Process for Licensing and Reimbursement of New Medications - Briefing Document

How are MS medicines made available in Ireland?

In Europe, all drug companies must apply to the European Medicines Agency (EMA) for licensing of their drugs. Once the EMA has granted a license for a specific drug the Health Products Regulatory Authority (HPRA) approves the licence for the Irish market. At this point the drug company who is the producer of the drug can formally request the HSE to consider reimbursing the drug and making it available to PwMS in the Irish health system.

To assess whether the drug should be reimbursed or not the HSE requests the National Centre Pharmacoeconomics (NCPE) to carry out a cost benefit analysis and/or a Health Technology Assessment (HTA) on the drug to assess its cost effectiveness. The NCPE then makes a recommendation in conjunction with the HSE's Corporate Pharmaceutical Unit (CPU) as to whether the drug should be reimbursed or not. If the HSE decides not to reimburse the drug, the Minister for Health can still overrule this decision ensuring that the drug will be reimbursed in the Irish health system.

If an MS treatment does not receive NCPE approval, it will not usually be reimbursed by the HSE. It will only be possible for people with MS to access a treatment with a 'no' decision from the NCPE if it is paid for privately or a clinician believes that the drug would be effective and if the hospital is willing to pay for the treatment through an individual funding request and out of its own budget, but this is unusual. Therefore, the likelihood of a hospital granting access to a medicine that the NCPE has decided is not cost-effective is seriously reduced unless individual circumstances prove to be exceptional.

In certain circumstances drugs can be made available to PwMS pending a licensing and or reimbursement decision. This can be done on a "Named PwMS Basis" and may relate to drugs being used in a clinical trial or where a drug meets an unmet clinical need. This requires HPRA approval.

Drug Companies may also agree to establish Early Access Programmes or Compassionate Access Programmes when a drug has been licensed but before it has been officially launched or a decision on reimbursement has been taken. These programmes are designed to provide treatment to PwMS early where there is an otherwise unmet clinical need. These can be established where the Drug company offers the drug for free, subsidises the cost of the drug or agrees a price with the relevant health authorities. All of these programmes require the advance approval of the HPRA.

MS Ireland
THE MULTIPLE SCLEROSIS SOCIETY OF IRELAND

Who are the main players and influencers in deciding what treatments can be used in Ireland?

The European Medicines Agency (EMA)

The EMA was set up in 1995 with funding from the European Union and the pharmaceutical industry, as well as indirect subsidy from member states, in an attempt to harmonise (but not replace) the work of existing national medicine regulatory bodies. The EMA considers scientific evidence including clinical trial data and other academic research when making decisions on licensing.

The Health Products Regulatory Authority (HPRA)

The HPRA was formerly known as the Irish Medicines Board (IMB) and grants licenses to companies to make, distribute and market medicines after a review of their safety, quality and effectiveness. The HPRA continuously monitors medicines, medical devices and other health products once they are available on the market and responds quickly to any safety or quality concerns. This includes operating national reporting systems, which allows people to report safety and quality issues directly to HPRA. The HPRA produces safety and quality information on health products for PwMS and healthcare professionals to support their safe use. The HPRA also inspects companies and facilities, which test, make or distribute health products to ensure that they comply with relevant standards and legislation. The HPRA also contributes to regulatory committees and working parties at a national, European and global level for all products under their remit.

The Health Services Executive (HSE)

The HSE functions as a single national agency delivering health services in Ireland. Senior figures from the HSE sit on the HSE Drugs Group which considers the recommendations of the NCPE and CPU as to whether a drug should be reimbursed or not. Once it is agreed that a drug will be reimbursed, the HSE will then determine how the drug will be reimbursed.

The National Centre for Pharmacoeconomics (NCPE)

The NCPE was established in 1998 and is funded by the Department of Health. Activities of the Centre include economic evaluation of pharmaceutical products and the development of cost effective prescribing. In addition, the research of the Centre focuses predominantly on the economic analysis of high cost areas. In collaboration with the CPU, the NCPE now considers the cost effectiveness of all new medicines following receipt of an application for reimbursement and makes a recommendation on reimbursement to the HSE on that basis.

Corporate Pharmaceutical Unit (CPU)

Within the HSE, the CPU is responsible for pricing, reimbursement and the provision of drugs and devices for PwMS. The CPU works with the NCPE to determine whether a drug is cost effective or

not and on that basis makes a recommendation to the HSE as to whether the drug should be reimbursed or not.

The Department of Health (DoH)

The DoH supports the Minister for Health and the Government by advising on the strategic development of the health system including policy and legislation and evaluating the performance of the health and social services. The Department may become involved in access and reimbursement issues and advises the Minister of Health on that basis.

The Minister for Health

The Minister for Health has overall political responsibility for the DoH. Ultimately it is the Minister who signs off on all major decisions made in the health system and it is the Minister and his Department who are accountable to the Dáil for health spending and have the final say on the reimbursement of medicines in the Irish system.

The Health Information and Quality Authority (HIQA)

HIQA conducts system wide HTAs and sets guidelines on HTAs that are used by the NCPE. It was established in May 2007 as an independent authority reporting to the Minister for Health.

Private Health Insurers

There are currently four private health insurance companies in the Irish market and these are; VHI, Laya Healthcare, Aviva and GloHealth. These companies make their own decisions with regard to what treatments and drugs they reimburse for their customers.

The role of patient organisations

Patient advocacy groups such as MS Ireland can play a role in the process of making new medicines available. The NCPE has a Patient Group Submission Template available which patient organisations can complete and submit during the pharmacoeconomic assessment process. The submission is intended to provide a summary of information which the patient group would like to have considered in the assessment of the technology, including the potential impact on quality of life, the difference between the medication being assessed and currently available products and how the new medication will address unmet needs.

Patient group submissions should describe the impact of the health problem (such as MS) on the lives of patients, carers and their families, and should include information about:

- symptoms,
- problems that patients experience carrying out every day activities or tasks where patients require assistance and support,
- the impact on personal /family relationships

- ability to work
- social life.

Patient groups can gather such evidence in a variety of ways, including information services, focus groups, published or unpublished research, user-perspective literature (e.g. personal stories) and one to one discussions.

If the NCPE does not recommend reimbursement of a medication following a pharmacoeconomic assessment, patient groups can continue to advocate for it to be made available using a variety of methods. This might include writing to the CPU or the Minister for Health, encouraging members to contact their own elected representatives, generating media attention of the issue and liaising with the pharmaceutical company regarding pricing of the product.

Useful websites

The European Medicines Agency:

www.ema.europa.eu/ema/

The Health Products Regulatory Authority:

www.hpra.ie/

The HSE Corporate Pharmaceutical Unit:

www.hse.ie/eng/about/who/cpu/

The National Centre for Pharmacoeconomics:

www.ncpe.ie/

The Department of Health:

http://health.gov.ie/

The Health Information and Quality Authority:

www.hiqa.ie/

This document has been prepared by Harriet Doig, Information, Advocacy & Research Officer, MS Ireland.

For questions and comments and to find out more about becoming involved in a Patient Group Submission to the NCPE, please contact Harriet Doig on 01 678 1600 or by email to harrietd@ms-society.ie.