PRESCRIRE AWARDS

1981-2007: 27 YEARS OF PRESCRIRE DRUG AWARDS

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Prescrire Drug Awards, Packaging Awards and Information Awards are carried out in total independence by Prescrire editors (see Rules on www.prescrire.org). They should be read in context of the review on new medicines in 2007 on page 78.

The table opposite lists the drugs along with their initial ratings in the New Products section of the French edition of this bulletin, *la revue Prescrire*. They are rated as follows:
B = Bravo
RA = Real Advance
OAA = Offers An Advantage

(1)	Golden Pill/Pilule d'or	Honours List
1981 (n°10)	• **VACCIN HEVAC B°** ***(hepatitis B vaccine)*** (B)	• Androcur° (*cyproterone*) (**RA**) • Armophylline°(*theophylline* LP) (**RA**) • Cordium° (*bepridil*) (**RA**) • Isoprinosine° (*inosine acedoben dimepranol*) (**RA**) • Pirilene° (*pyrazinamide*) (**RA**) • Tildiem° (*diltiazem*) (**RA**)
1982 (n°21)	(not attributed)	• Didronel° (*etidronic acid*) (**RA**) • Minirin° (*desmopressin*) (**RA**) • Nerfactor° *(isaxonine)* (**RA**)(2) • Vansil° *(oxamniquine)* (3)(**RA**)
1983 (n°31)	• **LOPRIL° *(captopril)*** (RA)	• Tigason° *(etretinate)* (**RA**)(3)
1984 (n°41)	(not attributed)	• Nizoral° *(ketoconazole)* (**RA**) • Orimetene° *(aminoglutethimide)* (**RA**) (3) • Ulcar° *(sucralfate)* (**RA**)
1985 (n°51)	(not attributed)	• Augmentin° *(amoxicillin + clavulanic acid)* (**OAA**)
1986 (n°61)	• **ZOVIRAX° I.V. and tabs.** ***(aciclovir)*** (B) and (RA)	• GHRH Clin Midy° *(somatorelin)* (**RA**) • Roaccutane° *(isotretinoin)* (**RA**)
1987 (n°71)	• **LUTRELEF° *(gonadorelin)*** (B) • **DECAPEPTYL° *(triptorelin)*** (RA)	• Introna° *(interferon alfa)* (**RA**) • Moscontin° (sustained release *morphine*) (**RA**) • Zovirax° cream *(aciclovir)* (**OAA**) • Rifadine° *(rifampicin)* (**RA**) • Tegretol° (new indications) *(carbamazepine)* (**RA**)
1988 (n°81)	• **LARIAM° *(mefloquine)*** (B) • **RETROVIR° *(zidovudine)*** (B)	• Anexate° *(flumazenil)* (**RA**) • Nimotop° *(nimodipine)* (**RA**)
1989 (n°92)	• **EPREX° *(epoetin alfa)*** (B) • **MECTIZAN° *(ivermectin)*** (B)	• Malocide° (new indication) *(pyrimethamine)* (**RA**) • Nimotop° inj. (new indication) *(nimodipine)* (**RA**) • Sandostatin° *(octreotide)* (**RA**)
1990 (n°103)	(not attributed)	• Mopral° *(omeprazole)* (**RA**) • Narcan° *(naloxone)* (**RA**) • Pentacarinat° *(pentamidine)* (**OAA**)
1991 (n°114)	(not attributed)	• Aredia° *(pamidronate)* (**RA**) • Minirin° inj. (new indication) *(desmopressin)* (**RA**) • Levocarnil° *(L-carnitine)* (**RA**) • Sandostatin° (new indication) *(octreotide)* (**RA**)
