

# The Independent

## Check on benzodiazepine-use must be done, say MPs

By Nina Lakhani

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The safety of tranquillising drugs prescribed to millions of people over the past 50 years must be urgently investigated, MPs and peers will demand this week.

A group of cross-party parliamentarians want publicly funded health bodies to be forced to carry out research into the dangers of benzodiazepines which they say have destroyed the lives of hundreds of thousands of people.

Their demand comes as the Medicines and Healthcare products Regulatory Agency (MHRA), the drug safety watchdog, admitted issuing 26 new licences for a powerful tranquilliser, Lorazepam, despite the fact it no longer holds any safety information about the drug.

Lorazepam, manufactured under the name Ativan by John Wyeth since 1972, is 10 times stronger than Valium, the most common tranquilliser drug, and many patients find it extremely hard to withdraw from it.

The MHRA has issued generic licences for the manufacture and distribution of the drug under a European directive which allows it to "bridge back" to the safety dossier and clinical trial evidence provided by the original manufacturers in their original licence application. John Wyeth voluntarily cancelled its licence for "commercial reasons" in 2008.

However, it has now admitted that it "no longer holds" the safety information because, after 15 years, "files are destroyed unless there is a legal, regulatory or business need to keep them, or they are considered to be of lasting historic interest". No one knows when or who reviewed the safety information last.

GPs issued more than 20 million prescriptions for benzodiazepines and similar Z-drugs – a group of nonbenzodiazepine drugs with effects similar to benzodiazepines – last year, including nearly one million prescriptions for Lorazepam. Around 1.5 million people are addicted to these drugs in the UK after being prescribed them for stress, anxiety, insomnia and muscle spasms.

MPs from across the country are fighting to secure help for many of these long-term users who cannot stop and display symptoms consistent with brain damage, sometimes years after they have stopped taking the drugs. Currently, the only NHS-funded withdrawal clinic is in Oldham.

Jim Dobbin, chair of the All-Party Parliamentary Group for Involuntary Tranquilliser Addiction, last night said the MHRA's policy of destroying drug safety information was

"absolutely frightening" and "irresponsible". He promised to raise the issue with the Health minister Anne Milton on Wednesday. The regulator has issued 5,200 product licences for 400 different drugs under the same EU directive since 2003.

Last month, The Independent on Sunday revealed that the government-funded Medical Research Council was warned nearly 30 years ago that benzodiazepines could cause brain damage in some people, similar to the effects of long-term alcohol abuse. Jim Dobbin wrote to Sir John Savill, the MRC chairman, more than a month ago asking him to explain why no further research has been carried out. He is still waiting for answers.

Meanwhile, lawyers are now examining those secret documents in order to determine what legal action could be taken against the MRC, which spent £704m of public money on research in 2008/09.

Mr Dobbin said: "The Government needs to get every one of these organisations into the same room so that they can stop blaming each other, stop passing the buck, and start listening to the victims. The cost to the individual and their families is huge; the cost to the taxpayer is horrendous. We want the Government to order a proper review into these drugs."

The Department of Health is currently conducting a review, but its narrow scope and delays have attracted widespread criticism from campaigners, victims, MPs and the Lords. Mr Dobbin is to meet with the Department of Work and Pensions Secretary, Iain Duncan Smith, in order to discuss the financial benefits of investing in support for addicts since so many are unable to function, never mind work.

Eric Ollerenshaw, Tory MP for Lancaster and Fleetwood since May, has asked a series of questions in Parliament about the safety of benzodiazepines after meeting a long-term addict, now a constituent, during his election campaign.

Mr Ollerenshaw, a former teacher, last night said: "I came into this completely objectively, but the more I have delved into it, the odder the situation appears. I know all drugs have side-effects, but these are ruining people's lives. There needs to be much more cross-checking and analysis between the public health organisations, who I had assumed would already be sitting around the same table to make sure drugs were safe. In my naivety, I thought the priority would be people's health. But if the priority is, in fact, a fear of litigation, then we have come to a pretty pass."