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An introduction to the key CNS Disorders

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An introduction to the key CNS Disorders

Alzheimer's Disease: Over the last 3 years, the value of the Alzheimer's disease market has grown by an average of 19% per year. Growth has been driven by increasing availability and reimbursement of Alzheimer's drugs. There are considerable opportunities within these markets due to an ageing population and the high unmet clinical need, particularly within the late stage of disease. In addition, research over the last 20 years has increased our understanding of the underlying mechanisms of disease progression and provided new targets for drug validation resulting in a number of novel drugs entering clinical trials.

Nootropic drugs or anti-Alzheimer's drugs are one of the largest segments of the neurodegenerative market and accounted for 33% of global sales (US\$2.6 billion in 2003 and equivalent to 4% of global CNS drug sales). The market for drugs to treat Alzheimer's disease has grown steadily since the launch of Aricept in 1996 and experienced 21% growth year-on-year in 2003. Whilst the US accounts for approximately 49% of global Alzheimer's drug sales, the majority of growth occurred outside the US with European sales increasing from 28% of sales in 2002 to 33% in 2003. This is largely due to the launch of Ebixa, the new NMDA receptor antagonist from Lundbeck/Forest, and the recognition by regulatory committees such as the NICE in the UK condoning the use of these agents in moderate-to-severe Alzheimer's disease. The most frequently prescribed anti-Alzheimer's drug is Aricept from Eisai/ Pfizer, which was launched in the major pharmaceutical markets in 1997. In 2003, Aricept generated global sales of US\$1.5 billion, accounting for approximately 54% of the market by value.

Further reading:

[CNS Drug Discoveries: What the future holds](#) [Alzheimer disease - new drugs, markets and companies](#) [Alzheimer's Disease - A Busy Future, with Diagnosis, Disease Modification and Prevention Key to Growing Market](#)

Multiple Sclerosis: It is estimated that over 350,000 Americans (approximately 1 in 1,000 aged over 30 years) live with multiple sclerosis (MS) and approximately 3 million live with it worldwide. However, the prevalence may be higher because of the uncertainty in diagnosing the condition. Women are twice as susceptible as men and it is more common in people in northern latitudes over the age of 18 years. In addition, siblings of an individual with multiple sclerosis have a higher chance of developing the disease. The incidence of multiple sclerosis varies throughout the world, although there is a significantly higher incidence of the disease found in the Northern Hemisphere. Multiple sclerosis is the most common cause of neurological disability in young adults in the UK. It is variable in presentation and progression. Although there is no cure, there are many symptomatic treatments available. However, many patients do not respond to current therapies (30%) and the more chronic forms (secondary-progressive MS) are poorly treated with existing

therapies.

Approximately 56% of multiple sclerosis global sales were derived from the US (US\$1.9 billion) in 2003, with the remainder largely derived in Europe (43%, US\$1.4 billion). Avonex (Biogen Idec) is amongst the few CNS drugs that generated blockbuster sales of over US\$1 billion globally in 2003. There has been considerable growth in sales as more beta-interferon-naive patients receive treatment due to reimbursement of injectable agents: Betaseron has benefited from European approval to treat secondary -progressive multiple sclerosis (around 40% of the patient population). Sales growth will be driven by current drugs gaining broader indications, MS medicine being prescribed earlier in treatment in clinically -defined multiple sclerosis patients and the longer-term use of combination therapies as more classes of drug become available.

Further reading:

[CNS Drug Discoveries: What the future holds](#) [Biotech in Autoimmune/Inflammatory Disease 2004 - Revolutionizing the Market](#) [Multiple Sclerosis - How to Find Opportunities in an Unremitting Market](#)

Attention Deficit Hyperactivity Disorder (ADHD): The value of the ADHD market was US\$1.7 billion in 2003 and it is now the 11th largest segment of the CNS market by sales and one of the fastest growing (+33% year-on-year). Global sales of ADHD are forecast to reach US\$3 billion by 2010. This will be due to greater penetration in the treatment of new patients particularly adult ADHD, improvements in patient compliance due to the launch of new formulations, new non-schedule II drugs and the development of novel classes of drugs in late-stage clinical trials. There has been a significant increase in ADHD diagnosis and prescription of medicine since the early 1990s due to wider understanding of the condition in the mental health community, increased use of medication and healthcare coverage and the launch of ADHD specific drugs (from 2000 onwards). ADHD is one of the most common psychiatric disorders of childhood and approximately 50% to 70% of children with ADHD will continue to experience symptoms into adulthood. In 2000, it was estimated that 4-5 million individuals (mainly children) were diagnosed with ADHD of whom, 75-85% were treated with psychostimulants. Over 8 million adults in the US may exhibit the symptoms of ADHD, while only an estimated 600,000 are being treated.

Approximately 97% of ADHD global sales were derived from the US in 2003, with the remainder from Europe. This is largely due to a higher diagnosis rate in paediatrics and availability of drugs for medical reimbursement. Over the last 3 years the value of the ADHD market has grown by an average of 37% per year. Growth has been driven by the launch of new non-stimulant drugs, new patients and the development of new formulations providing flexibility in dosing and higher patient compliance. The ADHD market is still in its infancy and is a classic example where a niche market has been exploited by biotechnological companies and pharmaceutical companies, having recognised its potential, are launching new agents to capitalise on future growth.

