

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 Wednesday 22nd September 2021.

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

MC3(21)01

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 Update Dr June Raine has been announced as the permanent CEO for MHRA. Members were made aware that the BP will remain working remotely and likely to remain the case for some time. It is anticipated that all EAG meetings will be held remotely for the time being.

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.

I MINUTES

MC3(21)02

The minutes and summary minutes of the meeting held on 24th February 2020 were confirmed.

II MATTERS ARISING FROM THE MINUTES

MC3(21)03

The following matters arising were noted.

Awaiting data from the MAH

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

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Future Laboratory investigations will be scheduled for:

- Eplerenone*
- Isotretinoine
- Alprostadil preparations
- Norethisterone & ethinylestradiol tablets
- Norgestimate & ethinylestradiol tablets
- Gestodene & ethinylestradiol tablets
- Clomifene Tablets
- Cytarabine Injection
- *prioritise for lab completion in 2021/22

For publication in BP2022

Folic Acid Oral Solution (N)

Betamethasone and Neomycin Ear Drops (N)

Betamethasone and Neomycin Eye Drops (N)

Betamethasone and Neomycin Nose Drops (N)

Fluticasone and Salmeterol Inhalation Powder, Metered-Dose (N)

Methadone Concentrate for Oral Solution (N)

Methadone Injection (R)

Methadone Tablets (R)

Methadone Oral Solution (R)

Pyridoxine Tablets (R)

Beclometasone Pressurised Inhalation (R)

Estradiol Vaginal Tablets (R)

III DISCUSSION TOPICS

623 BPCRS ALTERNATIVES

MC3(21)04

Secretariat to further investigate how to distinguish between BPCRS and EPCRS and continue to find suppliers for materials when BPCRS becomes unavailable.

624 ULM TRANSFERS

MC3(21)05

Secretariat to take on members recommendations to transfer ULM monographs to MC3 once reviewed and continue to use the usual process in establishing monographs when added to work programme.

IV MONOGRAPHS FOR THE BP 2023+

625 Escitalopram Preparations

MC3(21)06

The secretariat to continue investigating identification method.

626 IMIPRAMINE TABLETS

MC3(21)07

The draft monograph would be published BP2023.

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627 MOMETASONE CREAM MC3(21)08

Members agreed the Secretariat to contact the MAH to gather batch data and to identify the impurities.

628 ROPINIROLE PREPARATIONS MC3(21)09

Members agreed for the secretariat to further investigate the identification and assay tests.

V FOR INFORMATION

629 MC3 Work Programme MC3(21)10

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.

EUROPEAN PHARMACOPOEIA MC3(21)11

see www.pharmacopoeia.com for European matters

VII NEXT MEETING MC3(21)13

TBC