

BRITISH PHARMACOPOEIA COMMISSION
EXPERT ADVISORY GROUP: MEDICINAL CHEMICALS 3
SUMMARY MINUTES

A meeting of Expert Advisory Group (EAG): Medicinal Chemicals 3 (MC3) was held virtually on Thursday 24th September 2020.

Present: Professor M Almond (*Chairman*), Mr J Beach (*vice-Chairman*), Dr J Beaman, Dr K Foster, Mr P Hampshire, Dr B Rackstraw, Dr R Torano, Mr I Williams, Mr C Goddard

In attendance: Mr A Evans, Miss H Ashraf

Apologies: Dr K Pugh

Introductory remarks

The Chairman welcomed everyone to the meeting, the first meeting to take place virtually.

Declaration of interests

Members had all provided a declaration of their interest prior to the meeting and were asked to declare any specific interests on topics prior to the commencement of discussions; these would be noted in the minutes.

MHRA and BP Update

A Covid-19 update was provided.

MHRA future return to office – Staff continued to work from home and this was the case for the foreseeable future. The February meeting was likely to be virtual as well. The Secretariat had received positive feedback holding meetings virtually.

Some staff from the BP were seconded to the covid task force.

The staff at the Laboratory continued to work throughout the lockdown and had significantly adjusted their practices to observe new safe working requirements. During this period the work of the Laboratory had been prioritised and the BPCRS work was not interrupted to ensure the lack of standards did not hinder the supply chain of medicines.

Dr June Raine continues to be the interim CEO for MHRA.

Expenses

Members were reminded that any queries with regard to expenses should be sent to Mr Brian Delahunty at the Secretariat. Attendance fees for virtual meetings were permitted at the usual rate.

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I MINUTES

MC3(20)1a

The minutes and summary minutes of the meeting held on 24th February 2020 were deferred as notes from the meeting were not available as they were in the Canary Wharf office and could not be accessed whilst working from home. A draft set of minutes were provided for reference.

AQbD – BP/MHRA update

MC3(20)2a

Mr Maddocks, from the BP Secretariat/MHRA AQbD group, was invited to the meeting to present the latest information regarding AQbD from this group. The response to the public consultation was discussed, along with the next steps.

II MATTERS ARISING FROM THE MINUTES

MC3(20)2a

The following matters arising were noted.

Awaiting data from the MAH

- Flumetasone and Clioquinol ear drops
- Exemestane Tablets
- Zuclopenthixol Acetate/Injection

Fluorescein Preparations

A new related substance test was being investigated.

Future Laboratory investigations will be scheduled for:

- Escitalopram*
- Eplerenone*
- Imipramine*
- Alprostadil preparations
- Norethisterone & ethinylestradiol tablets
- Norgestimate & ethinylestradiol tablets
- Gestodene & ethinylestradiol tablets
- Clomifene Tablets
- Cytarabine Injection
- *prioritise for lab completion in 2021

For publication in BP2022

6 new monographs and 7 revised.

III MONOGRAPHS FOR THE BP 2021

600 ACARBOSE TABLETS

MC3(20)3a

The draft monograph had been developed with the cooperation of an MAH and the methods had been investigated by the laboratory.

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- 601 FOLIC ACID ORAL SOLUTION MC3(20)4a**
- The draft monograph would be published in a future edition of the BP.
- 602 BETAMETHASONE AND NEOMYCIN PREPARATIONS MC3(20)5a**
- Betamethasone and Neomycin Ear Drops – new
Betamethasone and Neomycin Eye Drops – new
Betamethasone and Neomycin Nose Drops – new
- The draft monographs would be published in a future edition of the BP.
- 603 FLUTICASONE AND SALMETEROL INHALATION POWDER, METERED-DOSE MC3(20)6a**
- The draft monograph would be published in a future edition of the BP.
- 604 METHADONE PREPARATIONS MC3(20)7a**
- Methadone Tablets – Revised
Methadone Oral Solution – Revised
Methadone Concentrate for Oral Solution – New
Methadone Hydrochloride Oral Concentrate – New*
Methadone Injection – Revised
- *no longer applicable
- The draft monographs would be published in a future edition of the BP.
- 605 PYRIDOXINE TABLETS MC3(20)8a**
- The draft monographs would be published in a future edition of the BP.
- 606 BECLOMETASONE PRESSURISED INHALATION MC3(20)9a**
- The draft monographs would be published in a future edition of the BP.
- 607 ESTRADIOL VAGINAL TABLETS MC3(20)10a**
- The draft monographs would be published in a future edition of the BP.
- 608 FLUMETASONE AND CLIOQUINOL EAR DROPS MC3(20)11a**
- Secretariat were contacted by the MAH to widen the content limits for clioquinol from 95.0 – 105.0% to 90.0-105.0%. Members agreed the information provided by the MAH was not sufficient to be able to investigate the issue. The Secretariat to contact the MAH for further information.

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IV MONOGRAPHS FOR THE BP 2022+

609 HYDROCORTISONE PREPARATIONS MC3(20)12a

A general discussion to gain expert opinion on the issue of related substances testing for hydrocortisone containing topical products was held. Members were informed that, during Covid-19 investigations into available standards for corticosteroid materials, several monographs utilised old technology or were missing tests for controlling related substances.

Members agreed that this could be an interesting piece of work but questioned if there was not enough of an impact for the outcome of the project to be beneficial and therefore justify the length of time this may take. The Secretariat agreed to complete a paper exercise review and bring the findings back the EAG at a future meeting.

610 ISOTRETINOIN CAPSULES MC3(20)13a

The secretariat were contacted by an MAH who requested consideration of their alternate method which controlled both assay and related substances requirements for inclusion in the BP monograph. The Secretariat noted that the formulation review and number of MAH would mean that the method would need to be investigated by the Laboratory prior to making the change.

It was noted that a prioritisation for this type of work would need to be undertaken and it may be necessary to review this type of work within the Secretariat technical groups or the BPC before beginning a large-scale project such as this.

611 INHALED PRODUCTS MC3(20)14a

The Secretariat shared a list of monographs that were affected by the mean delivery requirement for content to be 85.0 – 115.0% of label claim. The EMA guidance noted the mean of delivered dose should be + or – 15% of the label claim.

Members noted some products are old and unsure if they met requirements and suggested to contact the MAH.

V FOR INFORMATION

612 MC3 Work programme MC3(20)15a

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

613 Out of Stock BPCRS MC3(20)16a

The out of stock BPCRS that were used in the monographs that the EAG was responsible for were noted. The Laboratory confirmed the dates these were due back in stock

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VI EUROPEAN PHARMACOPOEIA

MC3(20)17a

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

VII ANY OTHER BUSINESS

MC3(20)18a

VIII NEXT MEETING

23 February 2021