Prescrire International Editorial

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Mythologising

In the world of pharmaceutical companies and drug regulatory agencies, people often talk about *"a drug's life cycle"*.

They refer to its *"international birth date"* and the *"family"* it belongs to, they attribute *"paternity"* to a particular inventor (although the drug is sometimes an *"orphan"*…), and they follow its "*development*" intently.

They are proud when *"it has demonstrated its efficacy*". They are thrilled when *"it obtains"* marketing authorisation (MA), as if this were a qualification bestowed by a sympathetic or unsupportive panel of examiners. As time goes by, the drug may be suspected of being *"responsible"* for a particular adverse effect, so studies are requested, again and again, to make sure that an innocent drug is not wrongfully blamed. And finally they mourn its *"death"*. The poor drug, once so *"promising"*, becomes another victim of a heartless, merciless pharmacovigilance system...

It's touching, even poetic.

But above all, it is dangerous mythologising.

Drugs are inanimate objects; they don't live or die. It is scientists who demonstrate efficacy — or inefficacy — against a particular disease, by designing and conducting rigorous clinical trials, not the drug which is simply being studied. It is pharmaceutical company executives who request and obtain marketing authorisation, not the mass-produced drug they have manufactured. It is patients who benefit from a drug's efficacy or who are the victims of its harmful effects, not the drug, which is simply a substance that humans have manipulated more or less successfully. It is pharmaceutical industry decision-makers, drug regulatory agency directors, and users who are (jointly) responsible for any beneficial or damaging effects, and in some cases liable to prosecution, not the drug; the drug is simply the means to achieve these effects, and it cannot be considered either innocent or guilty. There is no injustice in withdrawing a drug from the market if it has more harms than benefits, without waiting for exhaustive proof collected at the expense of the patients left exposed to its dangers.

Personification, this tendency to anthropomorphise a drug, is dangerous for several reasons. In market regulation, it shifts the focus away from the persons truly responsible. When investigating a causal link between a drug and a health problem, whether it is a matter of pharmacovigilance or victim compensation, this anthropomorphisation encourages undue leniency towards the drug. And insidiously, it diverts attention away from the real priority: patients' interests.

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