THE PRESCRIRE AWARDS FOR 2016

The three annual Prescrire Awards, for Drugs, Packaging and Information, are granted in total independence by the Prescrire Editorial Staff. These awards complement the annual review published at the beginning of each year in our French edition and the following May in *Prescrire International*. The rules governing the three Prescrire Awards are available online at english.prescrire.org.

2016 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 publish comparative systematic analyses of the data available on: drugs newly authorised in France and the EU, new therapeutic indications granted for existing drugs, and existing drugs marketed in a new form or with different packaging. The goal is to help the reader distinguish, among the plethora of new products, those worth adding to their list of useful therapies, those worth using instead of older products, and those to be avoided.

Our analyses are based on rigorous procedures that include a thorough literature search, critical review by a group of reviewers specific to each article, and various quality controls to verify in particular that the text is consistent with all the data available (see our website for further information: english.prescrire.org).

Total independence. The *Prescrire* Editorial Staff conduct these analyses free from any industry or institutional influence. Our independence is made possible by the fact that we are financed exclusively by our subscribers, carry no paid advertising in either the French or the English edition, and receive no grants or subsidies of any kind (see our annual financial report in each June issue of *Prescrire International*).

The *Prescrire* Drug Awards are compiled at the end of each year, based on the reviews published that year in our French edition, and taking into account any new data made available since the initial articles were published. These awards honour drugs that constitute a therapeutic advance, in that they offer better efficacy, less frequent or less severe adverse effects (for similar efficacy), or safer or easier administration.

Two drugs deemed "Noteworthy" in 2016. Two of the products featured in the New Products section of our French edition in 2016 earned a *Prescrire* Drug Award this year. None of the new products examined constituted a sufficient therapeutic advance to warrant a "Pilule d'Or" (Golden Pill) Award or even a place on the "Honours List".

"Pilule d'Or" not awarded for 2016

The two awards were for cancer drugs *Prescrire* deemed "Noteworthy". They have been shown to prolong survival by a few months on average, but with many serious adverse effects and a few that are sometimes fatal.

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.

2016	NOT AWARDED
2014 (Prescrire Int n° 157)	ORPHACOL° (*cholic acid*)
2007 (Prescrire Int n° 94)	CARBAGLU° (*carglumic acid*) (a second look)
2006 (Prescrire Int n° 88)	ORFADIN° (*nitisinone*)
1998 (Prescrire Int n° 40)	CRIXIVAN° (*indinavir*)
1996 (Prescrire Int n° 28)	DIGIDOT° (*digoxin-specific antibody*) (**a**)
1992 (Prescrire Int n° 4)	SURFEXO° (*pulmonary surfactant*) (**a**)
1989 (Rev Prescrire n° 92)	EPREX° (*epoetin alfa*) • MECTIZAN° (*ivermectin*)
1988 (Rev Prescrire n° 81)	LARIAM° (*mefloquine*) • RETROVIR° (*zidovudine*)
1987 (Rev Prescrire n° 71)	LUTRELEF° (*gonadorelin*) • DÉCAPEPTYL° (*triptorelin*)
1986 (Rev Prescrire n° 61)	ZOVIRAX° IV and tablets (*aciclovir*)
1983 (Rev Prescrire n° 31)	LOPRIL° (*captopril*)
1981 (Rev Prescrire n° 10)	VACCIN HEVAC B° (*hepatitis B vaccine*) (**a**)

Like this year no Golden Pill was awarded for 1982, 1984, 1985, 1990, 1991, from 1993 to 1995, for 1997, from 1999 to 2005, from 2008 to 2013, and for 2015.

a- No longer marketed in France.

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.

