A two-step approach

Healthcare professionals sometimes need to work at top speed, to deal with an emergency. In these situations, speed is as important as organisational efficiency and competence. It takes far more time to conduct medical research or to evaluate a health product or practice than to administer urgent health care.

The trend in recent years towards shortening drug evaluation times, on the grounds that patients urgently need access to new treatments, has intensified with the covid-19 pandemic, revealing a multitude of motives unrelated to patient care. For example, the Russian vaccine, including its name Sputnik V, appears to be a means for the president to promote his country on the international stage. Meanwhile, the then-president of the United States repeatedly urged the national drug regulatory agency, the FDA, to urgently approve various treatments for covid-19, without taking the evaluation data into account, motivated in large part, it would appear, by the approaching elections.

The pharmaceutical company Gilead acted swiftly to become the first company to obtain marketing authorisation for an antiviral drug for covid-19, remdesivir (Veklury°). The European Medicines Agency (EMA) hastily recommended granting marketing authorisation for this drug, based on very limited clinical data, after the FDA had authorised its emergency use.

On 13 July 2020, a few days after remdesivir received approval in Europe, Prescrire published a concise analysis of the clinical evaluation data available on the drug at the time, via “News Update” items on its French and English websites and its French mobile app, in order to give healthcare professionals immediate access to key information, helping them to see just how little this drug had been shown to offer in terms of outcomes that are tangible to patients. The same information channels were used to inform healthcare professionals, on several occasions from March 2020 onwards, that hydroxychloroquine, either alone or in combination with other drugs, had no proven efficacy against either mild or severe covid-19 (News Update 24 July 2020). Prescrire also informed health professionals that dexamethasone is beneficial in certain patients (News Update 24 June 2020), and which patients might benefit from anticoagulation (News Update 24 September 2020).

At the same time, Prescrire was also conducting a thorough and detailed analysis of the evaluation data on remdesivir, following our usual rigorous methodology (see “Remdesivir and covid-19”, p. 14 of this issue).

Prescrire is continuing to fulfil its mission via this two-step approach. Rapidly sharing key information with healthcare professionals, distinguishing fact from hypothesis and opinion. Then helping our readers to make rational choices, based on documented evidence rather than wishful thinking. Taking care not to confuse urgent action with undue haste.