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The Joint Committee for New Drugs Evaluation in Spain: six years of experience

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INTRODUCTION & OBJECTIVE

There are several Committees/Centres involved in new drugs evaluation throughout Spain. The Joint Committee for New Drugs Evaluation (JCNDE) was established in 2003 to improve efficiency in drug evaluation. Five Regional Drug Evaluation Centres are part of it (Fig.1) sharing common Standard Operating Procedures (SOPs)[1] which are regularly updated and improved. The objective of this study was to analyze the drug innovation degree scores assigned by the JCNDE and timing between the new drug commercialization and the JCNDE assessment publication.

METHODS

The JCNDE SOPs define a stepwise algorithm with 4 key criteria for new drug innovation ratings, compared with existing therapeutic alternatives: efficacy, safety, convenience and drug cost (Fig.2). The drug innovation scores range from 0 (insufficient experience with the drug) to 4 (relevant therapeutic improvement). The drug evaluation results were gathered for different publications from the JCNDE reports and from the Regional Drug evaluation centres reports[2-7] (as shown in Fig.3). The study analyzed the drugs assessed for 6 years (from 2004 to 2009). Commercialization date in Spain were obtained from IMS database.

Fig.1: Regions members of the JCNDE

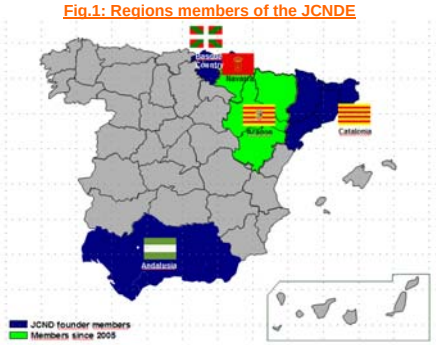
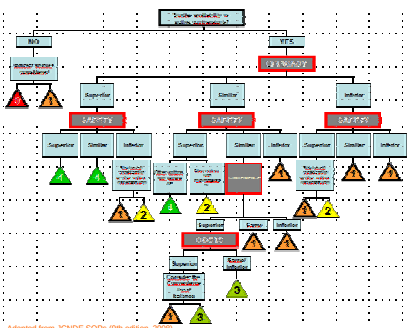
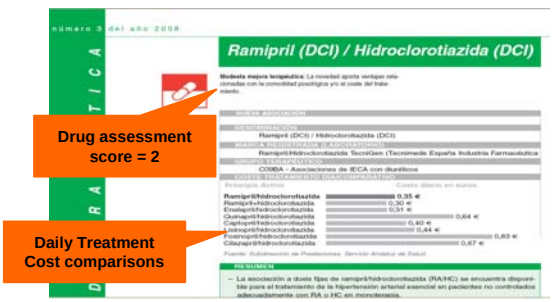


Fig.2: Algorithm for New Drugs Therapeutic Innovation degree



Adapted from JCNDE SOPs (9th edition, 2008)

Fig.3: New Drug brief report published example



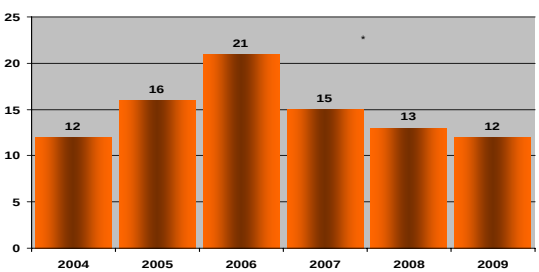
CADIME: Centro Andaluz de Información de Medicamentos (Andalusia)

RESULTS

Ninety drug evaluations were held during the study period, considering 86 different drugs and 11 evaluations for a new drug indication for the same drug (Fig.4). JCNDE evaluation rythm is rather constant, depending on the new drugs approval flow (Fig.5). Seventy-eight (87%) of the evaluations were considered as "negative" (scores 0-1), not finding any 0 during the last 2 years analyzed. Ten and 2 evaluations were scored as 2 and 3 respectively. None of the drugs assessed reached the top score of 4, considered as a relevant therapeutic improvement, compared to the therapeutic existing options (Fig. 6). Although the JCNDE activity is focused on reimbursed and high prescription potential drugs in the Primary Care (PC) setting, we found 5 drugs not reimbursed which were assessed.

Fig.4: Database of the JCNDE drugs assessed

Fig.5: # New Drugs assessed by the JCNDE (2004-09)



(*) 3 New drugs re-assessed for a new drug indication

Median time since drug commercialization date and its first evaluation publication available was 6 months, IQR: 2-11 months (Fig.7). Thirty-two drug evaluations could have been held by the JCNDE members before drug commercialization date, up to a maximum of 3 months after commercialization (Fig8); considering the the evaluation timing procedure described in the JCNDE SOPs.

Fig.6: New Drugs assessed scores (2004-09)

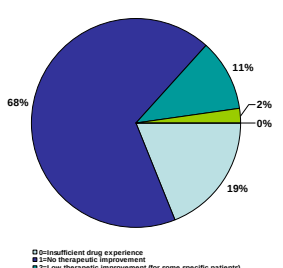


Fig.7: Time from product launch to JCNDE evaluation

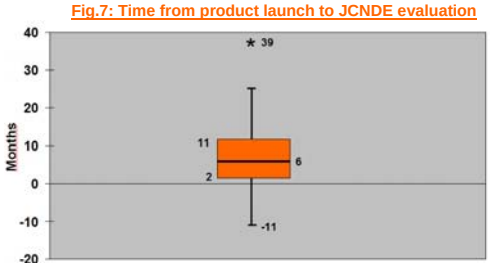
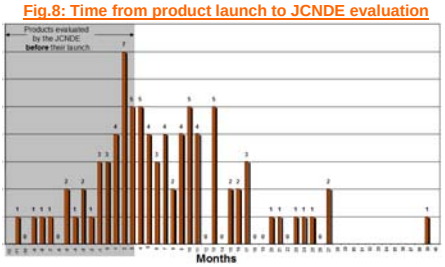


Fig.8: Time from product launch to JCNDE evaluation



CONCLUSIONS

The JCNDE has been an efficient instrument to develop new drugs assessments in the PC setting for the Regional Health Systems in Spain. Most of the assessments have been negative. These negative evaluations may be the payer argument to establish drug cost containment strategies, based on the low incremental innovation of the new drugs. At present, health-economics arguments are basically focused on the daily treatment cost comparisons. About 1/3 of the drug evaluations are started before drug commercialization. This point should be taken into account by the Pharma companies who want to monitor their new drug evaluation by the JCNDE.

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