

# Evaluation des médicaments après la commercialisation

## Efficacité réelle, population exposée et impact sur la santé publique

Catherine Le Galès,<sup>1</sup> Abdelkader El Hasnaoui,<sup>2</sup> Jean-Marie Goehrs<sup>3</sup> et les participants à la table ronde n° 2 de Giens XVIII<sup>†</sup>

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### Résumé

La table ronde n° 2 était consacrée à l'évaluation des médicaments après la commercialisation. Les débats ont porté à la fois sur les questions posées par l'évaluation post-mise sur le marché et sur les méthodes permettant d'y répondre. Les grandes catégories de questions susceptibles d'être posées ont été listées : efficacité en situation réelle ; tolérance en situation réelle ; facteurs pronostiques et patients répondeurs ; place dans la stratégie thérapeutique ; impact sur le système de soins ; population rejointe ; et pratiques d'utilisation. En outre, les approches méthodologiques ont été structurées dans trois catégories : l'approche expérimentale, l'approche observationnelle, et l'approche par modélisation. Chacune des approches méthodologiques a été qualifiée au regard de chacune des questions. L'objectif n'était ni de tenter un classement des méthodes selon le niveau de preuve, ni de proposer des recettes méthodologiques. Les participants se sont plutôt attachés à décrire les points forts et les limites des différentes méthodes successivement pour chacune des questions. Les débats ont ensuite porté sur le processus d'identification des questions pertinentes et des méthodes appropriées. Dans ce cadre, les participants de la table ronde ont apporté une analyse du dispositif actuel des projets d'études post-autorisation de mise sur le marché et formulé certaines propositions d'amélioration. Enfin, la place des bases de données existantes dans l'évaluation post-commercialisation a été discutée et les participants ont souligné l'importance de procéder à une expertise minutieuse des informations que pouvaient apporter de telles bases avant la mise en place d'études *ad hoc*.

**Mots clés :** évaluation, commercialisation, médicaments, efficacité, population exposée, santé publique

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### 1. Introduction: cadre de la réflexion

Le dispositif français d'inscription d'un médicament au tableau des remboursements et de fixation de son prix résulte d'un processus qui peut être divisé en trois étapes : une autorisation de mise sur le marché (AMM) délivrée de plus en plus souvent au niveau européen, l'inscription éventuelle du produit au tableau des spécialités remboursables et la fixation de son taux de remboursement après un avis de la Commission de la Transparence destiné aux Ministres en charge de la Santé et de la Sécurité

Sociale et la fixation du prix de vente au public du produit sur proposition du Comité Economique des Produits de Santé (CEPS).

Ce processus est maintenant bien établi. Toutefois, au cours des 2 dernières années, plusieurs événements ont conduit à mettre l'accent dans ce dispositif sur l'évaluation de l'intérêt pour la santé publique d'un médicament.

Tout d'abord, le décret du 27 octobre 1999<sup>[1]</sup> a clarifié les critères d'appréciation du service médical rendu habituellement utilisés par la Commission de la Transparence : efficacité ; effets

<sup>†</sup> Pour la liste des participants, voir en fin d'article.

\* Les articles, analyses et propositions issus des Rencontres de Pharmacologie Clinique de Giens n'engagent que leurs auteurs et ne préjugent pas de la position de leur organisme de tutelle.

# Evaluation Des Medicaments Apres La Commercialisation

**David Baud**



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