

March.05

The Scottish Medicines Consortium (SMC): Patient and Public Involvement

Sections 1 to 3 below are intended to provide members of the public with background information on the development, licensing and sale of medicines. Sections 4 to 6 and 8 provide information about why SMC came into being and how it fulfils its role. Section 7 describes SMC's public involvement opportunities. We hope you find this information helpful

1. Developing a Medicine

- 1.1 It generally takes about 12 years to develop a medicine and make it available to the public.
- 1.2 It may cost the pharmaceutical company over £300 million to bring that product to market.
- 1.3 During this time the medicine will be taken through a number of phases of development which culminate in clinical trials involving patients with the disease at which the medicine is targeted. Clinical trials are tightly regulated and no patient can be involved in such a trial without first giving consent.

2. Obtaining a Licence

- 2.1 Before it can be marketed the medicine needs to be granted a licence from either the UK Medicines and Healthcare Devices Regulatory Agency (MHRA) or the European Medicines Evaluation Agency (EMA).
- 2.2 The medicine will only be granted a licence if it can satisfy 3 criteria i.e.
 - i) safety
 - ii) efficacy (the medicine has been shown to work when compared to either a placebo i.e a substance known to contain no therapeutic qualities or the current 'gold standard' for the targeted disease); and
 - iii) quality (the substances used to make the medicine are of good quality, the end product is consistent and it has an appropriate shelf life).
- 2.3 Neither MHRA nor EMA make comparative judgements about the medicine in relation to any other medicine i.e. which works better, and costs are not considered.

3. Selling the Medicine

- 3.1 The pharmaceutical industry makes a significant contribution to the UK economy, both as an employer and source of investment.
- 3.2 The price that the pharmaceutical company can charge is regulated through the Pharmaceutical Price Regulation Scheme which is based upon a formulae for controlling company profits whilst continuing to allow them to generate sufficient profit to reinvest in development of future generations of medicine.
- 3.3 The pharmaceutical industry is tightly regulated by the government and represented by an organisation known as the Association of British Pharmaceutical Industries (ABPI).

- 3.4 All pharmaceutical industry sales, advertising and marketing activities are controlled by a Code of Practice established by the industry under a process of self-regulation. This Code is run by the Prescription Medicines Code of Practice Authority (PMCPA).
- 3.5 Any breach of the ABPI Code of Practice can result in financial penalties and damage to the company's image. A company is, for example, not allowed to promote prescription only medicines direct to members of the public.

For further information about developing, licensing and selling medicines please visit www.abpi.org.uk and www.mhra.gov.uk

4. Advising on the Availability of a Medicine

- 4.1 Prior to the establishment of SMC in October 2001 local health boards and their medicines committees (called Area Drug and Therapeutics Committees (ADTC) had to make individual assessments of each medicine as it became available.
- 4.2 This activity took up a considerable amount of time and the effort was duplicated across Scotland's 15 health boards. There were many differences between which medicines were made available in the different areas.

5. The Scottish Medicines Consortium (SMC)

- 5.1 In October 2001 the SMC was established to provide a single point of advice with the intention of minimising inequalities and variability across Scotland.
- 5.2 It is important to understand that whilst SMC *advises* on all new medicines, it is for the individual health boards to *recommend* which medicines should be used in their area but it is clinicians who finally *decide* what to prescribe.
- 5.3 SMC is a committee made up of people from across Scotland including lay people, specialist doctors, general practitioners, economists, pharmacists, nurses, directors of finance, health service managers and representatives from the pharmaceutical industry.
- 5.4 Members of SMC may serve on three sub-committees.

The first is called the *New Drugs Committee*: this group are responsible for the detailed clinical, economic and pharmacological assessment of each new medicine which may take four or more weeks. (Some members of NDC are not members of SMC.)

The second sub-committee is called the *Patient and Public Involvement Group*: this group are responsible for ensuring that the patient/carer perspective is considered in the medicine review process.

The third sub-committee is called the *User Group* and is made up of representatives from the pharmaceutical industry as well as members of SMC.

- 5.5 No members of the SMC or its sub-committees are paid for the work they undertake for SMC.
- 5.6 All members of SMC complete a declaration of interest register and re-declare any relevant interests during the course of a meeting which are minuted. An example of an interest that a member would have to declare

would be if he or she had received money from a pharmaceutical company to assist with a piece of research. Where appropriate, a member will be asked to leave the room whilst a particular medicine is discussed.

