

SUMMARY OF THE COMMITTEE ON SAFETY OF MEDICINES MEETING HELD ON THURSDAY 27 OCTOBER 2005

LICENSING

Product Specific

New Medicines

- The Committee considered and advised on a medicine to be used in the treatment of diabetes
- The Committee considered and advised on a medicine to be used as a muscle relaxant for the improvement in the appearance of moderate to severe vertical lines between the eyebrows seen as frowns in people younger than 65 years of age.

Variations

- The Committee considered and advised on the risk benefit of a medicine used in the treatment of early prostate cancer following the publication of data and suggested amendments to the product literature.
- The Committee considered and advised on a medicine used in the treatment of osteoarthritis and recommended dose reductions in the light of data provided by the company.

Legal Status

- The Committee considered and advised on the reclassification from prescription only medicine to pharmacy sales for a medicine used in the treatment of cold sores in adults and children over 12 years of age.
- The Committee considered and advised on the reclassification from prescription only medicine to pharmacy sales for a medicine used for the treatment sore throat pain.

PHARMACOVIGILANCE

- The Committee considered the risk management programme for a medicine used in the treatment of early prostate cancer
- The Committee considered and advised on issues relating to the use of progesterones.
- The Committee noted proposals for the establishment of an MHRA advisory committee to consider applications for research using data from the Yellow Card scheme or the General Practice Research Database.
- The Committee considered and advised on the continuing prohibition of Kava Kava.

- The Committee noted the Pharmacovigilance statistics for the month of September.
- The Committee received and endorsed the report of its working Group on Nicotine Replacement Therapy

OTHER ITEMS

9. Nurse and Pharmacy Prescribing: Expansion of Non Medical Prescribing

- 9.1. The Chairman reminded members that Professor Christine Beasley, CNO, Professor Jim Smith (formerly CPO) and DH colleagues Paul Robinson, Claire Potter, Mrs Gul Root and Dr Neil Maskrey would be attending to provide clarifications on matters that might be raised by CSM after its consideration of the responses from the national consultation exercise. Professor Kendall, who had chaired a Sub-Group of CSM to consider the outcome of the consultations held earlier in 2005, updated members on the history of independent prescribing by nurses. This was first introduced in 1999 for District Nurses and Health Visitors. The Nurse Prescribers' Extended Formulary (NPEF) was introduced in 2002, originally to manage minor illness, minor ailments, health promotion and palliative care but was subsequently expanded to cover a number of emergency care conditions. Nurses and pharmacists could also prescribe medicines as supplementary prescribers within the terms of a clinical management plan agreed by a doctor or a dentist for an individual patient. Nurses and pharmacists could only undertake prescribing responsibilities if they were accredited as such by their professional regulatory body. Both groups could also supply or administer named medicines under a Patient Group Direction. The Committee noted the complexity of existing arrangements, and the potential for confusion.
- 9.2. Currently, although around 400,000 nurses were registered with the Nursing and Midwifery Council, only a small number (approx 5,500 in Eng, and around 1,000 elsewhere in the UK) were Extended Formulary Nurse Prescribers (EFNPs). Those selected for prescriber status would normally have at least three years post-registration clinical nursing experience before acceptance on the course and would also have a minimum of 12 days practice supervised by a medical "mentor". Continuing Professional Development would ensure that prescribing skills remained relevant. Members had seen an outline of the NPEF courses offered by the Universities of York and Nottingham. Training courses for pharmacist supplementary prescribers have been accredited by the Royal Pharmaceutical Society and a number of the core modules were similar to those of the NPEF course. Some differences in emphasis were required as, in broad terms, nurses had clinical and therapeutic experience but little pharmacology whereas pharmacists were knowledgeable about clinical pharmacology and therapeutics but not so experienced in diagnosis other than related to "over the counter" products.

- 9.3. The consultations issued in February and March 2005 proposed a range of options, in which references to a “formulary” referred to the British National Formulary or sections from that Formulary. Members were reminded that those options were:

Nurses	Pharmacists
-----	Option 1: no change (ie, no independent prescribing by pharmacists)
Option A: no change - maintain the NPEF for specified medical conditions	Option 2: prescribing for certain conditions from a limited formulary
Option B: prescribing for any medical condition from a specific Formulary	Option 3: prescribing for any condition from a limited formulary
Option C: prescribing for specific medical conditions from a full Formulary	Option 4 : prescribing for specific conditions from a full formulary
Option D: prescribing for any medical condition from a full Formulary	Option 5 : prescribing for any condition from a full formulary
Option E: advanced practice nurses with a higher level of competencies	Option 6 : different approaches for the different clinical settings
-----	Option 7: a hybrid approach (between hospital, community and primary care based pharmacists)

The majority of replies to the consultation favoured options D and 5 although there was only limited support from medical bodies. The Committee’s Sub Group, which had met in September, had also supported options D and 5.