1992 (n°125)	• **SURFEXO° *(pulmonary surfactant)*** (RA)(3)	• Apokinon° *(apomorphine)* (**OAA**) • Videx° *(didanosine)* (**OAA**)
1993 (n°136)	(not attributed)	• Avlocardyl° (new indication) *(propranolol)* (**RA**) • Daivonex° *(calcipotriol)* (**OAA**) • Sporanox° *(itraconazole)* (**OAA**)
1994 (n°147)	(not attributed)	• Botox°-Dysport° *(botulinum toxin)* (**OAA**) • Zophren° (new dosages) *(ondansetron)* (**OAA**)
1995 (n°158)	(not attributed)	• Methadone hydrochloride AP-HP° *(methadone)* (**RA**) • Retrovir° (new indication) *(zidovudine)* (**RA**) • Cogenate° - Recombinate° *(recombinant factor VIII)* (**RA**)
1996 (n°169)	• **DIGIDOT° *(antidigitalin antibodies)*** (B)	• Ceredase° *(alglucerase)* (**RA**) (3) • Normosang° *(hemin arginine)* (**RA**) • Subutex° *(buprenorphine)* (**RA**) • Zocor° - Lodalès° (new indication) *(simvastatin)* (**RA**) • Zeclar° - Naxy° *(clarithromycin)* ; Clamoxyl° - Gramidil° *(amoxicillin)* ; Mopral° - Zoltum° *(omeprazole)* ; Ogast° - Lanzor° *(lansoprazole)* (new indication) (**RA**)
1997 (n°180)	(not attributed)	• Elisor°-Vasten° (new indication) *(pravastatin)* (**RA**) • Novatrex° (new indication) *(methotrexate)* (**OAA**) • Vesanoïd° (new indication) *(tretinoin)* (**RA**)
1998 (n°192)	• **CRIXIVAN° *(indinavir)*** (RA)	• Cystagon° *(cysteamine)* (**RA**) • Viagra° *(sildenafil)* (**RA**)
1999 (n°203)	(not attributed)	• Sustiva° *(efavirenz)* (**OAA**) • NorLevo° *(levonorgestrel)* (**OAA**)
2000 (n°214)	(not attributed)	• Remicade° *(infliximab)* (**OAA**)
2001 (n°225)	(not attributed)	• Esterasine° *(C1 esterase inhibitor)* (**RA**) (3) • Trolovol° (new indication) *(penicillamine)* (**RA**)
2002 (n°236)	(not attributed)	• Replagal° *(agalsidase alfa)* (**RA**) (4) • Ceprotin°, Protexel° *(human protein C)* (**RA**) • Stromectol° (new indication) *(ivermectin)* (**OAA**)
2003 (n°247)	(not attributed)	• Carbaglu° *(carglumic acid)* (**RA**) • IVheBex° *(hepatitis B immunoglobulin)* (**RA**) • Meningitec° *(conjugated meningococcal C vaccine)* (**OAA**)
2004 (n°258)	(not attributed)	• Diacomit° (*stiripentol*) (**OAA**) • Fuzeon° (*enfuvirtide*) (**OAA**) • Morphine Aguettant° syrup (oral *morphine*) (**OAA**)
2005 (n°269)	(not attributed)	• Varivax° (*chickenpox vaccine*) (**RA**)
2006 (n°280)	• **ORFADIN° (*nitisinone*)** (B)	• Egaten° (*triclabendazole*) (**RA**)
2007 (n°290)	• **CARBAGLU° *(carglumic acid)*** (a second look) (B)	• Glivec° (imatinib) (chronic myeloid leukaemia, a second look) (**RA**) • Herceptin°(new indication) (trastuzumab) (**OAA**)

