Profit and loss

Telithromycin was authorised in the European Union in 2001 and first marketed in France in 2002 under the brand name Ketek°. The company's objective for this antibiotic at the time was to achieve a leading position among the treatments available for respiratory infections. The promotion worked like a charm and sales soared, with over 1.3 million boxes reimbursed by France's national health insurance system in 2004.

Yet even back in 2002, despite spurious claims of a novel mechanism, *telithromycin* was the ninth macrolide on the French market (*Prescrire Int* n° 63, p. 8-11), was no more effective than the existing eight drugs in its class, but already had a disturbing adverse effect profile. In addition to the adverse effects it shared with other macrolides, those specific to *telithromycin* were detectable even in the initial trials and were confirmed over time: accommodation disorders, syncope, QT prolongation, as well as severe, and sometimes fatal, liver injury.

The next phase in the history of this drug was sadly typical (see for example France's recent delisting of drugs for Alzheimer's disease, at english.prescrire.org). In 2007, the European Medicines Agency (EMA) reviewed the drug's harm-benefit balance. It acknowledged that *telithromycin* exposes patients to a greater risk of serious adverse effects than other macrolide antibiotics. It issued a warning to this effect, but took no measures to withdraw it from the European market. Then little transpired until 2018, when the company announced it was withdrawing the drug from the market for economic reasons (see p. 210). The time for claiming that *telithromycin* marked "a new chapter in antibiotic therapy" was past. Profits had been generated, now was the time to forget. To forget that over a 16-year period, over 7 million boxes had been sold in France alone and patients had been endangered.

It is high time that drug regulatory agencies mustered the strength to compel pharmaceutical companies to do their job rather than raking in profits at patients' expense.

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EDITORIAL