see also pages 190 and 202

Translated from *Rev Prescrire* June 2007; **27** (284): 404

Winners and losers

The approval of testosterone (Intrinsa°), a male hormone, to increase women's sexual satisfaction, is yet another example of poor decision-making by regulatory agencies, a gamble in which only the public stands to lose (see page 190 of this issue).

The results of clinical trials are hardly reassuring: no tangible evidence of effectiveness in terms of sexual dissatisfaction; limited evidence on adverse effects but some disturbing indications of possible increased risks of cancer. These are especially worrisome given the existing evidence on cancer risks in men. In granting approval regardless, regulatory agencies gave the product the 'benefit of the doubt'. Rather than refusing approval, they insisted on a 'risk management programme' lasting several years. By the time results begin to emerge (and in all likelihood they will confirm concerns that have already been voiced) the manufacturer will have made a handsome profit from sales generated through intense product promotion. No doubt the manufacturer will claim that it did nothing wrong; none of its activities contravened existing regulations. Regulatory agencies will say that they took appropriate precautions, and incautious prescribers will reassure themselves that they prescribed the product for an approved indication. Meanwhile, who stands to lose in this gamble? Only the patient, unnecessarily harmed by a product without tangible evidence of effectiveness.

This is not a pessimistic view, it is a realistic one. For example, see in this issue on page 193 the case of the contraceptive patch containing norelgestromin and ethinylestradiol (Evra°). After several years on the market, there is evidence - as predicted on the basis of pre-market data - of a higher risk of venous thromboembolism, as compared with commonly used combined oral contraceptives, without any improvement in efficacy.

In this game of bluff played by profit-hungry drug companies and weak regulatory agencies, women are the losers.

Attachment

Joint contribution to the public consultation on national marketing authorisation variations.