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EDITORIAL

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OVER ACTIVE BLADDER (OAB) IN WOMEN – THE NEWEST OTC INDICATION

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On the 25th of January this year, the Food and Drug Administration announced the approval of Oxytrol® (oxybutinin patch applied every 4 days, delivering 3.9mg oxybutinin per day) as a non-prescription medicine for the treatment of overactive bladder in women over the age of 18 years[1]. This announcement ended a fallow period for switches in the United States, and many will hope it heralds a new era of innovation, in which more indications are brought into the US self-care arena.

Whenever a groundbreaking switch happens in a major jurisdiction, it is natural to ask when the benefits will be available to consumers in other parts of the world. There is no doubting the unmet clinical need in the case of overactive bladder in women. The condition, characterised by an urgent need to pass urine and sometimes leading to urinary incontinence, is common in women. A population based prevalence study[2] in 6 European countries reported an18% prevalence in women over the age of 40 years which rose further with increasing age. However, even in young women (aged 20-45 years) the prevalence of urge incontinence in a Netherlands population was 15% and led to a major impact on quality of life for sufferers[3]. The economic costs of the condition are considerable: direct annual costs to 5 European healthcare systems (Germany, Italy, Spain, Sweden and the UK) are estimated to rise to €5.2 billion by 2020[4].

In an opinion piece published in *SelfCare* in 2011[5], Dr Julian Spinks, a UK General Practitioner with a specialist interest in urology made the following observation about urinary incontinence: '*The challenge we face is how to both help existing patients and to reach out to the many who are not receiving active treatment. As health services are unlikely to be able to do this alone, self-care, supported by trained pharmacists, could, and should, become an important method for tackling this distressing condition. Widening the range of settings where help is available for those with urinary incontinence may also tackle some of the reticence to talk to doctors about the condition. Importantly, it may also start to de-stigmatise the problem.*' So if the need is great and the part self-care could play is clear – when can we expect OAB drugs to be switched to OTC in Europe and elsewhere?

In Europe, OAB in women has been talked about as an OTC indication for many years. In 2001 the indication was one of 2 case studies (cardiovascular risk was the other) in an Association of the European Self-Medication Industry (AESGP) report on new indications, sponsored by the European Commission. There are many reasons why new switches do not happen, but foremost

among these must be the lack of a committed sponsor. The commercial history of recent switches in Europe is not inspiring, and the enthusiasm of companies to embark on reclassification must also be tempered by the uncertainty that now prevails in the European regulatory environment.

Many newer medicines that have accumulated sufficient marketed experience to allow their consideration for re-classification will have been approved by the centralised system in Europe. This means that they must also be considered for reclassification by the same route. At this point US colleagues in sponsor companies often become excited – surely simultaneous approval in all of the EU member states must be a good thing? But all EU member states do not feel the same way about the role of non-prescription medicines, or about the ability of pharmacists to contribute to their management, or even about how such medicines should be labelled compared to their prescription entities. Seeking agreement on reclassification of a drug for an entirely new indication is a daunting prospect. There is also a concern that dedicated resources with expertise in the specialist evaluation of medicines for self-care are not sufficiently available in the European Medicines Agency (EMA). Uncertainty leads to inertia and there is an understandable fear that Europe will fall behind the rest of the world in the re-classification of newer medicines for breakthrough self-care indications.

In the US, a non-prescription medicine may be purchased without the involvement of a pharmacist or any other healthcare professional. It would be curious if more new indications for self-care start to appear first in the US, but not in jurisdictions where a more supervised environment operates. Consumers and their needs are not greatly different in the developed countries of the world and if Europe starts to lag behind the US in providing new opportunities for responsible self-care, then we should ask what is going wrong. One swallow does not make a summer, and perhaps a switch for OAB will soon happen in Europe. But the appearance of more new indications exclusive to the US OTC market would be a serious challenge to the European regulatory system.

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