6. Assessing a Medicine

- 6.1 A pharmaceutical company submits information to the SMC about the medicine it wishes to market once it has received a licence.
- 6.2 The *New Drugs Committee* provides a detailed draft report on the clinical, economic and pharmacological strengths and weaknesses of the product.
- 6.3 This includes consideration of how this medicine will work in the real clinical situation. This is important because patients selected for clinical trials may not be representative of patients who are likely to be treated with this medicine in everyday practice across Scotland. For example, the trial may not have included people who have more than one medical condition, are over 65, or are taking certain other medicines. NDC and SMC have access to clinical experts who can advise on such matters. These experts would also be required to make any declarations of interest to ensure transparency is maintained throughout SMC processes.
- 6.4 The assessment will also consider cost-effectiveness. This takes into consideration whether the medicine represents good value-for-money.
- 6.5 The *Patient and Public Involvement Group* ensure that the patient/carer perspective is added to the clinical, pharmacological and economic elements. In order to assist in this a public involvement strategy has been developed that enables patient interest groups to make a submission to SMC.

7. Public Involvement Opportunities with SMC

- 7.1 SMC has 3 lay members who offer a lay perspective within the assessment process and ensure that wider opportunities for public involvement have been made available.
- 7.2 Individual members of the public/patients/carers and organisations that represent patients i.e. patient interest groups can obtain information about SMC from its website www.scottishmedicines.org.uk.
- 7.3 The website makes it possible to view the list of medicines due for assessment within the next 3 months and to see what decisions were made about other previously assessed medicines.
- 7.4 An individual submission of evidence from either a patient or carer cannot be considered by SMC but individuals are encouraged to contact the relevant Patient Interest Group who will collate responses/evidence in their Patient Interest Group submission to SMC.
- 7.5 By contacting SMC secretariat, a Patient Interest Group can ascertain the deadline for their submission.
- 7.6 In order to submit information, the Patient Interest Group will need to know more about the medicine from the parent pharmaceutical company. In the first instance, the Patient Interest Group should contact SMC secretariat to find out if the company has provided a contact name and/or written materials about the medicine under review i.e. Summary of Information for Patients (SIP).

- 7.7 If available, the Summary of Information for Patients (SIP) is prepared by the submitting pharmaceutical company to assist Patient Interest Groups with their submission. It should be noted, however, that the SMC are acting only as a communication channel for the SIP and do not endorse the information it contains.
- 7.8 The Patient Interest Group submission should contain information about what it is like to suffer from the health problem to which the medicine is targeted. This includes information about the perceived advantages and disadvantages of existing medicines and the potential benefits and impact of the new medicine upon the lives of people with this health problem.
- 7.9 A Patient Interest Group Guide to Submission is available for download, as is a template on which the submission can be made.
- 7.10 There are worked examples of submissions from two patient interest groups on SMC's website.

Further information can be obtained by visiting www.scottishmedicines.org.uk and clicking on the Patient Interest Group Guide to Submission and its related Submission Template, both of which can be downloaded for use. Two worked examples of submissions from Patient Interest Groups are available to view. Details of medicines shortly to be reviewed can be found by clicking on the Work Schedule.

8. Decisions

- 8.1 SMC will make one of three decisions about the use of this medicine within the NHS in Scotland:
- i) to accept the medicine for general use; or
 - ii) to accept the medicine for restricted use e.g. restricted by who should initiate the prescription or which patients should receive it; or
 - iii) not recommended for use.
- 8.2 SMC's decision is communicated to NHS Boards, their medicines committees and the submitting pharmaceutical company who make the medicines and, 4 weeks later, made public via press release and website.
- 8.3 If an accepted medicine is classed by SMC as 'unique' it must be introduced uniformly across each health board in Scotland, usually within three months of the publication of advice by SMC.
- 8.4 If the medicine accepted by SMC is not classed as 'unique' health boards are able to decide whether to offer it to patients within their catchment area. Their decisions are influenced by factors such as geographical, population, illness and service provision profiles and the availability of equivalent alternative treatments within their area. It is important to remember that health board funds need to provide the full range of services whether it be maintaining buildings, providing operations, introducing new technologies, updating old equipment, or recruiting and training the workforce. Finding the money for medicines both old and new is but one call on their funds.
- 8.5 Their local decisions are made known within documents called Formularies although medicines that do not appear in the Formulary may be used in specific circumstances. Increasingly, these Formularies are made available to the public via the board's website.

For further information about SMC decisions please visit www.scottishmedicines.org.uk and click on Medicines. You may also wish to visit your local health board website (www.show.org.uk) and follow links to their formulary where these are available.