2016	No inclusions
2015 (Prescrire Int n° 162)	• Hemangiol° (*propranolol* oral solution)
2014 (Prescrire Int n° 157,154, 156)	• Glivec° (*imatinib*) • Malacef° (intravenous *artesunate*) • Sovaldi° (*sofosbuvir*)
2010 (Prescrire Int n° 114)	• Glivec° (*imatinib*)
2007 (Prescrire Int n° 98)	• Glivec° (*imatinib*) • Herceptin° (*trastuzumab*)
2006 (Prescrire Int n° 84)	• Egaten° (*triclabendazole*)
2005 (Prescrire Int n° 77)	• Varivax° (*varicella-zoster vaccine*)
2004 (Prescrire Int n° 76)	• Diacomit° (*stiripentol*) • Fuzeon° (*enfuvirtide*) • Morphine Aguettant° syrup (*morphine* oral solution) (1)
2003 (Prescrire Int n° 66,69,74)	• Carbaglu° (*carglumic acid)* • IVheBex° (*hepatitis B immunoglobulin*) • Meningitec° (*conjugate meningococcal C vaccine*)(1)
2002 (Prescrire Int n° 67,61)	• Replagal° (*agalsidase alfa*) (2) • Ceprotin° (1) - Protexel° (*human protein C*) • Stromectol° (*ivermectin*) (scabies)
2001 (Prescrire Int n° 53)	• Estérasine° (*C1 esterase inhibitor*) (1) • Trolovol° (*penicillamine*) (chelator)
2000 (Prescrire Int n° 50)	• Remicade° (*infliximab*)

Drugs were included on the Honours List every year between 1981 and 2007. No drugs were included for 2008, 2009, or 2011 to 2013. The full list of drugs included on the Honours List from 1981 to 2013 can be found in *Prescrire Int* n° 147 p. 79.

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 pp. 168-171.

Noteworthy

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

2016	• **OPDIVO° (*nivolumab*)** **Bristol-Myers Squibb** Metastatic or inoperable BRAF V600-negative melanoma (Prescrire Int n° 177) and metastatic or inoperable non-small cell lung cancer (Rev Prescrire n° 397)
	• **MEKINIST° (*trametinib*)** **Novartis** Metastatic or inoperable BRAF V600-positive melanoma, in combination with *dabrafenib* (Prescrire Int n° 177)

Nivolumab (Opdivo°) as monotherapy for some patients with melanoma or lung cancer. *Nivolumab* is a monoclonal antibody that stimulates T cell activity in particular, thereby activating the immune response to tumour cells.

In a trial in patients with metastatic or inoperable melanoma whose tumour was negative for the BRAF V600 mutation and who had not yet received treatment for this stage of the disease, *nivolumab* was far more effective than *dacarbazine*: the estimated proportion of patients alive after 1 year was about 70% with *nivolumab* versus about 40% with *dacarbazine*. Additional evaluation is required however, in particular because *dacarbazine*, used in Europe until the early 2010s, has not been shown in comparative trials to prolong survival. A direct comparison with *ipilimumab*, another immunostimulant, would more clearly establish the role of *nivolumab* in the treatment of these cancers.

In patients with metastatic or inoperable non-small cell lung cancer who had already received one line of platinum-containing chemotherapy, *nivolumab* prolonged median survival by about 3 months and increased the proportion of patients alive after 1 year by about 15% compared with *docetaxel*, with somewhat fewer serious adverse effects in two non-blinded randomised clinical trials, with consistent results.

Nivolumab can provoke a great variety of sometimes serious adverse effects, generally of immunological origin, in particular: rash, interstitial lung disease, elevated liver enzymes and hepatitis, thyroid disorder, neuropathy and encephalitis. As *nivolumab* is the first of a new drug class, its adverse effect profile is only partially known.

Trametinib (Mekinist°) combined with dabrafenib for some patients with melanoma. In patients with metastatic or inoperable BRAF V600-positive melanoma who had not yet been treated for this stage of the disease, the addition of the MEK inhibitor *trametinib* to first-line treatment with *dabrafenib*, an inhibitor of the defective BRAF protein, prolonged survival by about 7 months on average compared with BRAF inhibitor monotherapy in two trials with consistent results. The addition of *trametinib* increases the frequency of serious adverse effects, including heart failure, deep vein thrombosis, bleeding, neutropenia, and gastrointestinal perforation. *Trametinib* monotherapy has not been shown to constitute a therapeutic advance.

Few therapeutic advances again in 2016. Once again, 2016 provided no major therapeutic advances. The few advances in cancer therapy highlighted in this year's *Prescrire* Drug Awards are worth noting but rare. This reality is at odds with the hype surrounding the multitude of new products that appear on the market each year and the exorbitant prices charged by pharmaceutical companies for cancer drugs.

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