After considering in detail the responses to consultation and the review of its sub-group’s findings, the Committee agreed to seek further clarification in the following areas of concern related to patient safety:

- training and governance within and outside the NHS
- importance of prescribers developing a common understanding of diagnosis
- access to the patient record
- arrangements for the co-ordination of patient care where multiple prescribers could be involved
- arrangements for monitoring the effects of changes as they are introduced
- arrangements for dealing with potential conflicts of interest surrounding, for example, prescribing and dispensing responsibilities.

AFTERNOON SESSION 2pm

- 9.4. The Chairman welcomed the Chief Nursing Officer, the former Chief Pharmacist and members of DH who had been invited to discuss in further detail the options covered in the consultations. The Chairman provided an overview of the Committee’s discussions and its support for options D and 5 within the context of the concerns that had arisen in discussion (noted above). The Chairman appreciated that

Committee's advice was being sought only on the consultation options, rather than on specific concerns, although he felt that the future Commission on Human Medicines would, if requested, be prepared to offer further advice. Nonetheless, Members would be interested in the DH's views on the main areas of CSM's concerns. DH addressed each of the concerns as follows:

- training and governance within and outside the NHS: DH confirmed that a framework of competencies for nurse and pharmacist prescribers had been developed by the National Prescribing Centre and that they would strengthen this framework as required. The NMC was currently reviewing the standards for the outline curriculum for nurse prescribing and is responsible for quality assuring the specific programmes that Higher Education Institutions (HEIs) put forward for approval. The Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland are responsible for approving training programmes for prescribers and are likely to adopt a similar approach to that for pharmacist supplementary prescribers. Approval of HEI programmes for pharmacists is limited to a maximum of three years in the first instance.

NHS organisations need to have robust clinical governance arrangements in place. This means that the expansion of non-medical prescribing must be aligned to patient need, incorporate the best available evidence, be underpinned by education, training and continued professional development, be subject to regular audit and evaluation, and help the employing organisation meet its strategic goals for improving patient care. While non-medical prescribing was limited outside the NHS, the independent healthcare sector was expected to mirror the same governance arrangements as the NHS.

Professional governance fell to the appropriate professional regulatory body. All prescribers are personally responsible for their prescribing decisions to their line managers and employers, and are ultimately accountable to their professional body on any issues concerning clinical competence. Prescribers are expected to work within their professional code of conduct, have a professional responsibility to keep themselves abreast of clinical and professional developments and only to prescribe when they are fully competent to do so.

- importance of prescribers developing competence in diagnosis: DH understood and accepted the Committee's concern that patients may have or develop multiple disorders or that prescription of medication might not be the most appropriate treatment in all cases. The prescriber may already know the diagnosis from access to the patient's record but if not, they can only prescribe within their area of diagnostic competence. Experience will grow in diagnostic expertise and increasingly practice is moving towards more systematic methods for determining diagnoses. This will be enhanced by common training modules for prescribers and by continuous professional development. Additionally, organisations employing nurse and pharmacist prescribers need to have arrangements in place to make sure that they are satisfied that the individuals have the necessary clinical knowledge and skills in differential diagnosis, as well as prescribing skills.

- access to the patient record: DH agreed with the CSM's views that, save for some "out of hours" arrangements and Accident and Emergency Units, prescribers should have contemporaneous access to the relevant patient record before prescribing. This is already contained in DH guidance and that advice will be strengthened further. A prescriber will clearly also need to discuss with the patient what other medication he/she is already taking. Current plans indicate that electronic National Care Records for patients will be rolled out in England over several years, with completion expected in 2010. Meantime, the GP record will remain the main patient record. If there are any differences of opinion on prescribing or treatment regime between prescribers, the GP will remain the arbiter.
- arrangements for the co-ordination of patient care where multiple prescribers could be involved: while noting that patients can currently self-medicate in addition to taking prescribed medicines, DH said that they would strengthen existing DH guidance to stress the importance of contemporaneously updating the relevant patient record wherever possible. The central role of the GP would also help identify areas of potential concern. All prescribers were encouraged to report any suspected adverse drug reactions (ADRs) to the MHRA and a pilot scheme was also underway to accept such reports direct from patients. In principle, pharmacovigilance should improve as the reporting base for notifying ADRs expands. In reply to a question concerning the General Practice Research Database, DH said that, as such information was obtained from GP practices, there should be no reason why information on non-medical prescribing within practices should not be captured.
- arrangements for monitoring the effects of changes as they are introduced: The Non-Medical Prescribing Board, chaired by the Chief Nursing Officer, is the DH mechanism that sets the priorities for non-medical prescribing, securing resources and monitoring progress. All SHAs (and many PCTs and NHS Trusts) have a non-medical prescribing lead, who is charged with implementing the programme. In addition, all PCTs have prescribing/pharmaceutical advisors, who play a key role in monitoring prescribing in primary care. They also keep an eye peeled for any prescribing deemed to be inappropriate on clinical or cost effectiveness grounds and where there is evidence of this happening, take steps to improve prescribing. On a national basis, the DH Policy Research programme commissioned the University of Southampton to produce an independent Evaluation of Extended Formulary Nurse Prescribing late in 2002. The views of a range of stakeholders, including prescribing doctors and patients were also investigated. The evaluation was peer-reviewed by both Kings College and the University of Keele. The Department has also commissioned an evaluation of supplementary prescribing by nurses and pharmacists to be undertaken by the University of Sheffield, in partnership with University of Nottingham. Monitoring changes in prescribing practice in primary care will also be informed by prescribing data issued regularly by the Prescription Pricing Authority. For the future, DH plans to discuss the need for further work with its Policy Research Programme team. It is likely, for example, that DH will wish to audit the results of independent prescribing in the coming years. For instance, it may be sensible to compare and audit the results of nurse prescribing and pharmacist prescribing in 2005, with years 2006 and 2007.

