Drugs in 2017: a brief review

In 2017, as in previous years, few clinical advances were identified among the 92 new drugs analysed in our French edition. Increasingly early marketing authorisations and minimal evaluation result in patients being exposed to drugs with uncertain harm-benefit balances. Not to mention the exorbitant price of some drugs and the waste of collective resources.

Rev Prescrire 2018; 38 (412): 145-146

Thus drug evaluation becomes in part funded by health insurers, advertising for medicines is boundless, and patients are often exposed without knowing it to drugs with little or no data on efficacy, let alone on adverse effects. And, years later, it is often reported that post-authorisation studies have been used primarily to establish prescribing habits, not to answer outstanding questions (Prescrire Int n° 189 pp. 3 and 25).

Cancer drugs: gross illustration of regulatory failures. 28 out of 92 new medicines analysed in 2017 were used in cancer. Some of these marketing authorisations have been granted without comparative trials, for example: daratumab in monotherapy for multiple myeloma after failure of several treatment lines (Prescrire Int n° 188); nivolumab in Hodgkin lymphoma after failure of an autologous stem cell transplant, as well as brentuximab vedotin (Prescrire Int n° 191); crizotinib (Prescrire Int n° 404) and osimertinib (Prescrire Int n° 183) in certain lung cancers.

Of these 28 marketing authorisations for cancer drugs, 20 were granted on the basis of a single clinical trial, often of poor methodological quality, because not comparative, or with biases linked to the absence of blinding; or on the basis of laboratory or radiological outcomes that are not necessarily correlated with a longer survival or a better quality of life.

Some advances are noteworthy, however, such as pertuzumab (Prescrire Int n° 184) in metastatic breast cancer, nivolumab (Prescrire Int n° 185) in metastatic renal cell carcinoma, and eribulin (Prescrire Int n° 187) in inoperable or metastatic liposarcoma. Most other cancer drugs are poorly assessed, and many have an unfavourable harm-benefit balance, which should have prevented them from being approved.

In summary, in oncology, there are many commercialisations in a market made very attractive by its ease of access for companies, at exorbitant prices that are disconnected from therapeutic progress or research and development costs (see p. 107-109).

Marketing withdrawals too slow. In addition to the very lax requirements for granting marketing authorisation, there is also a great deal of immobility on the part of the agencies when it comes to withdrawing or suspending the marketing authorisation of medicines whose adverse effects are disproportionate to the expected benefits.

At the beginning of 2017, in France, a drinkable solution containing vitamin D (Uvestérol° D - Rev Prescrire n° 400 and n° 401) was withdrawn from the market by the French Health Products Agency.
The drugs were:
- enzalutamide in AR-positive metastatic prostate cancer (Prescrire Int n° 183);
- eribulin in inoperable refractory or relapsed liposarcoma (Prescrire Int n° 187);
- erlotinib in non small cell lung cancer (Prescrire Int n° 179);
- everolimus in non functioning neuroendocrine tumours (Rev Prescrire n° 405);
- fentanyl/ionsophoretic in pain (Rev Prescrire n° 409);
- guanfacine for attention deficit with hyperactivity (Prescrire Int n° 186);
- infliximab in Crohn's disease (Prescrire Int n° 184);
- ivacaftor + lumacaftor in cystic fibrosis (Prescrire Int n° 188);
- ivacaftor in cystic fibrosis (Prescrire Int n° 188);
- lilotristat in primary hyperparathyroidism (Prescrire Int n° 189);
- lumacaftor in cystic fibrosis (Prescrire Int n° 188);
- mepolizumab in severe eosinophilic asthma (Prescrire Int n° 184);
- paclitaxel in epithelial ovarian cancers (Prescrire Int n° 185);
- pembrolizumab in metastatic or inoperable lung cancers (Rev Prescrire n° 407);
- pertuzumab in metastatic or inoperable breast cancers (Rev Prescrire n° 407);
- palbociclib in inoperable or metastatic breast cancers (Rev Prescrire n° 410);
- pembrolizumab before breast cancer surgery (Rev Prescrire Int n° 184);
- ramucirumab in gastrin dependent gastroesophageal reflux disease (Rev Prescrire n° 408);
- ruxolitinib in primary myelofibrosis (Prescrire Int n° 184);
- selinexor in multiple myeloma (Prescrire Int n° 184);
- selumetinib in KRAS mutated colon cancer (Prescrire Int n° 184);
- selumetinib and trametinib in metastatic melanoma (Prescrire Int n° 184);
- sitagliptin in type 2 diabetes (Prescrire Int n° 189);
- talimustine in lymphoid malignancies (Prescrire Int n° 183);
- temsirolimus in epithelial ovarian cancers (Prescrire Int n° 185);
- teniposide in medulloblastoma (Prescrire Int n° 187);
- toسفلوزيروف + سيلفافيور in hepatitis C (Prescrire Int n° 192).

In short. Not enough regulation on the part of health authorities, increasingly accelerated marketing authorisations, minimal drug evaluation: health-care professionals have a central role to play in choosing drugs that have a demonstrated benefit and in limiting patients’ exposure to drugs that are poorly assessed, provide no tangible therapeutic value or are more dangerous than useful.

It is a question of resisting the massive overmedication of society, with its major consequences for victims of adverse effects or drug addiction. Overmedication which is also a waste of collective resources, amplified by the exorbitant cost of certain medicines (Prescrire Int n° 406).

Individually, one may feel helpless in the face of such a large and complex phenomenon, especially in the absence of collective and concerted responses. There are, however, important ways of resisting and acting with full awareness, starting with freeing oneself from the influence of interests that are not those of patients, and also by talking with patients about the limitations of the drug treatments they are offered or may have heard about.