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Benfluorex: negative data in France, but still on the market

● **Neuropsychiatric disorders, pulmonary hypertension and heart valve damage.**

In 2007 the French Regional Pharmacovigilance Centre in Besançon re-examined French pharmacovigilance data on neuropsychiatric disorders and pulmonary hypertension linked to *benfluorex* (1).

In addition to the 39 cases of neuropsychiatric adverse effects notified up to November 2005, the authors found 4 new cases: one case of depression, one case of agitation and two cases of delirium (1,2).

They also found 3 new cases of pulmonary hypertension, in addition to the 17 cases notified up to November 2005. These cases involved three overweight women aged 50 to 58 years who had taken *benfluorex* for respectively 3 years, 3 months, and 10 years. There was no evidence that any of the women used another amphetamine appetite suppressant.

A case of cardiac valve damage was reported to another French pharmacovigilance centre. A 48-year-old woman developed severe mitral regurgitation and tricuspid regurgitation necessitating valve replacement surgery (3). No other potential cause was identified.

The French National Pharmacovigilance Committee considered that the risk-benefit balance of *benfluorex* was undermined by the lack of efficacy in treating hypertriglyceridaemia; at best modest efficacy in diabetes (with reservations concerning the quality of the main trial in this indication); formation of *fenfluramine* derivatives during *benfluorex* metabolism; reports of cases of pulmonary hypertension and valve disease similar to those that led to the market withdrawal of *fenfluramine* appetite suppressants; neuropsychiatric adverse effects; and the fact that *benfluorex* is used almost exclusively in France (88% of global sales).

Yet, while the experts dither, *benfluorex* continues to be sold and patients remain exposed to an unjustified risk of adverse effects.

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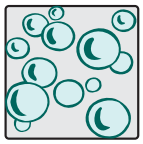

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BCG SSI°: adverse effects still reported

● **Mainly severe local reactions.**

In 2008, the Irish Medicines Board released a review of the adverse effects reported with the BCG SSI° tuberculosis vaccine (1).

This vaccine was first licensed in Ireland in 2001 and was the only BCG vaccine on the market in 2002. A marked increase in the number of adverse reaction reports was observed between 2002 and 2004, with nearly 100 cases reported in 2004.

After healthcare professionals were informed of these adverse effects, the number of reports fell noticeably in 2005. Nevertheless 36 cases were reported in 2007, consisting of severe local reactions including abscess formation, lymphadenopathy and/or secondary infections.

Some cases required treatment with antibiotics or surgical drainage and excision.

In the first half of 2007, 297 adverse reactions to BCG SSI° were reported in France, including 141 abscesses. 16% of the abscesses required hospitalisation and 26% surgery. There was one fatal case of generalised infection in a neonate with severe immune deficiency (2).

Problems persist and improvements in the packaging of the BCG SSI° vaccine are still needed (3).

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Translated from ***Rev Prescrire*** **September 2008; 28 (299): 664**

Exenatide: renal failure

● **Risk-benefit balance becoming uncertain.**

In May 2008, at the express request of *Prescrire,* The European Medicines Agency (EMEA) released a list of the renal adverse effects of *exenatide*, a blood glucose lowering agent for type 2 diabetes (1).

The EMEA was aware of 86 reports of renal fallure or increase in blood creatinine levels between October 2006 and March 2007. 10 patients underwent haemodialysis. 47 of these patients were concomitantly receiving another drug with renal adverse effects, including diuretics, angiotensin converting enzyme inhibitors (ACE inhibitors) or nonsteroidal anti-inflammatory drugs (NSAIDs). 44 patients had gastrointestinal disturbances that could have led to dehydration or hypovolaemia. In total, 65 patients exhibited one or more factors predisposing to renal impairment (1).

The outcome was known to 47 of these patients, with renal disorders improving 39 times, usually after withdrawal of *exenatide*. Tubular necrosis was shown in 5 patients.

The list of *exenatide's* worrying adverse effects is growing and its value becoming increasingly slight (2,3).

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