

BRITISH PHARMACOPOEIA COMMISSION
EXPERT ADVISORY GROUP: MEDICINAL CHEMICALS 3

SUMMARY MINUTES

A meeting of Expert Advisory Group (EAG): Medicinal Chemicals 3 (MC3) was held at 10 South Colonnade, Canary Wharf, London E14 4PU on Tuesday 26th February 2019.

Present: Professor M Almond (*Chairman*), Dr J Beaman, Dr K Foster, Mr P Hampshire, Dr R Torano.

In attendance: Mr A Evans, Miss H Ashraf, Ms K Busuttil, Ms M Nanasi.

Apologies: Mr J Beach, Mr C Goddard, Dr K Pugh, Dr B Rackstraw, Mr I Williams.

Introductory remarks

The Chairman welcomed everyone to the meeting.

The Chairman welcomed Dr Foster to her first meeting and invited all to participate fully in the discussions. Members were reminded of the confidential nature of the papers and discussions.

Declaration of interests

Dr Beaman, Mr Hampshire and Dr Torano and declared interests in one or more agenda items and appropriate action was taken.

Emergency evacuation procedure

The emergency evacuation procedure for 10 South Colonnade was noted.

I MINUTES MC3(19)1

The minutes and summary minutes of the meeting held on 8th October 2018 were confirmed.

II MATTERS ARISING FROM THE MINUTES MC3(19)2

The following matters arising from the meeting held on 8th October 2018 were noted.

Acarbose Tablets MC3(19)3

The marketing authorisation holder had sent the updated data package to the Secretariat. The updated draft monograph would be discussed and potentially developed with other international pharmacopoeias.

Midazolam Oromucosal Solution MC3(19)4
Phytomenadione Preparations

Awaiting stability data from MAH prior to revising limits.

Expert Advisory Group Medicinal Chemicals 3

Diflucortolone Preparations **MC3(19)5**

The requirement to have separate monographs for 'oily cream' and 'cream' had been investigated. These were considered separately by the BNF and in prescribing software, therefore the Secretariat had retained both monographs in the BP.

Progesterone Injection **MC3(19)6**

The Secretariat had previously agreed to investigate if the BPCRS used in the related substances system suitability requirement could be removed and reference to the EPCRS made. The Secretariat confirmed that the EPCRS could be used in the injection monograph.

Calcipotriol and betamethasone Cutaneous Foam **MC3(19)7** **Calcipotriol and betamethasone Gel** **Calcipotriol and betamethasone Ointment**

The monographs had been temporarily paused whilst the use of non-routine techniques were discussed. The monographs would be published in a future edition of the BP.

Fluorescein Preparations **MC3(19)8**

A new related substances test was being investigated.

Laboratory investigations were in progress for: **MC3(19)9**

- Methadone preparations
- Tamoxifen preparations
- Mometasone preparations

Future Laboratory investigations will be scheduled for: **MC3(19)10**

- Alprostadil preparations
- Norethisterone & ethinylestradiol tablets
- Norgestimate & ethinylestradiol tablets
- Gestodene & ethinylestradiol tablets
- Clomifene Tablets
- Cytarabine Injection

In progress Laboratory reports **MC3(19)11**

- Methadone Preparations
- Mometasone Preparations

BP 2019 **MC3(19)12**

9 new monographs and 7 significantly revised monographs that were the responsibility of EAG MC3 had been published in the BP 2019. Members were thanked for their contributions and hard work, helping to publish this number of monographs.

III MONOGRAPHS FOR THE BP 2020

557 AMITRIPTYLINE PREPARATIONS **MC3(19)13** Amitriptyline Tablets and Oral Solution

The draft monograph would be published in a future edition of the BP
Members agreed that the monographs should be published in the BP 2020.

Expert Advisory Group Medicinal Chemicals 3

558 CAPECITABINE TABLETS MC3(19)14

The draft monograph would be published in a future edition of the BP.

559 CABERGOLINE TABLETS MC3(19)15

The draft monograph would be published in a future edition of the BP.

560 DUTASTERIDE CAPSULES MC3(19)16

The draft monograph would be published in a future edition of the BP.

561 ROTIGOTINE TRANSDERMAL PATCHES MC3(19)18

The draft monograph would be published in a future edition of the BP.

