

Australia a laboratory for OTC switches

The future of self-care was on the agenda at this year's combined meeting of the AESGP and the WSMI. **Michael Thompson** reports

Australia is an interesting laboratory for exploring the potential of medicines in over-the-counter environments, according to Juliet Seifert, executive director of the Australian Self-Medication Industry.

Speaking at the combined annual meeting of the Association of the European Self-Medication Industry and general assembly of the World Self-Medication Industry in Geneva last week, Ms Seifert said that Xenical (orlistat) had been launched as an OTC medicine in Australia only four years after its launch as a prescription medicine.

Ms Seifert said that people taking Xenical — which became available from pharmacies in May 2004 — were able to lose almost twice as much weight during weight loss programmes as those taking placebo.

Xenical had been placed in Australia's "pharmacist only" category for medicines which could only be sold with appropriate advice and counselling and for which specific approval would be required for any planned advertising.



Juliet Seifert: Xenical became an OTC medicine after only four years

Roche had applied for the reclassification three times before being successful. The first application, in June 2002, failed because of concerns over the weight of responsibility to be placed on pharmacists for counselling and

worries about promotional weight loss claims that might be made. A second application, in February 2003, also failed. The third, successful application was made in October 2003, but no brand advertising was approved — only generic weight loss advertisements were allowed, which directed people to pharmacies for advice.

Xenical was suitable for OTC switching, Ms Seifert said, because pharmacists could easily diagnose obesity, orlistat had a high safety and tolerability profile, interactions were minimal, close monitoring of patients was not required and its adverse effects militated against abuse. Also, the incidence of serious side effects was the same as for placebo.

The OTC availability of Xenical led to a near doubling of the number of people who sought weight loss advice from pharmacies from 29 per cent to 54 per cent. Since, May 2004, 200,000 packs of OTC Xenical had been sold and an estimated 210,000kg of excess weight lost.

Pace of UK switching is accelerating

The accelerating pace of over-the-counter switching in the UK was outlined by June Raine, director of the Medicines and Healthcare products Regulatory Agency's post-licensing division.

The key to moving products from prescription control to OTC availability lay in laws that facilitated the change coupled with high level support for switching, Dr Raine explained.

This was proved by the fact that only six ingredients had been switched across the EU from 2000–2004. But in the UK 30 switches had taken place in the past three years, compared with 15 in the preceding 10.

Dr Raine told the meeting that consultations on plans to make products to treat migraine and cystitis available over-the-counter would be launched in the UK in the next few months. Potential future switches included products for urinary incontinence and appetite suppressants.

Health professionals are not enough

Health professionals cannot meet the world's demand for care for chronic diseases, the meeting heard.

JoAnne Epping Jordan, World Health Organization co-ordinator of health care for chronic conditions, said that health professionals needed to be able to equip the real providers of primary care — patients themselves — to manage their own conditions. Patients needed to be able to recognise changes in their own diseases and adjust their

care accordingly. They had to be trained to find and use available health care resources, interact effectively with health care providers and to manage their conditions on a day-to-day basis.

To this end, evolution in the basic training of all health professions was needed. Five new core competencies — patient-centred care, partnering, quality improvement, information and communication technology, and public health — were essential.

A new EU approach towards self-medication

The EU approach to self-medication was evolving from a mechanistic approach of setting criteria that products must meet in order to be freely available to one of official recognition that self-medication has a role to play in promoting public health.

Key factors contributing to this change included recognition that self-medication could reduce the burden placed on public health systems in terms of cost and pressure on health professionals, coupled with demands from patients for a greater say in their own treatment, said Georgette Lalis, director of consumer affairs in the European Commission directorate general of enterprise and industry.

Mrs Lalis took the opportunity presented by the meeting to announce a new EU strat-

egy for the pharmaceutical sector intended to restore Europe's place as the world's pharmacy. Part of this strategy was aimed at increasing competitiveness on pricing.

"We see no health or public benefit reason for price controls," Mrs Lalis said. "Most states don't have them."

Other elements of the strategy sought to promote innovation, particularly by helping smaller companies develop biotechnology, and to improve patient information through a public-private partnership.

Mrs Lalis expected substantial progress to be made within two to three years. She hoped that the timescale would be shorter where information for patients was concerned, but feared that progress on pricing would take longer.

Details

The combined annual meeting of the **Association of the European Self-Medication Industry** and general assembly of the **World Self-Medication Industry** took place in Geneva, Switzerland, from 1 to 3 June. Michael Thompson attended the conference courtesy of the Proprietary Association of Great Britain