioning Report'** to certain patients who meet clinical criteria. In addition, it establishes an expenditure ceiling per patient and an annual review of sales, requiring that it is registered in Seguimed.

Modifications to the pharmaceutical offering under the NHS funds

This new section includes agreements relating to the modification of reimbursement and pricing conditions, i.e. **prices increases or decreases, prescription and dispensation conditions, exclusion of medicinal products previously subject to reimbursement under the NHS funds.**

Price increases are established for two presentations of Hemicraneal® (ergotamine + paracetamol + caffeine) and two others of Diprosalic® (betamethasone + salicylic acid). The price increase ranges from **19.8% to 25.1%.** These price increases are justified, according to the CIPM, according to the criteria established in article 96.2 of RLD 1/2015, which establishes that "**the price of a medicine may be modified when changes in economic, technical or health circumstances or in the evaluation of its therapeutic usefulness demand it**". In these cases, the CIPM has also considered "the therapeutic value of medicine, and the acceptable increase in the budget impact which the revision entails".

New indications and change of conditions

With the information now provided in the reports, it is also easier to determine the pricing consequences of approvals of new indications for the same product. This is the case of Zebinix of Laboratorios Bial, which has added two new treatment indications and, as a consequence, has reduced the price of the drug by 12.2%.

Rejected agreements

Regarding rejected financing agreements, it should be noted that the **CIPM now details the reasons for the non-inclusion agreement**. The rejection criteria refer to:

- the therapeutic value of a pharmacological treatment;
- the existence of uncertainties related to the disease or its diagnosis;

- the cost-effectiveness ratio with respect to other alternatives in the market;
- not being of interest to the NHS based on the value provided by the drug and the existence of other alternatives;
- motivations in relation to the rationaliaation of public expenditure due to the high budget impact caused by an "excessive price proposed" by the laboratory.

Among the rejected agreements it is also possible to find **rejections to requests for price increases**, such as the case of Vejicur® (bacillus Calmette–Guérin) de Gebro, **or exclusions from the pharmaceutical provision**.

Antidiabetics

The CIPM considered at their May 30th's meeting the allegations made by Boehringer Ingelheim and Novo Nordisk to the proposed resolutions to reduce prices of some anti-diabetics, including Jentadueto® (linagliptin/metformin), Trajenta® (linagliptin) and Victoza® (liraglutide).

The CIPM justified its decision for not accepting such allegations and proceeding to reduce on the basis that "**it has been found that the cost-treatment-day is far removed from that of other similar medicines**". In addition, it is pointed out that "**this group of medicines has experienced a very significant growth in its consumption in recent years and, therefore, the associated budget impact**". The reasons are also centred on the fact that in the case of drug combinations "**the price is far from that resulting from the sum of the components separately**" and, finally, it is pointed out that "**a lower price has been detected in other countries of the European Union**" for the same medicinal products.

In addition, **it is warned that an annual review of the reimbursement conditions will be conducted, with the aim of ensuring that** it remains **within the legally established parameters**, and **if this is not the case, to adjust it by means of the corresponding discount.**

Composition of the CIPM until December

The MoH has also updated information about the composition of the CIPM for the next six months. The main novelty is that it already specifies the participation of **the 14 Autonomous Regions that are "auditors"**, in addition to **the three that will exercise their functions with voice and vote until December: Balearic Islands, Extremadura and Madrid.**

REFERENCE

1. Diariofarma. Diariofarma La información clave de la farmacia y del medicamento [Internet]. 2019. Available from: https://www.diariofarma.com/