562 TAMOXIFEN PREPARATIONS

- Tamoxifen Tablets (revision)
- Tamoxifen Oral Solution (New)

The Laboratory had completed their investigation into the tablets and oral solution. Suitable methods had been developed and recommended for publication in the BP. The Secretariat had included these recommendations in the draft monographs.

Members thanked the Laboratory for the work completed and the draft monograph would be published in a future edition of the BP.

563 BETAMETHASONE AND NEOMYCIN PREPARATIONS MC3(19)19

- Betamethasone and Neomycin Ear Drops
- Betamethasone and Neomycin Ear Drops
- Betamethasone and Neomycin Ear Drops

The draft monograph would be published in a future edition of the BP.

564 HYOSCINE BUTYLBOMIDE TABLETS MC3(19)20

Dissolution The original method in the published monograph had been based on data received from an MAH. After further investigation with the MAH, the Secretariat had confirmed that the dissolution procedure should include a run time of 45 minutes. Members agreed to increase the dissolution run time to 45 minutes and publish the amendment in the BP 2020.

Expert Advisory Group Medicinal Chemicals 3

565 ALENDRONIC ACID AND COLECALCIFEROL TABLETS MC3(19)21

The draft monograph would be published in a future edition of the BP.

566 ADAPALENE PREPARATIONS MC3(19)19

- Adapalene Cream
- Adapalene Gel

Related substances A manufacturer from overseas had written to the Secretariat requesting wider limits for unknown impurities and the increase in the disregard limit, in line with the ICH requirements.

The Secretariat informed members that, following their investigations, there was no safety reason for requiring tighter specifications than ICH and recommended that the limits be amended to reflect ICH. Members agreed to the change and that the change should be published in the BP 2020.

567 PHENOBARBITAL INJECTION MC3(19)23

The Secretariat once again thanked members for their input and correspondence which allowed the expedition of the amendments to the monograph. The Secretariat noted that the product was now released, and the shortages reported by the NHS were under control.

Related substances the known impurities were measured against phenobarbital in the draft monograph. During the publication consultation it was noted that there were issues with the response factor of the impurities and a correction factor for both would be required. As the Laboratory did not have sufficient samples to complete the work to ascertain the correction factors, the Secretariat included external standards to control the impurities, negating the need for correction factors. Members agreed that this approach should be followed and that the monograph should be published in the BP 2020.

IV MONOGRAPHS FOR THE BP 2021+

568 BECLOMETASONE PRESSURISED INHALATION MC3(19)24

The Secretariat had investigated inhaled products to ensure they were in line with BP policies. Members were informed that the monograph was deficient in some areas and would benefit from being updated. Members agreed that the monograph should be added to the EAG MC3 Work Programme and specific tests for related substances and uniformity of delivered dose be included.

Expert Advisory Group Medicinal Chemicals 3

569 LORAZEPAM TABLETS MC3(19)25

The Secretariat had been contacted by an overseas MAH requesting that a new impurity was included in the monograph with a limit above the identification threshold. The new impurity was found to be the oxidation product of Impurity E. Members were informed that MHRA had recently reviewed the toxicity of the new impurity and deemed it acceptable at the proposed limit, members agreed to including this in the monograph.

570 EXEMESTANE TABLETS (Supplementary paper) MC3(19)26

The draft monograph would be published in a future edition of the BP.

V FOR INFORMATION

571 OMISSIONS FOR THE BP 2020 MC3(19)28

4 API and 11 finished product monographs were highlighted for omission from the BP 2020.

VI FOR INFORMATION

Members Details MC3(19)29

Members were asked to check the circulated contact details and to inform the Secretariat of any amendments required.

MC3 Work Programme MC3(19)30

A copy of the work programme for the EAG was provided for information. Members were asked to contribute data should they have an interest in any of the products.

VI EUROPEAN PHARMACOPOEIA MC3(19)31

Members were directed to go to the BP website to view the latest text from the Ph. Eur.

VII ANY OTHER BUSINESS

Out of stock BPCRS The Secretariat presented a paper on out of stock BPCRS that were used in monographs that were under the remit of the EAG.

VIII NEXT MEETING

24th September 2019