1- Year and issue of the French edition *la revue Prescrire* in which the Awards were published.
2- Now withdrawn from the French market, because of adverse effects.
3- No longer marketed in France.
4- New data led us to amend our score (see *Prescrire International* n° 67).

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2007 NEW DRUG AWARDS

The *Prescrire* Drug Awards focus on products evaluated during the previous year in the New Products section of our French edition (issues 279 to 290 in 2007).

Each month the 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 aim is to help the reader to distinguish, among the plethora of lavishly promoted new commercial products (despite the failings of the licensing authorities), those medications worth adding to their drug list or using instead of existing drugs.

This evaluation follows rigorous procedures (details on www.prescrire.org) that include a thorough literature search, a large panel of reviewers (specific to each drug), and a quality control system to check, among other things, that the text is consistent with the references.

Independence. This work is carried out in total independence: our activities are 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 the next issue).

At the end of each year, the *Prescrire* Drug Awards are based on review articles published that year. Note that the selection process takes into account any new data available since the initial article was published.

The rules governing the Drug Awards are also available on the *Prescrire* website at www.prescrire.org.

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

2007: therapeutic progress for some patients. As in 2006, we considered that a drug introduced to the French market during the previous year deserved the Golden Pill award (see page 74). However, very few patients will benefit from this therapeutic advance. In the vast majority of clinical situations the lack of real innovation continues (see pages 78-82 of this issue). And, unable to introduce enough new drugs to the market that represent a tangible therapeutic advance, most drug companies are simply marking time, cutting up the indications for their existing products into thinner and thinner slices, using numerous strategies to exploit their remaining patents to the fullest, and are using and abusing advertising in all its different forms to boost sales.

In this stagnant situation, what patients need most are more dynamic and demanding regulatory authorities.

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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.

carglumic acid	**CARBAGLU°** Orphan Europe	five years of follow-up of about 20 patients showed that oral carglumic acid ensures normal long-term survival of children with a rare fatal urea cycle disorder (this issue page 50)

Honours list

The following drugs (in alphabetical order of international nonproprietary names) provide a clear advantage for some patients, in comparison to existing therapeutic options, albeit with certain limitations:

imatinib	**GLIVEC°** Novartis	chronic myeloid leukaemia (with longer follow-up) (*la revue Prescrire* n° 290)
trastuzumab	**HERCEPTIN°** Roche	adjuvant treatment of some forms of breast cancer (*Prescrire International* n° 89)

Noteworthy

The following drugs (in alphabetical order of international nonproprietary names) made a modest contribution to patient care:

artemether + lumefantrin	**RIAMET°** Novartis	treatment of uncomplicated *Plasmodium falciparum* malaria attacks (this issue page 54)
darunavir	**PREZISTA°** Janssen-Cilag	HIV infection after failure of multiple antiretroviral drug regimens (*la revue Prescrire* n° 289)
levetiracetam	**KEPPRA°** UCB	myoclonic epilepsy from age 12 years (*la revue Prescrire* n° 287)
methotrexate	**MÉTHOTREXATE BELLON°** Sanofi Aventis	psoriatic rheumatism (*Prescrire International* n° 91)
triamcinolone (hexacetonide) (intra-articular)	**HEXATRIONE°** Daiichi Sankyo	juvenile idiopathic arthritis (*Prescrire International* n° 92)
papillomavirus 6,11,16,18 vaccine	**GARDASIL°** Sanofi Pasteur MSD	prevention of high-grade cervical dysplasia (*Prescrire International* n° 89)

Special mention: ***meningococcal B vaccine*** *strain 44/76* (MenBvac°) approved under exceptional circumstances by the French Health Ministry and manufactured by the Norwegian National Institute of Public Health (*la revue Prescrire* n° 288).

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2007 PACKAGING AWARDS

The Packaging Awards focus on the packaging quality of drugs evaluated during the previous year in the New Products section of our French edition (issue 279 to 290 for 2007).

Packaging awards

• **Codenfan° sirop Bouchara Recordati (codeine)**
For the excellent design of the packaging, which is well-adapted for paediatric use: the pharmaceutical formulation and drug concentration are adapted to children; the bottle is equipped with a safety cap and an oral spoon-shaped cylinder graduated in milligrams of codeine, making it easier to prepare and administer the precise dose; and the information provided in the patient leaflet has been improved (*la revue Prescrire* n° 287)

Prescrire's Packaging Awards are intended to draw patients' and healthcare professionals' attention to the fact that high-quality packaging is an important factor in safe and effective treatment. They also provide us with an opportunity to congratulate manufacturers that design patient-friendly packaging, and to encourage other manufacturers to improve their packaging. Poor quality packaging is awarded a yellow or red card, depending on the degree of risk it creates.

