

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 via MS Teams on Wednesday 22nd February 2023.

Present: Mr J Beach (*acting Chairman*), Dr K Foster, Mr C Goddard, Mr P Hampshire, Dr V Ibekwe, Dr R Torano, Mr I Williams.

In attendance: Mr A Evans, Mrs M Dmitrieva, Miss Annie Estlin
Mr Carlo Emanuele Giartosio (BP Commission Member),
Dr. S Greatorex (BP Laboratory)

INTRODUCTORY REMARKS

The Chairman welcomed everyone to the meeting.

Declaration of Interests Members had all provided a declaration of their interests 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 Mr Julian Beach had taken on the position of the group Chairman. It was announced that Mr. James Pound, the former BP Secretary and Scientific Director had moved to the Deputy Director of Standards and Compliance position.

I MINUTES

MC3(23)01

The minutes of the meeting held on 28th September 2022 were confirmed.

II MATTERS ARISING FROM THE MINUTES

MC3(23)02

The following matters arising were noted.

Awaiting data from the MAH

- Flumetasone and Clioquinol Ear Drops
- Brimonidine Eye Drops
- Zuclopenthixol Acetate/Injection

Awaiting data from the LAB

- Betamethasone Preparations
- Neomycin Preparations
- Diazepam preparations

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Awaiting for the European Pharmacopoeia action

- Naloxone Hydrochloride (mutagenic impurity D).

For publication in BP2023

Calcipotriol and Betamethasone Foam (R)
Calcipotriol and Betamethasone Gel (R)
Calcipotriol and Betamethasone Ointment (R)
Citalopram oral drops (R)
Citalopram Tablets (R)
Colecalciferol Tablets (R)
Cytarabine Injection (R)
Dutasteride Capsules (R)
Ergocalciferol Tablets (R)
Imipramine Tablets (R)
Methadone Oral Solution (R)
Methadone Concentrate for Oral Solution (R)
Mirtazapine Oral Solution(R)
Mirtazapine Orodispersible Tablets(R)
Mirtazapine Tablets(R)
Pancuronium Injection(R)
Prednisolone Sodium Phosphate Oral Solution (R)

III DISCUSSION TOPICS

653 BP Green initiatives MC3(23)03

The topic was presented by the Secretariat for further discussion. The EAG members acknowledged the necessity and timeliness of the Green Initiatives project

654 Harmonisation of Pharmacopoeial Standards MC3(23)04

The EAG members were provided with the results of the pharmacopoeial requirements comparison in terms of the extractable volume of parenteral preparations. Members agreed that harmonisation was important.

IV MONOGRAPHS FOR THE BP 2024+

655 Estradiol Tablets MC3(23)05

Members agreed that the Secretariat should make amendments and publish the monograph in the BP 2024.

656 Cytarabine Injection MC3(23)06

It was agreed that the Secretariat should make amendments and publish the monograph in the BP 2024.

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- 657 Citalopram Preparations MC3(23)07**
- Members agreed that the Secretariat should make amendments and publish the monograph in the BP 2024.
- 658 Morphine Sulfate Injection MC3(23)08**
- Members agreed that accelerated stability data should not be used to justify increasing the limits for impurities.
- 659 Colecalciferol for system suitability EPCRS Containing Monographs MC3(23)09**
- Members agreed that the Secretariat should make editorial amendments and publish the monographs in the BP 2024.
- 660 Atracurium Besilate Injection MC3(23)10**
- Members agreed that the Secretariat should explore the possibility of elaborating on two monographs – Atracurium Besilate Powder for Injection and Atracurium Besilate Injection.
- 661 Oxytocin Injection MC3(23)11**
- It was agreed that the Secretariat should contact the MAH and make a decision about including this item in the work program.
- V FOR INFORMATION**
- 662 OMISSIONS MC3(23)12**
- The following EAG MC3 monographs would be omitted from the BP 2024.
- Estramustine Sodium Phosphate (API)
 - Estramustine Phosphate Capsules
 - Diflucortolone Valerate (API)
 - Diflucortolone Ointment
 - Diflucortolone Oily Cream
 - Diflucortolone Cream
- 663 MC3 Work Programme MC3(23)13**
- 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.
- VII NEXT MEETING**
- 19th September 2023 – To be confirmed.