

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 28th September 2022.

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

In attendance: Mr A Evans, Miss H Ashraf

Apologies: Dr K Foster

INTRODUCTORY REMARKS

The Chairman welcomed everyone to the meeting.

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 Members were made aware the Canary Wharf office was now officially open and a hybrid working has been put in place. A further update on recruitment was also provided to members.

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(22)16

Draft minutes and summary minutes of the February 24th 2022, meeting have been circulated to the EAG members via email. Members were asked for comments and the minutes were signed off as accurate.

II MATTERS ARISING FROM THE MINUTES

MC3(22)17

The following matters arising were noted.

- Betamethasone and neomycin preparations. A problem with the related substances test was being investigated.
- Diazepam preparations. Work with MAH to investigate suitable methods was ongoing.

Expert Advisory Group Medicinal Chemicals 3

IV MONOGRAPHS FOR THE BP 2024

- 639 Escitalopram Preparations** **MC3(22)18**
The draft monograph would be published BP2024.
- 640 Citalopram Preparations** **MC3(22)19**
The draft monograph to be sent to public consultation.
- 641 Brimonidine Eye drops** **MC3(22)20**
The draft monograph would be published BP2024.
- 642 Flumetasone and Clioquinol Ear Drops** **MC3(22)21**
Members agreed for the secretariat to contact the MAH for more information regarding their degradation issue.
- 643 Dutasteride Capsules** **MC2(22)22**
The draft monograph would be published BP2024.
- 644 Morphine Sulfate Injection** **MC3(22)23**
The draft monograph would be published BP2024.
- 645 Naloxone Hydrochloride (API)** **MC3(22)24**
Members agreed BP secretariat should continue discussion with the Ph. Eur. regarding the impurity D.
- 646 Discussion Topic 1** **MC3(22)25**
BP included in Finished Product Specification
Members discussed expectations on industry and any significant impacts when the BP create their standards. Discussion on regulatory burden, impact of the MAH and considerations when an MAH registered in-house product becomes the BP method.
- 647 Discussion Topic 2** **MC3(22)26**
Chromatographic Separation Techniques revised Ph. Eur. text
This was for information only. Members discussed the harmonisation of the Chromatographic Separation Techniques chapter.

Expert Advisory Group Medicinal Chemicals 3

648 Omissions MC3(22)27

Members were happy with the omissions and felt they will not have an impact on the BP if removed.

**V FOR INFORMATION
649 MC3 Work Programme MC3(22)28**

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(22)29

see www.pharmacopoeia.com for European matters

VII NEXT MEETING MC3(22)30

22 February TBC