General Pharmaceutical Council of Spain

PAM PANORAMA ACTUAL DEL Medicamento

PUBLICACIÓN DEL CONSEJO GENERAL DE COLEGIOS OFICIALES DE FARMACÉUTICOS

Assessment of drugs in the Panorama Actual del Medicamento 2006-2015

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PURPOSES

To reflect the assessment activity in the last decade (2006 to 2015) regarding the innovation of all new drugs included, whose main pharmacological active ingredients had not been previously commercialised in Spain.

To highlight the importance of rigorous, unbiased information on new drugs as informational support for the pharmacist to optimise their use.

MATERIALS AND METHODS

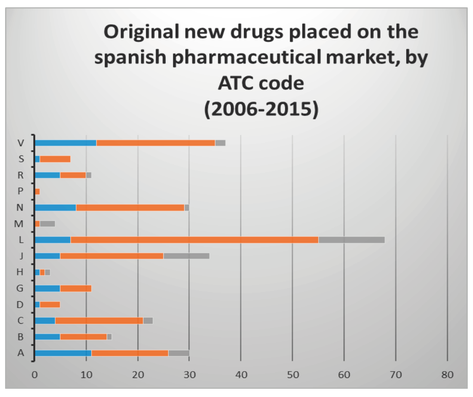
All the assessments published in Panorama Actual del Medicamento (PAM) between 2006 and 2015 have been reviewed, classifying the original new drugs placed on the pharmaceutical Spanish market according to their degree of innovation at the time of their commercialisation: no innovation (*), moderate innovation (**) and important innovation (***). To classify each new drug, contrasted clinical evidence and scientific plausibility were taken into account.

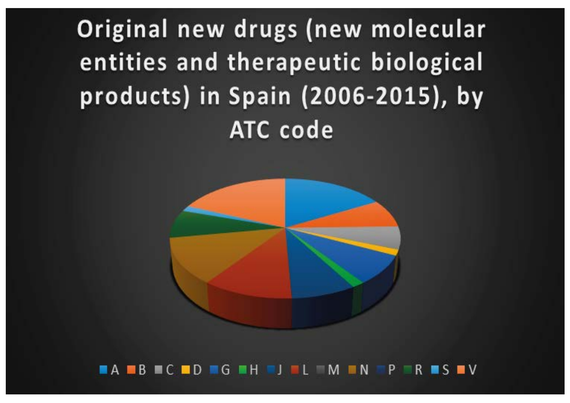
What does it mean to evaluate a drug?

• Systematically analyze all relevant aspects of the new drug: quality, effectiveness, security, and place (compare) such aspects in the current scientific context of pharmacotherapy (state of the art)

• State of the art: highest development achieved at a particular time on any device, technical or scientific field level (Metaphysics, Aristotle).

• **What is the therapeutic innovation?** Any improvement of a new product in any of the aspects of pharmacotherapy interest.





RESULTS

A total of 279 assessments of new drugs carried out by Panorama Actual del Medicamento were reviewed: 177 moderately innovative (63%), 37 extremely innovative (13%) and 65 (24%) with no significative innovation. The therapeutic groups with most extremely innovative drugs were those of anti-neoplasia therapy and immunomodulatory agents (L; 13 drugs), and those of systemic anti-infection therapy (J; 9).

BASIC CRITERIA FOR EVALUATION OF THERAPEUTIC INNOVATION OF NEW DRUGS, IN PANORAMA ACTUAL DEL MEDICAMENTO

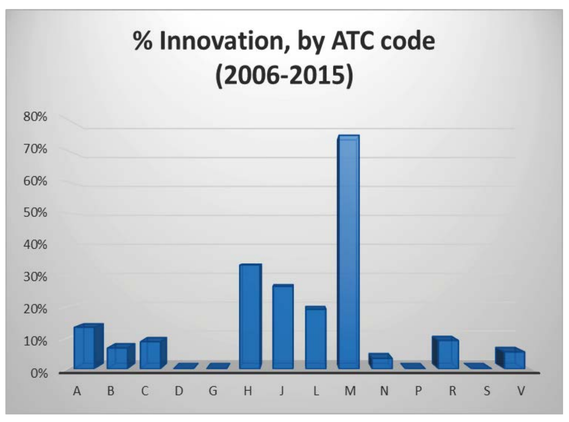
Levels of scientific evidence for rating innovative aspects of the new drugs:

- **Quality of clinical evidence:** through comprehensive controlled studies, specifically designed and developed to demonstrate what purports to be a breakthrough or improvement over standard therapy, with regard to clinical efficacy and/or profile and incidence of adverse effects.

- **Potentiality:** specific aspects of the drug that could rationally improve the current therapy, but whose practical results have not been adequately demonstrated through clinical trials, either for ethical reasons or due to the impossibility of carrying at the time of marketing the new drug: profile of drug/food interactions, New mechanisms that allow new therapeutic approaches, new biochemical profiles against microbial resistance mechanisms, possibility to combine with other medications to get better for the same therapeutic indication, potential effects on therapeutic adherence (use of administration routes more comfortable and safe for the patient, requirement of fewer administrations, etc.), etc.

DRUG RATING

A medicine is valued with an important level of innovation **just** when their alleged innovative qualities are supported by adequate clinical trials, preferably controlled. **In any case it is considered that a new drug holds an important innovation just on the basis of potential advantages.**



1. ***Rating clinical and therapeutic innovation***

2. ***Rating molecular innovation:*** significant variations in molecular structure and/or mechanism of action, with potentially useful results:

3. ***Rating safety innovation:*** Rate any improved toxicity profile relative to current standard therapy. To do this, consider:

4. ***Rating innovation in physical chemistry aspects:*** It is considered the existence of improved pharmacokinetic characteristics, or more favorable impact on the conditions of use and patient response.

5. ***Rating innovation in Pharmacoeconomics:*** Cost reduction (pharmacological, surgery, days off work, etc.) over current therapeutic alternatives, demonstrated by pharmacoeconomic studies in actual use conditions in Spain.

6. ***Rating technological innovation:*** production more efficient, cheaper and/or safe, or from sources without limits, vs. current standard drug therapy

CONCLUSIONS

One out of 8 new pharmacological active ingredients commercialised in Spain are extremely innovative. Assessment of new drugs incorporating active ingredients previously not commercialised in Spain improves drug knowledge in its therapeutic context and optimises its use by pharmacists in their professional work, in terms of both providing health care and the public and private management of therapeutic resources.

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