Further reading:

[CNS Drug Discoveries: What the future holds](#) [Adult ADHD - Strattera](#) Grows Up

Focusing on Insomnia: The insomnia market is on the verge of considerable growth due to the launch of new formulations of leading drugs, new classes of drugs with improved side-effect profiles and patient dynamics - an ageing patient population. New formulations are reaching the market and leading brand products face competition from generics and from the new GABA-A receptor agonists: Estorra (Sepracor) to be launched in late 2004, Indiplon (Pfizer / Neurocrine) and Gaboxadol (Lundbeck/Merck) in mid-2005 and early 2007, respectively. Sleep disorders cover a range of problems, the best known types being insomnia, sleep apnoea and restless legs syndrome. Insomnia is the most prevalent sleep disorder and it is estimated that it affects over 37 million US citizens and over 100 million people worldwide with approximately 25% of elderly people and 15% of the general population suffering from the condition.

Studies suggest that less than 20% of insomniacs seek help and less than 20% of sufferers are prescribed medication.

Approximately US\$2.5 billion is currently spent on hypnotics and sedatives in the treatment of insomnia the 8th largest segment of CNS drug sales. The global market for insomnia drug sales is unevenly distributed. In 2003, the US insomnia market accounted for 57% of the global market compared to 32% in Europe and 11% in the rest of world (largely Japan). This is largely due to the pricing differential between the European and the US market. GABA-A receptor agonists (non-benzodiazepines) will continue to remain the cornerstone for the treatment of both acute and chronic insomnia. However, the launch of several new products over the next 3 years will help to increase patient awareness, particularly in the elderly, and help the market to grow to US\$4.9 billion by 2010.

Further reading:

[CNS Drug Discoveries: What the future holds](#) [Insomnia - Wake-Up Call for a Sleepy Market](#)

Depression: The depression market is the largest segment of the CNS market with global sales of US\$15.5 billion in 2003, and has grown by 12% year-on-year. This is a mature market with a number of the leading brands facing patent expiration in the next 6 years. The dynamics of the marketplace are changing as new classes of drugs such as the selective noradrenaline reuptake inhibitor, Cymbalta (Eli Lilly), and new formulations of drugs such as the 5-HT1A antagonist, Wellbutrin XL (GSK), are launched. It is estimated that depression affects over 18.8 million US citizens and over 121 million people worldwide, with approximately 20% of the global population at risk of developing major depression at some point in their lives. Women are twice as likely to suffer from depression as men (9.5% versus 5.8%), but prevalence figures vary from country to country. Depression costs the US an estimated US\$44 billion each year. The WHO predicts depression will become the leading cause of disability by the year 2020.

The global market for antidepressants is unevenly distributed. In 2003, the US antidepressant market accounted for 71% of the global market compared to 24% in Europe and 5% rest of world (largely Japan). We believe the depression market has matured and there are now 5 key areas of unmet clinical need that will need to be addressed in order to drive further growth of the market. These include improvements in the efficacy, speed of onset, safety/tolerability of drugs and a reduction in remission rates and relapse/recurrence.

Further reading:

[CNS Drug Discoveries: What the future holds](#) [Depression - Novel therapies key to market penetration](#) [Anxiety Disorders - More Than Just a](#) [Comorbidity](#) [Antidepressants - Sliding SSRI Revenues Inevitable](#)

Focusing on Neuropathic Pain: Pain products generated global sales of nearly US\$40 billion in 2003 (including anaesthetics and antimigraine agents) and this is expected to double by 2010. Pain is associated with a broad range of diseases and is often poorly diagnosed and treated. There has been tremendous research activity into the treatment of pain and many types of pain remain relatively unexplored. Approximately 26 million patients worldwide (10 million in the US, 3 million in Europe and 1.5 million in Japan) suffer from some form of neuropathic pain, spending an estimated US\$2.5 billion globally in 2003. There remains a high unmet clinical need within neuropathic pain as current therapies such as antidepressants are under-utilised and many patients in Europe have inadequate pain management programmes and limited access to opioids.

It is difficult to determine the exact amount spent on the management of pain as several classes of drug are used "off-label" in the treatment of pain such as antidepressants and anti-epileptics. We anticipate that by 2010, sales of neuropathic pain drugs will double to US\$5.5 billion. Sales will be driven by the launch of novel therapeutic drugs that specifically target subsets of neuropathic pain associated with: HIV infection, shingles, diabetes, immune disorders and toxic neuropathies (for example following treatment with chemotherapeutics). These include the development of

antidepressants (Cymbalta), antiepileptic agents (Lyrica and Prialt) glutamate antagonists (Namenda, Lamictal and CNS 5161) and the cannabinoid agonist (Sativex).

Further reading:

[CNS Drug Discoveries: What the future holds](#) [Pain Therapeutics - Drugs, Markets and Companies](#) [Neuropathic Pain - Comparative Overview of Treatment Preferences Across the Seven Major Markets](#) [Diabetic Neuropathic Pain - Market Success is Not Limited to Pregabalin](#) [HIV Related Neuropathic Pain - Useful Niche for Peripheral Companies](#) [Neuropathic Low Back Pain - Off-label Revenue Despite Diagnostic Challenge](#) [Cancer Pain - Physician Awareness and Novel Drug Delivery Will Drive Market](#)

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