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.

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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 euros, a 13.3% increase over 2008. In 2010, the authorities asked the welfare services auditor (*Inspection générale des affaires sociales*, IGAS) and the financial comptroller (*Inspection générale des finances*) to analyse these costs and to suggest ways of controlling them (1).

Medically justified spending. On average, per-person healthcare consumption via the AME system was similar to that of the general population: it was 1741 euros in 2008, versus 2606 euros for users of the CMUC system and 1580 euros for persons with standard national health insurance (1).

Most AME users were men, of whom 80% were single. Their health was generally poorer than that of people of similar age who qualified for health insurance. In particular, they were more likely to have hepatitis C, cancer and diabetes. Hospital care accounted for the bulk of AME spending (1,2).

Administrative bias. The report states that the rise in AME healthcare spending was not due to an increase in the number of users or more frequent treatment, nor to abuse or fraud, but rather to more efficient billing of AME healthcare procedures by hospitals, and to dumping on the AME system of costs that were actually incumbent upon the standard health insurance or CMUC systems (1).

Harmful measure. Without waiting for the report to be published, and despite protests from several members of parliament and NGOs, the government's budget statement for 2011 included an "admission ticket" of 30 euros per year per adult AME user, and stated that all costly hospital care must receive prior administrative approval (3).

However, the report stressed that any attempt to make AME users "more responsible" by financial means would be ineffective and hinder access to treatment, resulting in major health risks not only for the patients concerned but also for the general population (1).

Until this unfortunate measure is repealed, patients and aid groups will need extra help on the ground.

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QUERIES AND COMMENTS

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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 condition 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 authorised 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 ▶▶

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