

2009 Prescrire Drug Awards

Products evaluated during the previous year in the New Products section of our French edition are eligible for the Prescrire Awards for new drugs and indications (in 2009: issues 303 to 314).

Each month, the *Prescrire* editorial staff presents systematic and comparative analyses of available data on all newly approved drugs in France, and on new therapeutic indications granted for existing drugs. The goal is to help the reader distinguish, among the plethora of lavishly promoted commercial products, those medications worth adding to their drug list, or worth using instead of existing drugs. This evaluation follows rigorous procedures that include a thorough literature search, a large panel of reviewers (specific to each project) and a quality control system to verify that the text is consistent with the data in the references.

Total independence. This work is carried out by the editorial staff in total independence. *Prescrire* is financed exclusively by individual readers' subscriptions: neither the French nor the English edition carries any paid advertising, nor do we receive grants or subsidies of any kind (see our annual financial report in each *Prescrire International* June issue). At the end of each year, the Prescrire Drug Awards are based on the review articles published that year, and take into account any new data available since the initial articles were published. The rules governing the Drug Awards are available online, at www.english.prescrire.org.

Therapeutic advance is defined as better efficacy, fewer or less severe adverse effects (for similar efficacy), or safer or more convenient administration.

2009: two minor advances. In 2009, as in 2008, none of the new drugs we examined was awarded the Golden Pill award or mentioned on the Honours List (see above and page 85).

However, two drugs that had already been on the market for several years were granted useful new indications. *Caspofungin*, an antifungal echinocandin, was approved as last resort therapy for some children with invasive aspergillosis, a rare but frequently fatal opportunistic infection. Clinical evaluation in this setting is still limited, but *caspofungin* is a welcome treatment option.

Thalidomide was approved for first-line treatment of multiple myeloma in patients over age 65. Two trials conducted by the same team showed that adding *thalidomide* to the standard *melphalan + prednisone* combination prolonged overall survival by at least 1.5 year in 50% of patients. However, three other trials showed no increase in overall survival; therefore, the precise survival benefit remains to be determined. *Thalidomide* has frequent and potentially severe adverse effects, including neuropathy and venous thrombosis. It is also highly teratogenic.

Stagnant situation. Once again, in 2009, the paucity of new products offering even a modest therapeutic advantage stands in stark contrast to the large number of new products exposing patients to unjustified risks: about 20 per year over the last 5 years (see pages 90 and 92).

The international system of incentives intended to encourage real therapeutic advances is clearly not working. There are also flagrant shortcomings in the marketing authorisation procedures and post-marketing pharmacovigilance.

If they are to regain the trust of patients and healthcare professionals, drug regulatory agencies and drug companies must shift the focus to more rigorous and more transparent clinical studies designed to meet important health needs.

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Pilule d'Or/Golden Pill

The "Golden Pill" award is granted to drugs that provide a major therapeutic advance in a field in which no effective treatment was previously available.

NOT AWARDED IN 2009

Honours list

Drugs included on the Honours List provide a clear advantage for some patients in comparison to existing therapeutic options, albeit with certain limitations.

NO INCLUSIONS IN 2009



Noteworthy

The following drugs (in alphabetical order based on their international nonproprietary name (INN: " a drug's real name") made a modest contribution to patient care:

caspofungin	CANCIDAS° MSD-Chibret	Invasive aspergillosis in children in whom injectable *amphotericin* B and/or *itraconazole* is ineffective or poorly tolerated (*Prescrire Int* 102)
thalidomide	THALIDOMIDE CELGENE° Celgene	First-line treatment of multiple myeloma in selected patients over 65 years of age, in combination with *melphalan* and *prednisone* (*Prescrire Int* 100)

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