

Negligence

According to a World Health Organization (WHO) news release from 27 October 2022, almost 11 million people worldwide fell ill with tuberculosis in 2021, including about a million children. More than 1.5 million people died from tuberculosis. Tuberculosis was the second leading cause of death from infectious diseases that year, after covid-19, killing more people than Aids. Most people with tuberculosis live in “poor” regions or neighbourhoods. Tuberculosis is even more serious in its multidrug-resistant forms, which are resistant to the standard antibiotics that have helped prevent numerous tuberculosis-related deaths.

It is also one of the world’s so-called neglected diseases, i.e. a disease for which insufficient efforts are put into the research and development of health products and technologies for its prevention and treatment. For example, in 2017, only \$3.6 billion were invested in research and development for all of the neglected diseases combined. In contrast, the pharmaceutical industry’s total global expenditure on research and development stood at about \$150 billion (see “Diseases still being neglected” *Prescrire Int* n° 209).

If society is to tackle tuberculosis and reduce the number of deaths it causes, antibiotics that are more useful than dangerous are needed. But genuine therapeutic advances in this field are lacking as of early 2023. *Delamanid* (Delyba®) was initially authorised for use in adults, yet no robust evidence of bacteriological efficacy or reduced mortality was demonstrated (see “Delamanid and multidrug-resistant pulmonary tuberculosis” *Prescrire Int* n° 181). It is now also authorised for use in children and adolescents, on the basis of yet another sub-standard evaluation (see p. 61 of this issue). The basic principles for conducting a compelling evaluation, one capable of demonstrating that a drug represents a therapeutic advance for patients, were once again neglected. Neglected by the pharmaceutical company which failed to conduct relevant clinical trials. Neglected by the drug regulatory authorities which authorised *delamanid* without robust evidence of its efficacy based on clinical endpoints, despite the serious adverse effects it can provoke in the children concerned.

In January 2020, at a time when only three cases of covid-19 had been identified in France, some claimed that this disease was confined to a single distant country, namely China. Will it take a global epidemic of multidrug-resistant tuberculosis to come knocking on the door of “rich” countries before we stop neglecting the patients dying of this disease, wherever they might live?

Prescrire