

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 February 23rd 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

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)00

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

II MATTERS ARISING FROM THE MINUTES

MC3(21)1

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:

- Escitalopram*
- Eplerenone*
- Imipramine*
- Isotretinoine
- 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

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 MONOGRAPHS FOR THE BP 2022

614 ALENDRONIC ACID AND COLECALCIFEROL TABLETS MC3(21)3

The secretariat to continue investigating alternative methods.

615 CLOMIPRAMINE (BPCRS CHANGE) MC3(21)4

The draft monograph would be published for public consultation.

616 FLUMETASONE AND CLIQUIONOL EAR DROPS MC3(21)5

Members agreed the Secretariat to contact the MAH for further investigation regarding the content limits.

IV MONOGRAPHS FOR BP2022+

617 Brimonidine Tartrate Eye Drops - Numerical limits MC3(21)6

Monograph sent to the laboratory for testing.

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- 618 IMIPRAMINE TABLETS MC3(21)7**
- The draft monograph to be updated and put forward for publication consultation.
- 619 SODIUM PICOSULFATE ORAL DROPS MC3(21)8**
- The draft monograph to be updated and put forward for publication consultation.
- 620 INHALED PRODUCTS MC3(21)9**
- Members agreed the secretariat to continue to liaise with MAH to investigate the content limit changes
- V FOR INFORMATION MC3(21)10**
- LC-UV/DAD**
- An overview was provided on the adoption of new analytical technologies: LC/UV-DAD for identification in BP monographs. Members were given information on the background of this and guidance on how to adapt this into BP monographs.
- 621 MC3 Work Programme MC3(21)11**
- 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.
- 622 Out of Stock BPCRS MC3(21)12**
- A table of the out of stock BPCRS were presented to the members.
- EUROPEAN PHARMACOPOEIA MC3(21)13**
- see www.pharmacopoeia.com for European matters
- VII NEXT MEETING MC3(21)14**
- TBC