



Sativex licensed

In June 2010 the UK Medicines and Healthcare products Regulatory Agency (MHRA) licensed Sativex for use as an add-on treatment for MS related spasticity when people have shown inadequate response to other symptomatic treatments or found their side effects intolerable.

[For more on Sativex, see page 10](#)

Tysabri labelling information updated

The labelling of natalizumab (Tysabri) has been amended to reflect the increased risk of a potentially fatal infection after two years of treatment.

Tysabri is licensed for people who are experiencing severe relapsing remitting MS with several relapses a year. Although very effective at reducing relapse rates, it is associated with a rare but potentially fatal brain infection called PML. The risk of PML appears to increase with duration of treatment, particularly after two years. The patient information leaflet has now been revised to include information about the signs of PML, which are similar to some MS symptoms. The new information stresses the importance of contacting health professionals if people experience new symptoms.

Male continence problems guidelines published

NICE has issued new guidelines on the treatment of bladder related symptoms in men. Around a quarter of men over 40 have continence problems - and amongst men with MS the proportion is much higher.

The guidelines cover assessment and treatment along with recognition of the need to provide appropriate information and emotional support for symptoms that can have a profound impact on an individual's independence and self esteem.

National Institute for Health and Clinical Excellence.
Lower urinary tract symptoms: The management of lower urinary tract symptoms in men. CG97
London; NICE: 2010.

Risk-sharing Scheme criticism ignores benefits to people with MS

Articles in the BMJ in June branded the MS Risk-sharing Scheme "a costly failure" and called for it to be discontinued and the money spent elsewhere in the NHS.

The Scheme was set up by the Department of Health in 2002 following the decision by NICE that the disease modifying drugs - beta interferon and glatiramer acetate - were not cost effective for use by the NHS. The Scheme involves a ten year study of the drugs, with the price being adjusted if they prove less effective than expected.

In an accompanying editorial, Professor Neil Scolding acknowledged flaws but pointed out that the Scheme has spawned an extremely successful infrastructure of specialist MS care in the UK and that the drugs prescribed will have prevented thousands of relapses.

Professor Richard Lilford, the chair of the Scheme's Scientific Advisory Group, strongly rejected the suggestion that any advice given was based on anything other than scientific rigour. He also challenged the claims that decisions should be based on data after only two years. This is an important point as some press reports incorrectly took criticism of the Scheme to mean there are doubts about the clinical efficacy of the drugs.

Prior to the Scheme, access was beset with problems of postcode prescribing and without it many people with MS would be denied treatment. Since its introduction, more than 14,000 people have been prescribed the drugs. Additionally, support for the Scheme has seen the development of multidisciplinary MS centres and a doubling in the number of MS specialist nurses - improvements that have benefits for all people with MS.

McCabe C, et al.
Continuing the multiple sclerosis risk sharing scheme is unjustified.
BMJ 2010;340:c1786.

Rafferty J.
Multiple sclerosis risk sharing scheme: a costly failure.
BMJ 2010;340:c1672.

Scolding N.
The multiple sclerosis risk sharing scheme.
BMJ 2010 340: c2882.

Lilford RJ.
Risk Sharing Scheme could not yield valid data after only two years follow up. BMJ [rapid response on website]. 4 June 2010.
Available from http://www.bmj.com/cgi/eletters/340/jun03_1/c1672