

## Merck Serono to Appeal CHMP Opinion on Cladribine Tablets in MS

Merck Serono has notified the European Medicines Agency (EMA) of its intention to request a re-examination of the opinion issued by the Committee for Medicinal Products for Human Use (CHMP) in September regarding Cladribine Tablets as a treatment for relapsing-remitting multiple sclerosis (MS).

"We are committed to the potential of Cladribine Tablets to meet an unmet medical need and to make this treatment option available to patients who could benefit from it," said Elmar Schnee, President of Merck Serono. "We will continue working closely with the CHMP to address the committee's concerns and pursue a way forward."

In accordance with European regulations, applicants may appeal a CHMP opinion provided they notify the EMA in writing of their intention to appeal within 15 days of receipt of the opinion. The applicant must provide to the agency with detailed

grounds for a re-examination of the opinion within 60 days after receipt of the opinion.

### Cladribine Approved in Australia

On 3rd September, The Australian Therapeutic Goods Administration (TGA) approved Cladribine Tablets for the treatment of relapsing-remitting multiple sclerosis. Cladribine Tablets will be registered in Australia under the trade name Movectro®.

Cladribine Tablets, also under the trade name Movectro, became the first oral MS treatment in the world to gain marketing authorisation when health authorities in Russia approved it in July 2010.

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## Milestone Ruling for Alzheimer's Disease Patients Announced

The National Institute for Health and Clinical Excellence (NICE) has announced new draft guidance which represents a significant step towards ensuring patients with Alzheimer's disease in England and Wales receive treatment for their condition, from the early stages of disease.

New draft NICE guidance recommends that acetylcholinesterase inhibitors, including Aricept® (donepezil), should be made available to patients in England and Wales as options for managing mild to moderate disease. This is a significant change to an earlier 2006 NICE ruling which restricted access to these medicines for patients with moderate disease only.

"This provisional decision by NICE is an important milestone for the thousands of Alzheimer's patients currently unable to receive treatment for their condition. Early diagnosis and access to medication is critical to help reduce both the short and long-term impact of this devastating condition on patients, families and carers," says Professor Roy Jones from The Research Institute for the Care of Older People (RICE) Centre, Royal United Hospital, Bath, UK.

The announcement supports the Department of Health's National Dementia Strategy (NDS). The NDS encourages the active management of Alzheimer's disease from its earlier stages to minimise the burden of the condition on patients, their carers and society. In addition, the need for greater access to dementia-specific treatments is in line with the recent Alzheimer's Disease International report which calls for governments to make dementia a higher health priority, to help tackle the huge burden of the disease. The draft NICE recommendations on Alzheimer's disease treatment will now go into consultation, with final guidance expected in early 2011.

*For the full guidance, see <http://guidance.nice.org.uk/Type/TA/Published>*

## Government Listens to Epilepsy Campaigners

The government has decided not to make generic prescription of NHS drugs compulsory.

Supporters of The National Society for Epilepsy's (NSE's) 'Count Epilepsy Out' campaign sent campaign postcards and letters, earlier this year, to the Minister of State for Health saying that cutting costs on epilepsy drugs doesn't add up. It could provoke seizures or side effects – with a high cost to both the NHS and the person with epilepsy. The NSE also submitted an in-depth response to the consultation laying out the potential dangers of generic substitution to people with epilepsy. This backed up an earlier report that was formative in the government's decision to consult on their plan.

This campaign contributed to the government's rejection of the scheme. In the Department of Health press release Health Minister Lord Howe says, "We have listened to the concerns from the public, patients and other interested parties... It is

not clear whether the proposals would have provided a substantial benefit to the NHS."

People with epilepsy have been nervous about the long wait since the Department of Health's consultation closed in March 2010. Breakthrough seizures can be caused if their drug is swapped for non-clinical reasons. One breakthrough seizure is devastating and could cause serious injury and harm, rob someone of their driving licence and affect their job.

"Thank you to all our supporters who sent a postcard and wrote to the Minister of State," said NSE chief executive Graham Faulkner. "Working together we have made a big contribution to a great result for people with epilepsy. This does show that we can make a difference."

*For the full guidance, see <http://guidance.nice.org.uk/Type/TA/Published>*

## Advancing Scientific Understanding of Autism

The Wales Autism Research Centre at the School of Psychology, Cardiff University, has been established with support from the charities Autism Cymru and Autistica, and from the Welsh Assembly Government.

Autism affects up to one child in every 100. Those affected have difficulties in communicating, forming relationships and making sense of the world. The new Centre will research new areas in identification, diagnosis, development and intervention.

Director of the Centre, Professor Susan Leekam said, "The launch of the Wales Autism Research Centre marks the beginning of an exceptional opportunity to advance scientific research. We will not only be carrying out internationally competitive research projects but also helping to build evidence-based policy and

practice. This mission is supported by partnerships between scientists, practitioners and government policy makers, and makes the purpose of this research centre unique in the UK."

The Centre already has a number of new projects underway. These include research on sensory processing using neuroimaging techniques, research on clinical symptoms and diagnostic tools and research on the effects of interventions. The team has also been contributing to a schools training programme, evaluating diagnosis services, assisting with awareness-raising materials and investigating the potential for new databases of information.

Researchers at the Centre have also set up new collaborations and networks with the University's pioneering Cardiff University Brain

Research Imaging Centre (CUBRIC) and Cardiff Neurosciences Centre.

The Welsh Assembly Government's Strategic Action Plan for Autism Spectrum Disorder is believed to be the first of its kind anywhere in the world. Uniquely, the Centre works with practitioners and government policy makers within this action plan to integrate research evidence with policy and practice. It also aims to raise public and professional awareness of autism research, highlighting the importance of reliable, scientific evidence and breaking down some of the myths surrounding it.

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