

BRITISH PHARMACOPOEIA COMMISSION

Committee CX: Excipients

SUMMARY MINUTES

A meeting of this Committee was held at Market Towers, 1 Nine Elms Lane, London, SW8 5NQ on Monday 21st March 2006.

Present: Prof. G Buckton (*Chair*), Mr C Mroz (*Vice-Chair*), Mr A C Cartwright, Dr. R Cawthorne, Dr. E Anno, Dr. B R Matthews, Dr. M I Robertson.

In attendance: Dr G Lee (part meeting), Mr S Young and Mr W Payne

Apologies for absence: Dr T Duffy*, Mr V Fenton-May*,

* BP Commission member

I INTRODUCTORY REMARKS

037 **Welcome** The Chairman welcomed all those present to the meeting.

038 **BP Commission** The Committee noted the appointment of Professor David Woolfson as the next Chairman of the British Pharmacopoeia Commission. Members also noted the appointment of six new professional and two lay members to the Commission.

039 **Code of Practice** The results of the review of all Section 4 (Medicines Act) Committees were outlined. BPC Committees would be renamed Expert Advisory Groups and in future would receive fees for the work involved with their attendance at meetings. Individual members of the BPC Expert Advisory Groups such as Committee CX were permitted to hold interests providing these were declared formally on an annual basis and at any meeting where the potential for a conflict of interest, or perception thereof, might arise.

040 **Future Publication** Members noted the decision of the BP Commission that the next edition would be entitled the *British Pharmacopoeia 2007* and have an effective date of 1st January 2007. This would reflect more accurately the period for which the publication was in effect.

041 **Secretariat Staff News** Members were informed that two members of scientific staff had joined the BP Secretariat on 1st November 2005.

II MINUTES

042 The minutes of the meeting held on 26th September 2005 were confirmed as a true record.

III MATTERS ARISING FROM THE MINUTES

043 The following matters arising from the meeting held on 26th September 2005 were noted.

International Non-proprietary Names (minute 24) Members were informed that Panel N Secretariat had advised that there is no governmental exemption from the INN fee. The current

Committee CX: Excipients

fee is \$6000. One member noted that there were significant differences in nomenclature for excipient hydrates between the European and United States Pharmacopoeias and that this has caused labelling difficulties for industry.

Replacement of Chloroform in Emulsifying Wax monograph (minute 029) This would be actioned as soon as Laboratory resources allowed.

IV REPORTS AND CORRESPONDENCE

044 **Replacement of Chloroform as a Solvent** CX(06)03

Members noted the workplace exposure limits of commonly used solvents extracted from a Health & Safety Executive publication and the specific data concerning dichloromethane. The point was made that all organic solvents are harmful and their use should be minimised where practical. Dichloromethane was less harmful to an analyst but not very different with respect to environmental impact.

045 **Licensed Excipients Listing** CX(06)04

Members were informed that the Commission had discussed the proposal that Committee CX (or a subgroup thereof) should carry out a review of the MHRA list of licensed excipients to identify errors, omissions and synonyms. The conclusion was that this was outside of the Commissions remit under the Medicines Act and not a task for a BP advisory group.

046 **Stearic Acid – Acid Value test** CX(06)05

Members noted that the UK Delegation had requested a revision to the Acid Value test used for identification in this monograph. The small sample titre (3.6 ml) in the test could lead to errors in the determined results. Members were asked to advise the Secretariat of any other similar revisions that were necessary. The Committee agreed that nominal titres should be (of the order of) not less than 10 ml.

047 **Industrial Methylated Spirit – Name Change** CX(06)06

The Committee noted that Her Majesty's Revenue and Customs had introduced the Denatured Alcohol Regulations 2005, which effectively changed the name of the material from Industrial Methylated Spirit(s) to Industrial Denatured Alcohol. Members noted the decision by Commission to add a subsidiary title in the BP2007 publication and to rename the monograph when the term Industrial Denatured Alcohol becomes commonly accepted within UK industry. One Member noted that this change came into effect in January 2006 and that his Company were placing orders for IDA rather than IMS. Members noted that the BP monograph applied to two grades of IMS; one containing 99% and the other 95% by volume of alcohol (also known as 74 OP and 66 OP respectively), and that the monograph is the responsibility of Panel CI. Members were of the opinion that a previous BP monograph existed covering purple-coloured 'Methylated Spirit' (spirit-burner fuel) and suggested that this needed to be considered within the review.

V NEW MONOGRAPHS CX(06)07

048 **Monograph Initiation**

Members noted the list of monographs approved by Commission for elaboration by Committee CX and were asked by the Secretariat to identify further 'excipient-based' products for

Committee CX: Excipients

consideration. Members recommended an article in PJ and approaching the NHS Purchasing & Supply Agency for additional suggestions. Members noted that Carbomer 940/980 Liquid Gel had been assigned to Committee A; the Chairman agreed to write to Commission about including this product in future allocations to Committee CX.

049 **Carmellose Sodium Eye Drops** CX(06)08

One member noted that his employer was a competitor of the manufacturer of this product, although they did not make the actual product concerned. The Chairman stated that this did not constitute a specific conflict of interest.

The draft monograph for Carmellose Sodium Eye Drops would be included in a future publication, subject to comments from manufacturers.

050 **Alginic Acid Tablets** CX(06)09

Draft monographs for 'Alginate Raft-Forming Chewable Tablets' and 'Alginate Antacid Chewable Tablets' would be included in a future publication, subject to comments from manufacturers.

VI **MONOGRAPHS IN PROGRESS**

051 **Alginate Raft Forming Oral Suspension** CX(06)10

The draft monograph for Alginate Raft Forming Oral Suspension would be included in a future publication, subject to comments from manufacturers.

052 **Compound Alginate Antacid Oral Suspension** CX(06)11

The draft monograph for Compound Alginate Antacid Oral Suspension would be included in a future publication, subject to comments from manufacturers.

VII **REVISION OF MONOGRAPHS**

053 None to report.

VIII **EUROPEAN PHARMACOPOEIA**

054 **Comments on Draft Monographs of the Ph Eur** CX(06)12

No comments had been received for monographs within the remit of this Committee published in Pharmeuropa 17.4 and 18.1 since the last meeting. Members were actively encouraged to send comments on the draft monographs to the Secretariat as this was the most effective way to

Committee CX: Excipients

ensure that UK concerns were heard in Europe.

055 **Group of experts No. 13H: Progress Report** CX(06)13

Members noted the progress of European Pharmacopoeia Group of Experts No. 13H (Fatty Oils and Derivatives).

056 **FRC Working Party: Progress Report** CX(06)14

Members noted the inaugural meeting of European Pharmacopoeia Working Party on Functionality Related Characteristics (FRC).

Members noted that a general monograph (chapter) will be published for comment in June 2006. This had been written with Industry involvement and would describe guidelines on FRC test selection and appropriate methodology. Members noted that this was a useful opportunity to standardise testing.

057 **Ph Eur Publications** CX(06)15

Members noted new, revised and corrected texts (general chapters and monographs) that had been issued in Ph.Eur. Supplement 5.5.

IX ANY OTHER BUSINESS

058 The Chairman informed members of his intention to write to the new chairman of the BP Commission, prior to the June review of Expert Advisory Groups, concerning the responsibilities and future role of Committee CX. He invited Members to raise any such issues with him outside of the meeting.

X DATE OF NEXT MEETINGS

059 Tuesday 26 September 2005