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The Prescrire Awards 2015

The three annual Prescrire Awards, for Drugs, Packaging and Information, are granted in total independence by the *Prescrire* Editorial Staff.
The rules governing the three Prescrire Awards are available online at english.prescrire.org.

2015 Prescrire Drug Awards

New products or new indications evaluated during the previous year in the New Products section of our French edition are eligible for the *Prescrire* Drug Awards.

Each month, the *Prescrire* Editorial Staff presents systematic comparative assessment of available data on drugs newly approved in France and the EU, and on new therapeutic indications granted for existing drugs. The goal is to help the reader distinguish, among the plethora of lavishly promoted new products, those medications worth adding to their drug list or worth using instead of existing products, as well as drugs to be avoided.

This evaluation is based on rigorous procedures that include a thorough literature search, input from a group of reviewers specific to each review, and various quality controls to verify that the text is consistent with the data in the references (see our website for further information: english.prescrire.org).

Total independence. This work is carried out by the *Prescrire* Editorial Staff in total independence, free from any industry or institutional influence. *Prescrire* is financed exclusively by its subscribers. 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 June issue of *Prescrire International*).

At the end of each year, the *Prescrire* Drug Awards are based on the reviews published that year in the French edition, and take into account any new data made available since the initial articles were published.

Pilule d'Or / Golden Pill

The Pilule d'Or (Golden Pill) has been granted since 1981 to drugs that constitute a major therapeutic advance in a field in which no treatment was previously available

2015	NOT AWARDED
2014 (n° 376)	ORPHACOL° (*cholic acid*)
2007 (n° 292)	CARBAGLU° (*carglumic acid*)
2006 (n° 280)	ORFADIN° (*nitisinone*)
1998 (n° 192)	CRIXIVAN° (*indinavir*)
1996 (n° 169)	DIGIDOT° (*digoxin-specific antibody*) (1)
1992 (n° 125)	SURFEXO° (*pulmonary surfactant*) (1)
1989 (n° 92)	EPREX° (*epoetin alfa*) • MECTIZAN° (*ivermectin*)
1988 (n° 81)	LARIAM° (*mefloquine*) • RETROVIR° (*zidovudine*)
1987 (n° 71)	LUTRELEF° (*gonadorelin*) • DECAPEPTYL° (*triptorelin*)
1986 (n° 61)	ZOVIRAX° IV and tablets (*aciclovir*)
1983 (n° 31)	LOPRIL° (*captopril*)
1981 (n° 10)	VACCIN HEVAC B° (*hepatitis B vaccine*)

No Golden Pill was awarded in 1982, 1984, 1985, 1990, 1991, 1993, 1994, 1995, 1997, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2008, 2009, 2010, 2011, 2012 and 2013.

1- No longer marketed in France.

These awards honour drugs that constitute a therapeutic advance, in that they offer better efficacy, fewer or less severe adverse effects (for similar efficacy), or safer or easier administration.

No Golden Pill awarded in 2015. Three of the products featured in the New Products section of our French edition in 2015 earned a *Prescrire* Drug Award this year. One was included on the Honours List, two were deemed "Noteworthy", but none constituted a sufficient therapeutic advance to warrant a Golden Pill Award. None of these three products contain a novel active ingredient. However, in the clinical situation for which they were granted marketing authorisation, they constitute an advance over the products already available.

Propranolol oral solution and severe haemangioma: a chance discovery, followed by development of a paediatric form. Some infants have a severe haemangioma that could cause complications (due to its size and location), ulceration, bleeding or disfigurement. *Propranolol* oral solution has become the drug of choice in this situation. It is more effective than placebo and its adverse effects are more acceptable overall than that of long-term oral corticosteroid therapy. Treatment initiation and dose increases should take place in hospital, with careful monitoring of the child. *Propranolol* oral solution has been granted marketing authorisation in the European Union solely for paediatric use. Its packaging is conducive to safe use and safe dose preparation.

