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EDITOR'S CHOICE

INDIA EDITOR'S CHOICE

Flouting evidence in a rush to the market: do we know enough about the drugs we prescribe?

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The Indian health ministry's decision to ban the diabetes drug pioglitazone has come as a huge surprise. With nearly three million patients currently on this drug, this move is likely to have far-reaching implications for their care (doi:10.1136/bmj.f4366). Doctors have voiced concerns that the ban would restrict prescribing choices for diabetes patients, and may even necessitate a quicker transition to insulin injections. Given the need to take these drugs for the long term, this is often a difficult and sometimes an impractical choice for patients. Patients might also need to be shifted to other classes of oral hypoglycaemic agents, potentially increasing the cost of treatment.

A boxed warning, as has been done in the United States for pioglitazone, has been suggested as an alternative to a complete ban. However, given the Indian practice context, it is debatable how many patients, pharmacists, or doctors would heed these warnings. Although the health ministry has cited an increased risk of bladder cancer as the reason for the ban, an economic angle is also suspected with a consequent shift to the production and sale of insulin and newer classes of diabetes drugs.

What emerges most clearly amid these ambiguities is a failure of the government in the manner of imposing this ban. A consultative due diligence should have been conducted by the ministry, to consider hard evidence and balance the risks, benefits, and realities of Indian clinical practice. And if this has been done, the details of the process and views of the different stakeholders that led to the decision should have been made public.

Even as we wait for the clouds to clear on this issue, Deborah Cohen, in a scrupulous investigation, shows that safety concerns for incretin mimetics such as exenatide, sitagliptin, and liraglutide, touted as the "darlings of diabetes treatment," may have been downplayed. In an exposé that is startling and upsetting, the report illustrates the disregard and selective reporting of evidence that these drugs might lead to an increased risk of pancreatic cancer. Critical safety studies on these drugs were not conducted by companies, nor did regulators request these. So, doctors and patients may not have been adequately informed; as academics point out in the linked feature (doi:10.1136/bmj.f3680), "The story is familiar. A new class of anti-diabetic agents is rushed to market and widely promoted in the absence of any evidence of long-term beneficial outcomes. Evidence of harm accumulates, but is vigorously discounted."

Further, access to raw data that could clearly show the magnitude of safety concerns is restricted. In our recent Head to Head debate, Ben Goldacre emphasises that it's not enough for regulators alone to see all the information on clinical trials. This possibly even goes against the very grain of science to allow independent scrutiny of the methods and results of an experiment (doi:10.1136/bmj.f1880). In a move to foster greater transparency, the new *BMJ* policy requires authors of drugs and devices trials to commit to making the relevant anonymised patient level data available on reasonable request (doi:10.1136/bmj.e7888). Sharing of patient data may not be without challenges however. As John Castellani suggests, placing individual patient data in the public domain may "threaten patient privacy and jeopardize their willingness to participate in clinical trials, which would delay the availability of new therapies." (doi:10.1136/bmj.f1881)

What do you think: Are clinical trial data shared sufficiently today? Do cast your vote in the latest *BMJ* poll.

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