Throughout the year the editorial staff examines the packaging of all new drugs. They focus on the outer packaging (the box), the primary internal packaging (bottle, blister pack, tube, etc.), the patient information leaflet, and on any devices provided for administration, such as spoons, graduated oral syringes, syringes and needles for injection. The unit doses are also evaluated for convenience of use and patient safety (tablet divisibility, patch adhesiveness).

This systematic analysis is based on standardised forms. It focuses on drug identifiers (labelling, printing, colour coding), other items contributing to safe use (child-proof caps, dose identifiers), and items helping to provide information to patients (labels, package leaflets). The risk-benefit balance of the product is also taken into account, along with the categories of patients and caregivers most likely to use the drug (e.g. children) and the modes of administration (especially for self-medication).

A summary of the results of our 2007 packaging analyses can be found in this issue, page 82.

At the end of each year, the Packaging Awards are granted following a review of the year's analytical forms, in total independence and with no input from drug or packaging manufacturers (rules available from www.prescrire.org).

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Yellow cards

• **Dexafree° eye drops** Théa **(dexamethasone)**
For the lack of information provided on the labelling on the plastic ampoules and the absence of the international nonproprietary name (INN) and red line to show that this drug is on the list of toxic substances; as the same type of ampoule is used for other eye drops, the labelling should clearly identify this steroid (*la revue Prescrire* 290)

• **Euraxsepti° solution for local application** Novartis Santé Familiale **(chlorhexidine)**
The route of administration is not mentioned on labelling on the plastic ampoules, creating a risk that patients will confuse this antiseptic solution with eye drops for example, when it is in fact designed for cutaneous application (*la revue Prescrire* 287)

Red cards

• **Actifedduo LP rhinite allergique° tablets**, Pfizer Santé Grand Public **(cetirizine + pseudoephedrine)**
For the absence of the INNs on the tablets of a product, designed for self-medication and part of an umbrella brand (**a**), creating a risk of confusion with potentially serious consequences (*la revue Prescrire* 283)

• **Dextroref° Gé capsules**, Chemical Farma **(dextropropoxyphene + paracetamol)**
For the absence of the INN on the tablets of this generic, exposing patients to a risk of error and overdose in case of concurrent use of other products containing this analgesic combination, with potentially severe adverse effects (*la revue Prescrire* 279)

• **Strefen° pastilles to suck**, Reckitt Benckiser Healthcare **(flurbiprofen)**
These tablets look like children's sweets, when in fact they contain a nonsteroidal anti-inflammatory drug (NSAID), exposing patients to adverse effects; the patient leaflet fails to mention other marketed NSAIDs, thereby failing to protect patients against drug interactions, particularly during self-medication (*la revue Prescrire* 281)

• **Primperan enfants et nourrissons° oral drops**, Sanofi Aventis **(metoclopramide)**
For the lack of an accurate dosing device for this neuroleptic used to treat gastrointestinal disorders in young children, and for the lack of a child-proof cap, creating a risk of massive ingestion by children and a risk of neurological disorders (*la revue Prescrire* 288)

• **Toplexil sans sucre° oral solution**, Sanofi Aventis OTC **(oxomemazine)**
For the lack of a child-proof cap, even though this solution contains a sedative psychotropic and has an attractive caramel flavour, creating a risk of massive ingestion by children (*la revue Prescrire* 284)

• **Vaccine BCG SSI° powder + solvent for injectable suspension**, Sanofi Pasteur MSD **(BCG vaccine)**
For inadequate improvement in the packaging, that still contains 10 to 20 vaccine doses, and for the continued presence of a syringe with a graduation scale 10 or 20 times above the recommended dose, leading to a risk of overdose and adverse effects (*la revue Prescrire* 285)

• **Xylocaine° urethral gel**, AstraZeneca **(lidocaine)**
For keeping a prefilled syringe on the market which, if incorrectly opened, carries a risk of introducing plastic fragments into the urethra, potentially resulting in pain and bleeding (*la revue Prescrire* 288)

a- Umbrella brands comprise several products with different compositions but with brand names including a common stem. For example: Actifedduo° (pseudoephedrine + cetirizine) and Actifed jour et nuit° (tablets containing paracetamol + pseudoephedrine and others containing paracetamol + diphenhydramine).