Permethrin in scabies, ketoconazole in Cushing's syndrome: welcome marketing authorisations. *Permethrin* 5% cream is at last readily obtainable in France to treat classic scabies, since being granted full marketing authorisation, and being made available in the community and reimbursable by the national health insurance system. Its main value is for the treatment of young children, because *ivermectin* is not approved for use in children weighing less than 15 kg.

After about 30 years of off-label use in the rare but serious endogenous Cushing's syndrome, oral *ketoconazole* has finally been granted marketing authorisation for this indication. In this situation, data from non-comparative case series in a total of 800 patients suggest that oral *ketoconazole* is effective in more than half of patients. However, its use requires precautions on account of its hepatotoxicity and strong potential for drug interactions.

Few therapeutic advances. While many new marketing authorisations were granted in 2015, few constituted a real therapeutic advance. Knowing how to sift through the multitude of available drugs to identify those with the best harm-benefit balance in a given situation, and knowing to avoid drugs that are more dangerous than useful is also an area where important advances can be made for the benefit of patients (see Towards better patient care: drugs to avoid in 2016 on english.prescrire.org and in April issue).

Regulators and policy makers should impose stricter requirements on new drugs, by demanding evidence that they actually constitute a therapeutic advance. This would prevent inundation of the market with products that offer no advantages in patient care and that, in some cases, are more dangerous than useful. It would also help contain the excesses this situation generates: extravagant marketing aimed at health professionals and patients, incentives to prescribe and purchase drugs, and spiralling health expenditure.

Honours list

Drugs are included on the Honours List because they represent a clear advance for some patients compared with existing therapeutic options, albeit with limitations.

2015	• **HEMANGIOL° (*propranolol* oral solution)** Pierre Fabre Dermatology - Severe infantile haemangioma (Prescrire Int n° 162)
2014 (n° 376)	• Glivec° (*imatinib*) (acute lymphoblastic leukaemia in children) • Malacef° (intraveinous *artesunate*) (severe malaria) • Sovaldi° (*sofosbuvir*) (hepatitis C)
2010 (n° 328)	• Glivec° (*imatinib*) (unresectable or metastatic gastrointestinal stromal tumours, with more follow-up)
2007 (n° 292)	• Glivec° (*imatinib*) (chronic myeloid leukaemia with more follow-up) • Herceptin° (*trastuzumab*)
2006 (n° 280)	• Egaten° (*triclabendazole*)
2005 (n° 269)	• Varivax° (*varicella-zoster vaccine*)
2004 (n° 258)	• Diacomit° (*stiripentol*) • Fuzeon° (*enfuvirtide*) • Morphine Aguettant° syrup (oral *morphine*) (1)
2003 (n° 247)	• Carbaglu° (*carglumic acid*) • IVheBex° (*hepatitis B immunoglobulin*) • Meningitec° (*conjugate meningococcal C vaccine*)
2002 (n° 236)	• Replagal° (*agalsidase alfa*) (2) • Ceprotin° (1) - Protexel° (*human protein C*) • Stromectol° (*ivermectin*) (scabies)
2001 (n° 225)	• Esterasine° (*C1 esterase inhibitor*) (1) • Trolovol° (*penicillamine*) (chelator)
2000 (n° 214)	• Remicade° (*infliximab*)

Drugs were included on the Honours List every year between 1981 and 2007. No drugs were included in 2008, 2009, 2011, 2012 or 2013. The full list of drugs included on the Honours List from 1981 to 2013 can be found in *Prescrire International* n° 67 page 168.

1- No longer marketed in France; **2-** New data published after the inclusion of this drug on the Honours List led us to revise our rating, see *Prescrire Int* n° 67 page 168.

Noteworthy

Drugs deemed "Noteworthy" provide a modest improvement in patient care.

2015	• **TOPISCAB° (*permethrin* 5% cream)** Codexial Dermatologie – Scabies from 2 months of age (*Rev Prescrire* n° 384)
	• **KÉTOCONAZOLE HRA° (*ketoconazole*)** HRA Pharma – Endogenous Cushing's syndrome (*Rev Prescrire* n° 386)