SUMMARY OF 2018 DECISIONS FROM THE SPANISH INTERMINISTERIAL MEDICINAL PRODUCTS PRICING COMMITTEE (CIPM)

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A total of 78 laboratories passed through the CIPM in the last 12 months

(original article link here)

Up to 78 laboratories have seen the approval of their medicinal products passed by Spanish Interministerial Medicinal Products Pricing Committee (CIPM) since November 2017. Out of these, 43 laboratories have presented new drugs or combinations, of which in the first meeting 46 were approved (54.8%) and 38 were rejected (45.2%).

This analysis conducted by Diariofarma based on the information contained in the informative notes from the CIPM, which the Ministry of Health publishes since November 2017, and, for the time being, has made the information available to nine meetings.

The laboratories with the highest number of medicinal products with new active substances or combinations presented to the CIPM are Sanofi (eight), AbbVie (five) and Merck, Roche and Alexion (four).

The fortune of each of them has been very different on that first occasion of drug review by the CIPM. Sanofi obtained four favourable agreements and another four unfavourable ones; AbbVie full approvals; Alexion, on the other hand, four negative agreements; Merck three favourable agreements and one unfavourable and Roche four favourable ones.

New indications

In regard to the application of new indications, a total of 50 presentations, from 15 different laboratories, which have gone through that procedure, 28 have been approved (56%). By companies, Jannsen has requested the approval for 15 presentations, of which 13 were for different forms of Eprex; Novartis for seven presentations of five different active susbtances; BMS four presentations, like Grifols, Lilly or MSD.

Decisions of the CIPM according to laboratory and type of internal procedure

Medicinal products undergoing allegations

Laboratory	Favourable	Unfavourable
AbbVie		5
Amgen	3	2
Celgene	5	
Alexion Pharma Spain		4
Amryt		3
Bayer Hispania	1	2
Shire Pharmaceuticals		3
Takeda Farmacéutica		3
Vertex Pharmaceuticals Spain	2	1
Astrazeneca	2	

Other medicinal products

Laboratory	Favourable	Unfavourable
Rovi	29	
Techdow Europe Ab	29	
Amgen	5	4
Biogen Spain	2	6
Krka Farmacéutica	5	
Bluepharma	4	
Accord Healthcare	3	
Novartis	1	2
Aristo Pharma Iberia		2
Industrial Farmacéutica Cantabria	2	

Respecting the medicinal products undergoing allegations procedures, of which 67 presentations from 32 laboratories and 33 (49.3%) have been approved, AbbVie stands out with five allegation procedures, all negative; Amgen with three favourable decisions and two opposing ones; Celgene with five favourable and Alexion with four unfavourable.

On the other hand, the procedure comprehended under the heading of “other medicinal products” has processed a total of 119 medicinal products from 29 laboratories. Among them include Rovi and Techdow, with 29 presentations each of their low molecular weight heparins; followed by Amgen, with nine applications (five favourable and four negative); Biogen with eight (two approved and six not) and KRKA Farmacéutica with five approved.

It is necessary to make clear that the cases of Amgen and Biogen is due to the non-reimbursement of some presentations of their biosimilars of adalimumab in a decision made while approving others.

Pfizer and GSK, almost absent

Lastly, it is interesting to highlight that two laboratories which are on the top-ten global sales have been almost absent in the nine analysed meetings of the CIPM. They are Pfizer and GSK. The American multinational has only obtained pricing for a new drug throughout a year. Specifically, it is their meningococcal group b vaccine, Trumenba. In addition, it has obtained a new indication for Tygacil. For its part, GKS has only obtained authorisation for their treatment of lupus, Benlysta.

In relation to the decisions recorded, it is necessary to make clear that this is about the times that a certain presentation has gone through the CIPM, not about medicinal products that have been approved or rejected since there are many drugs that initially received a negative decision and after going through the process of allegations were finally approved.