



ASTRAZENECA'S RESPONSE TO THE

EUROPEAN COMMISSIONS'S GREEN PAPER

**Improving the mental health of the population.
Towards a strategy on mental health for the European Union**

For more information contact:
Neil Mulcock
Global Government Affairs & Policy
AstraZenca Plc
15 Stanhope Gate
London W1K 1LN

Introduction

AstraZeneca is one of the world's leading pharmaceutical companies, dedicated to the discovery, development, manufacturing and marketing of high quality, effective prescription medicines that bring benefit for patients and wider society.

Our medicines are designed to fight disease in important areas of medical need: cancer, cardiovascular, gastrointestinal, infection, neuroscience, respiratory and inflammation.

We have a strong European heritage. Over 22,000 people are employed in the EU. Our corporate headquarters are based in London and our Research and Development headquarters are based in Södertälje, Sweden. We spend over \$14 million every working day on the research and development of new medicines that will meet patients' needs.

We have made a considerable long-term investment in this therapeutic area, with several dedicated research bases, including centres of excellence in:

- Wilmington, Delaware, USA – focus on psychiatry
- Södertälje, Sweden – focus on neurology
- Montréal, Canada – focus on analgesia

With a growing ageing population, the requirement for improved therapies is set to increase. The World Health Organisation forecasts that over the next two decades neurological and psychiatric disorders will rank high in the list of major disease burdens. We are committed to meeting the needs of patients, carers, physicians and health care professionals for improved medicines.

Major steps forward in the neuroscience knowledge base, new research technology and scientific breakthroughs have provided new insights into CNS diseases. This has helped our scientists to develop novel therapies for a broad range of neurological and psychiatric disorders including schizophrenia, bipolar disorder, migraine and acute stroke.

Consultation

AstraZeneca welcomes the publication of the Green Paper and the opportunity to contribute to the consultation. Our involvement in the consultation goes beyond the submission of this paper, however.

In order to help identify priority issues for the development of future EU mental health policy AstraZeneca co-hosted a meeting along with EUFAMI and Rethink which brought together a group of leading experts, including representatives from the European Parliament, Member States and patient groups. Participants were asked firstly, for their insight into the challenges of improving mental health care in Member States and secondly, to review a survey, designed to gather information on this subject from patients, their families and carers. Our response partly takes into account views expressed at that meeting.

The survey sponsored by AstraZeneca and jointly run by EUFAMI and Rethink gives carers and patients with mental illness a unique opportunity to express their views and comment directly on the issues which are most important to them.

The results of the survey will be launched at an event in the European Parliament, hosted by John Bowis MEP on the 31st May 2006.

Comments on the Green Paper

AstraZeneca welcomes the approach adopted by the European Commission. In particular we support the Commission's recommendation to focus on a comprehensive approach that promotes mental health and prevents mental ill health. We would like to submit our response under three headings:

- (1) Prevention of mental ill health is a laudable aim but it must be balanced with meeting the needs of those already suffering from mental ill health.
- (2) Adopting a holistic approach to mental health is an appropriate strategy if it includes medical intervention where appropriate.
- (3) There is a wide discrepancy of access to treatments within and between Member States and it is appropriate for the Commission to recommend action to reduce these inequalities of access. However inequalities of access also exist on an international level, for example between the EU and United States.

1. Prevention

The Green Paper quotes widely published research on the burden of mental health. This includes estimated costs to the economy of up to 3% - 4% of GDP. It also notes that mental disorders are a leading cause of early retirement and disability pensions. More than one in four citizens experience some form of mental ill health during their lifetime and 58,000 people die each year in the EU from suicide – more than the annual deaths from road traffic accidents, murder or HIV/AIDs.

Mental ill health therefore is a significant health burden in the EU. Moreover it has other associated costs such as those to the social, educational and the criminal and justice systems.

These facts suggest action at an EU level is required to improve core treatment for those who are suffering from mental illness. Moreover their successful treatment will not only improve the quality of those lives affected but through their integration back into society and employment, the societal costs will also be reduced.

AstraZeneca therefore recommends that in addition to focussing on mental health and the prevention of mental illness, the Commission promotes and supports policies that can provide optimum treatment for the individual patient suffering from mental illness. In developing an EU strategy we suggest a fifth aspect is added to section 5 on page 8 which develops policies to improve access for patients to treatments for mental illness across the EU as a whole. It would answer the question posed by the Commission on page 14 *Are initiatives proposed...appropriate to support the coordination between Member States, to promote the integration of mental health into the health and non health policies and stakeholder action and to better liaise research and policy on mental health aspects?*

The consultation paper highlights the prevalence of those suffering from mental illness who commit suicide and seeks views on how the prevalence can be reduced. While acknowledging that there are a variety of ways that the prevention of suicide can be tackled, it is important to acknowledge that medical intervention can have an important part to play.

