other national drug regulatory agencies are additional resources.

In France, some boxes contain bilingual package leaflets: French/English; French/Arabic. The pharmaceutical company that distributes the drug will sometimes provide a translation on request. ©Prescrire

Sources
1- Prescrire Editorial Staff “Packaging of pharmaceuticals: Still too many dangers but several encouraging initiatives” Prescrire Int 2007; 16 (89): 126.


Trabectedin and ovarian cancer (continued)

We would like to make the following remarks following publication of an article on trabectedin in la revue Prescrire (December 2010, n°326) and Prescrire International (April 2011 p.93).

In the column mentioning list I status, approval for hospital use is described as follows: “Unusually, on 8 November 2010, approval for hospital use was granted on the basis that a predefined care delivery process is followed: during the first three cycles, prescription and administration in a restricted list of hospitals (generally, one per region); then, for the following cycles, treatment may take place in other authorized cancer treatment centres close to the patient’s home.”

This restriction does not apply to Yondelis® combined with pegylated liposomal doxorubicin (Caelyx®), which is indicated for patients with platinum-sensitive recurrent ovarian cancer, but rather to patients with advanced-stage soft-tissue sarcomas, after failure of treatments based on anthracyclines and ifosfamide, or patients who are unable to receive these drugs (1).

In addition, concerning the restrictions in care delivery, which only concern patients with advanced-stage sarcomas, the list of centres is growing, resulting in better nationwide coverage (the number of centres increased from 25 to 38 by decree on 4 February 2011, modifying the original list).

The title of the article “Trabectedin and ovarian cancer (Yondelis®): no to statistical trickery” is wrongly associated with the results of clinical assessment of trabectedin in ovarian cancer, for the following reasons.

The study mentioned in the article is an open phase III randomised trial that led to marketing authorisation of trabectedin combined with pegylated liposomal doxorubicin in patients with platinum-sensitive recurrent ovarian cancer. This study was conducted in a population of 672 patients with recurrent ovarian cancer after failure of first-line platinum-based chemotherapy. A noteworthy proportion of patients with platinum-resistant disease were included (35% in the two treatment arms), in order to be representative of the population of patients with recurrent ovarian cancer. The aim of this study was to compare the efficacy and safety of trabectedin combined with pegylated liposomal doxorubicin to that of pegylated liposomal doxorubicin alone, in the population.

This study included central review of the treatment response by independent

France's AME: medical apartheid

In France, the AME (Aide médicale d’État, state medical aid) is intended to provide free healthcare to illegal immigrants who have been living in France continuously for more than 3 months and whose income is below the threshold that qualifies legal residents for “complementary universal healthcare coverage” (Couverture médicale universelle complémentaire, CMUC). In 2010, this threshold amounted to 634 euros per month for a single person (1).

In 2009 the AME system was used by 267 000 people and cost a total of 540 million (1). In 2010, the authorities asked the welfare agencies who have been living in France continuously for more than 3 months and taxpayers who have been living in France continuously for more than 3 months and cost a total of 540 million (1).

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