Translated from *Rev Prescrire* December 2007; 27 (290): 884

Hypocrisy

It has long been established that maintenance treatment for asthma, when indicated, should be based on the lowest effective dose of an inhaled corticosteroid, carefully tailored to the individual patient. Asthma attacks should be treated, without delay, with a short-acting beta-2 agonist (see page 57 of this issue).

AstraZeneca recently obtained approval for on-demand use of a product combining budesonide and formoterol (Symbicort°). This use of a steroid plus a long-acting beta-2 agonist to treat asthma attacks exposes patients to an added risk of adverse effects with no tangible gain in efficacy. Above all, it is in total contradiction with the information normally provided to patients to help them better manage their asthma.

How could the drug regulatory agencies even contemplate approving such a step in the wrong direction?

An application for the same changes to the approved product indications was rejected, with good reason, in 2004. And, even now, the 'therapeutic indications' section of the SPC does not mention the treatment of asthma attacks. Yet in late 2006 regulatory agencies caved in to the company's demands and agreed to include mention of on-demand use in the 'posology' section.

This hypocritical compromise was just what the firm needed to launch an aggressive advertising campaign. The damage to asthma patients' health that is likely to result from this decision will be quantified later, through a 'risk management plan'. Let's at least hope it is well managed.

As usual, patients and caregivers will be the first victims of this hypocrisy. The European authorities have once again undermined their credibility by putting a drug company's financial interests before the health and safety of the citizens they are supposed to protect.

Attachment

New European pharmacovigilance legislation: getting it right

A joint response by HAI, ISDB and Medicines in Europe Forum to the European Commission's public consultation on legislative proposals for pharmacovigilance.