It is worth noting that those suffering from schizophrenia or bipolar disorder have a greater tendency to commit suicide. In schizophrenia studies have show that 30% of

patients diagnosed with schizophrenia attempt suicide at least once during their lifetime¹ and about 10% of patients die by suicide.²

Suicide amongst patients suffering from bipolar disorder is also more prevalent. The risk of suicide in patients with bipolar disorder is more than twenty times higher than in the general population. In fact 25-50% of patients with bipolar disorder attempt suicide at least once in their life.³

Providing the most effective treatment for patients suffering from these two illnesses will, it is reasonable to conclude, reduce the incidence of suicide across the EU.

Section 6.1.1 asserts that mental health is strongly determined during the first years of life and promoting mental health in children and adolescents is an investment in the future. Improving parental skills, social competencies and learning coping skills will undoubtedly be of benefit to the child as it goes through life. However there is no evidence to suggest that this approach by itself will prevent anyone from developing mental illness particularly if they have a genetic disposition to do so.

2. Comprehensive approach

AstraZeneca supports the comprehensive approach recommended by the Commission to treat mental illness. Indeed there are a variety of ways in which different degrees of mental illness can be treated. In some cases it must be noted that medical intervention is the most effective option. This is particularly the case with the severe forms of illness, such as schizophrenia and bipolar disorder.

Studies of schizophrenia for example have shown that at most only 20 per cent of patients experience a single episode after which satisfactory clinical and social recovery occurs. Generally patients require long-term care and support for life.

Failure to successfully treat schizophrenia is associated with high costs to society with indirect costs to being at least equivalent to direct costs. The most expensive component of direct costs is hospitalisation with medication costs comprising only a small fraction of the total cost of the illness at less than 5%.⁴

This suggests that there are clear economic as well as health benefits to the patient if schizophrenia is treated early and successfully. Moreover the need to stabilise patients becomes all the more imperative when policy makers consider the recommendation contained on page 11 of the Green Paper, the change in the paradigm to deinstitutionalise mental care. In order for it to be done successfully it is important that the patient receives the most appropriate medical treatment as part of a holistic approach.

This is in fact acknowledged by the Green Paper which refers as a priority of providing effective, accessible treatment services. AstraZeneca would suggest these services should include access to medical treatments which most effectively address medical need. Moreover given the nature of mental illness and the variations of patients' response and the side effect profiles to certain treatments it is important that

¹ Radomsky, E.D., Haas, G.L., Mann, J.J., Sweeney, J.A., 1999. Suicidal behavior in patients with schizophrenia and other psychotic disorders. *Am. J. Psychiatry* 156 (10), 1590–1595

² Caldwell, C.B., Gottesman, I.I., 1990. Schizophrenics kill themselves too: a review of risk factors for suicide. *Schizophr. Bull.* 16 (4), 571–58

³ Baldessarini RJ, Tondo L and Hennen J Suicide risk and treatments for patients with bipolar disorder *JAMA* 2003; 11: 1517-1519

⁴ Knapp and Kavanagh Economic Outcomes and costs in the Treatment of Schizophrenia 1997

physicians and patients have a choice of medication. A greater choice in treatment options will allow for better treatment.

3. Access to medical treatment

The Green Paper also acknowledges that across the EU and within Member States access to medicines varies. Given the diversity of Member States and their traditions and cultures AstraZeneca acknowledges that it is not possible to propose uniform solutions. However, what AstraZeneca would propose is for the Commission to encourage all Member States to provide a full range of safe and effective treatment to patients suffering from mental illness. This may in the case of hospitalisation result in budget savings since medical costs are significantly cheaper than institutional care.

While encouraging greater access to modern treatments within the EU, AstraZeneca also believes the Commission should encourage all Member states to provide the same access to modern treatments that is available in United States.

It is worth noting that EU citizens' ability to gain access to modern medicines lags behind US citizens, even though in many cases the medicine may have been discovered and developed in the EU. According to IMS Health data, 70% of sales of new medicines marketed since 1999 are generated on the US market, compared with 19% on the European market.⁵

While encouraging greater access to modern treatments within the EU, AstraZeneca also believes the Commission should endeavour to achieve equal access to medications for EU citizens compared to their United States counterparts, particularly in areas of high unmet medical need. This would include creating a regulatory framework, which fosters the timely provision of safe and effective new treatments for mental illness to the patient. There is a noticeable disparity between the EU and US in terms of the time to when such medications for mental illness can be made available. This is exemplified in the recent decision by an FDA Advisory Committee that treatments can be licensed for acute treatment of psychiatric conditions without the need for long-term efficacy data in the initial submission, and that these longer-term data can be delivered by the applicants as a commitment. We would therefore suggest that the Commission addresses global inequalities in treatment options, in addition to pan-EU and that scientific progress should be reflected within EU regulatory policy in order to see the benefit of evolving research knowledge transferred to the patient. Regulatory policy on mental health is arguably not revisited with high enough frequency to align with developments in science and medicine.

⁵ www.efpia.org

This paper represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.