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2007 INFORMATION AWARDS

The Information Awards focus on the quality of information provided to *Prescrire* by the companies whose products were assessed in the previous year's New Products sections of our French edition (issue 279 to 290 for 2007).

Prescrire's review articles dealing with new drugs and indications are based on a thorough literature search for all documents relating to the drug's pre-approval assessment, especially clinical trial reports.

In addition to textbooks and standard bibliographic databases, we search the websites of drug regulatory agencies, health economics institutions, health technology assessment agencies, and other institutions specialising in the relevant therapeutic field. We also search other independent journals belonging to the International Society of Drugs Bulletins (ISDB) and any independent institutions that have evaluated the drug in question.

Assessing drug company transparency. We also question the companies that market drugs in France, to ensure that we take into account all documents, including unpublished data, used to justify approval for marketing. The regulatory agency that approved the product, and/or the applicant, may also possess important unpublished data, including unpublished clinical trial reports.

Some regulatory agencies release most of these data into the public domain, through publication of their assessment reports. The French regulatory agency AFSSAPS, and EMEA, the European agency, are very slowly opening up their work to public scrutiny, especially with respect to postmarket follow-up data (see page 78 of this issue).

As with the other Prescrire Awards, a systematic and totally independent process is used to grant Information Awards. The rules are available on our website, at www.prescrire.org

Rewarding accountable companies. Some drug companies respond to our requests for information in a timely manner, providing us with the documents, including unpublished data, submitted in support of their application for marketing approval. These companies are mentioned on the Honours List opposite.

Honours list (in alphabetical order)

- **Oustanding:** Orphan Europe and Sanofi Pasteur MSD
- **Followed by:** Ageps-Établissement pharmaceutique des hôpitaux de Paris, Automedic, Baxter, BioAlliance, Biogaran, Biomarin, CSL Behring, DB Pharma, GlaxoSmithKline, Nordic, Nycomed and Solvay

Red cards for withholding information (in alphabetical order)

- Beaufour Ipsen, Chiesi, Daiichi Sankyo, Genévrier, Lundbeck, Menarini, Procter & Gamble, Sanofi Aventis and Shire

There are fewer generic manufacturers than in previous years, owing to our decision not to examine all new generics (1). However, we continue to contact these companies for information on the planned release dates of their generic drugs.

The companies rated as Outstanding provided us with exhaustive and detailed documentation without delay.

Encouraging companies to be more open. Other drug companies either fail to respond to our repeated requests for information, or grudgingly provide limited data that are already in the public domain. They tend to reply at the very last moment, so that their advertising campaigns can proceed unhindered before the relevant issue of the Journal goes to press. They may also omit the most relevant data, coming up with excuses like "the regulatory department is too busy", "the administrative services are too slow" or "the clinical data in question are confidential". Others withhold information as a form of retaliation because they didn't like the conclusions of one of our earlier product reviews.

Few drug companies persistently withhold information. For patients' sake, we hope that refusal of transparency or lack of respect for independence, in the interests of biased product promotion, do not constitute reasons for withholding information.

Company commitment to transparency and treatment choices. A drug company's commitment to transparency is the 'fifth dimension' to be taken into account when choosing a drug, after efficacy, safety, convenience and price. When two drugs are otherwise indistinguishable, then it is in patients' and healthcare professionals' best interests to select the product manufactured by a company that puts its cards on the table, and that does not try to hide information, including the limitations of their products.

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1- Prescrire Editorial Staff "Les copies du mois. Mieux faire face à l'avalanche de copies" *Rev Prescrire* 2007; **27** (280): 106.

Each article examining a new drug is accompanied by a symbol (one of four) and brief summary rating the transparency of the manufacturer for their response to our requests for information concerning their product (see this issue p. 60):

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