Such work would come under the auspices of the Non-Medical Prescribing Board as it is responsible for the totality of the programme of work.

- arrangements for dealing with potential conflicts of interest surrounding, for example, prescribing and dispensing responsibilities: DH restated their view that they would normally expect separation of prescribing and dispensing roles in keeping with the principles of safety, and of clinical and corporate governance. However, in exceptional circumstances - as currently for dispensing doctors and for pharmacists in relation to supplementary prescribing and “over the counter” products - dispensing and prescribing can co-exist, provided clear accountability arrangements are in place to ensure patient safety and probity and where audit and clinical governance arrangements exist which can track prescribing and dispensing. Where the two roles do co-exist, a final accuracy check must be carried out by another person. In addition, both the NMC and the Royal Pharmaceutical Society of GB have professional guidelines. Nurses may well prescribe and administer a medicine, but they do not normally write a prescription and then supply a medicine. Neither do nurses normally dispense medicines. In cases where a pharmacist prescribes and dispenses a medicine, a “second check” must be carried out. The RPSGB has recently updated pharmacists’ Code of Ethics and Standards to include a service specification for prescribing. It is intended to publish further specific guidance for pharmacists working as prescribers. Pharmacists already have links with the pharmaceutical industry on a day-to-day basis and are well equipped to deal with inappropriate commercial influences.

9.5. The Chairman thanked DH colleagues for their views and clarifications, restating that the Committee would support options D (for nurses) and 5 (for pharmacists) within the context of the concerns they had raised. In thanking the CSM on behalf of herself and the Chief Pharmacist, the Chief Nursing Officer said that while the original limitations on the NPEF were understandable, subsequent expansions had made it complex. Safe practice included making legislation and procedures easy to understand and therefore easy for individuals to act correctly. Adopting the options recommended by the Committee in partnership with clinical governance structures would provide a strong accountability framework which would underpin improvements in patient care and make the best use of professional skills.

- The Committee noted the Department of Health consultation document on transferring the responsibilities of the National Biological Standards Board (overseeing the National Institute for Biological Standards and Control) to the Health Protection Agency. This had arisen as a result of the Review of ‘Arms Length Bodies’ in 2004.

Information that could identify the companies and the names of the products is being withheld on the grounds that this advice remains confidential at the date of this summary and publication would be premature while regulatory action continues. The

advice will be published in due course. Section 22 of the Freedom of Information Act 2000 applies.

Procedural Items

- i. In addition, the Committee completed its usual procedural business including the need to observe the confidentiality of the meeting, and to declare interests. Apologies, announcements, approval of minutes and updates following the September CHMP meeting were discussed. Professors Dargie, Langman Ralston and Woodhouse declared interests in one or more agenda items.
- ii. A list of Members who attended the meeting is at **Annex A**.
- iii. Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.
- iv. The meeting started at 10am and finished at 3.55pm.

This was the last meeting of the Committee on Safety of Medicines. The Chairman noted the 40 year history of the Committee and thanked members for their contributions. The new Commission on Human Medicines, which replaces both the Committee on Safety of Medicines and the Medicines Commission, will hold its first meeting on 9 November 2005.

Useful website links

Current problems in Pharmacovigilance:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=current+problems+in+pharmacovigilance

Member's declaration of interests:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=member%27s+declaration+of+interests

European Medicines Evaluation Agency updates:

<http://www.emea.eu.int/whatsnewp.htm>

MHRA Website:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=5

Yellow Card Website:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=yellow+card+website

<http://www.yellowcard.gov.uk>

Deleted: Current problems in Pharmacovigilance:¶
<http://medicines.mhra.gov.uk/ourwork/monitorsafeequalmed/currentproblems/currentproblems.htm>¶

¶ Member's declaration of interests:¶
<http://medicines.mhra.gov.uk/aboutagency/regframework/csm/decinterests.htm>¶

¶ European Medicines Evaluation Agency updates:¶
<http://www.emea.eu.int/whatsnewp.htm>¶

¶ MHRA Website:¶
<http://medicines.mhra.gov.uk/aboutagency/regframework/csm/csmhome.htm>¶

¶ Yellow Card Website:¶
<http://medicines.mhra.gov.uk/ourwork/monitorsafeequalmed/yellowcard/yellowcardscheme.htm>¶
<http://www.yellowcard.gov.uk>

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