BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group: Antibiotics

SUMMARY MINUTES

A meeting of Expert Advisory Group: Antibiotics was held via videoconference on Tuesday 13th September 2022.

Present: Dr R Horder (*Chair*), Dr G Cook (*Vice-chair*), Dr G Clarke, Mr E Flahive, Mr V Jaitely, Dr W Mann, Prof J Miller, Mr J Sumal and Mr I Williams. Mr S Jones also attended the meeting.

Apologies: Mr G Blake.

In attendance: Mr P Crowley, Ms A Thomson, Ms C Swann, Mr K Rakowski, Ms K Busuttil and Mr C Thompson.

548 Introductory remarks

Welcome The Chair welcomed members to the meeting as well as Ms K Busuttil and Mr C Thompson from the BP Laboratory. A special welcome was extended to Ms C Swann and Mr K Rakowski, new staff members of the BP Secretariat, and to Mr S Jones who was attending the meeting as a new member of the BP Commission.

549 General Matters **ABS(22)14**

Declaration of Interests Members were reminded of the requirement to declare specific interests via Microsoft Forms, and as they arose during the meeting.

Confidentiality Members were reminded of the confidential nature of discussions and minutes of the meeting, with all papers marked OFFICIAL-SENSITIVE.

Freedom of Information Members were asked to refer any FOI requests they receive to the Secretariat.

Membership Members were asked to inform the Secretariat of any changes to their contact details.

I MINUTES **ABS(22)15**

550 The minutes of the meeting held on 22nd February 2022 were confirmed.

II MATTERS ARISING FROM THE MINUTES **ABS(22)16**

551 The following matters arising from the meeting held on 22nd February 2022 were noted.

Pivmecillinam Tablets (minute 535 refers) This monograph had been published in the BP 2023.

Teicoplanin for Injection (minute 535 refers) This monograph had been published in the BP 2023.

Clarithromycin Granules for Oral Suspension (minute 535 refers) Laboratory evaluation of the revised dissolution and related substances procedures had started and would be reported at a future meeting of this EAG.

Cilastatin and Imipenem for Infusion (minute 536 refers) This monograph had been published in the BP 2023.

Vancomycin Preparations (minute 537 refers) These monographs had been published in the BP 2023.

Tacrolimus Preparations (minute 538 refers) The draft monographs would be included in a future publication, subject to resolution of any outstanding points.

Chloramphenicol Preparations (minute 539 refers) These monographs had been published on the website for Q3 2022 public consultation with a view to publishing in the BP 2024. No comments had been received.

Levofloxacin Preparations (minute 541 refers) The draft monographs would be included in a future publication, subject to resolution of any outstanding points.

III MONOGRAPHS FOR THE BP 2024

552 CEFALEXIN ORAL SUSPENSION (Revised) ABS(22)17

Monographs for Cefalexin Capsules, Oral Suspension and Tablets had been reviewed by members at the October 2021 meeting of this EAG and published for consultation between October and December 2021. No comments had been received and so the Secretariat had contacted manufacturers directly for comment. One manufacturer of the Oral Suspension had responded with concerns on the Dissolution test.

Dissolution Comments put forward by the manufacturer were discussed by the members. It was agreed that the dissolution test should be removed from the monograph for publication in the BP2024.

It was noted the BP contained limited guidance on dissolution testing of Oral Suspension. Members agreed that EAG: PCN should be asked to consider developing specific guidance on dissolution of Oral Suspensions to supplement Appendix XII B1.

553 CICLOSPORIN PREPARATIONS ABS(22)18
Ciclosporin Eye Drops (Revised)
Ciclosporin Eye Ointment (New) (Veterinary)

The BP Laboratory had completed an assessment of the Ph. Eur. Related Substances and Assay procedures and found them to be suitable for the licensed Eye Drops and Veterinary Eye Ointment products with a number of modifications.

The draft monograph for the Eye Ointment would be included in a future publication, subject to resolution of any outstanding points.

Identification Members requested removal of the secondary requirement of concordant retention time in the Assay, stating that IR is sufficiently discriminatory.

Acidity or alkalinity Members requested that the pH limit in the Eye Drops monograph be brought in line with the sole UK manufacturer, to pH 4.2-7.2.

Related substances The Laboratory made several modifications to the isocratic LC procedure from the Ph. Eur. Ciclosporin monograph for it to be suitable for the product formulations, mainly due to the low concentrations of drug substance in the products and challenging excipients. Members endorsed modification of the diluent to prevent the sample solution forming an emulsion, reduction in solution concentrations and increased injection volume to ensure column loading was maintained.

The Laboratory also noted that the Eye Drops product contained a late eluting excipient which required a much longer run time than the Ph. Eur. procedure. Members considered a gradient wash proposed by the Laboratory but agreed that users could vary the procedure to account for any excipients specific to their product and so the longer isocratic procedure should be published. It was noted that the gradient programme could be included in the chromatographic details of the additional information document which would accompany the monograph.

It was noted that in the licensed impurity specifications for the Eye Drops, the limit for impurity C reduced from 1.7% at release to 1.0% at end of shelf life. Although unusual, it was agreed that monograph would need to cover the widest limits and so 1.7% should be specified.

SECRETARIAT NOTE*: It was noted that the retention of Impurity C needed to be confirmed in order to demonstrate the method was suitable to control it. The Laboratory was to inject this impurity prior to this monograph being confirmed for publication.*

Assay The Laboratory found the modified LC procedure harmonised with the Related substances to be suitable for determination of Assay. All samples were found to comply with the standard 95.0 – 105.0% content statement although it was noted that the lower limits included in the specifications for the Eye Drops were 92.0%. Members agreed to retain the standard lower limit of 95.0% and review and comments and data from manufacturers following the public consultation

554 ENROFLOXACIN PREPARATIONS (New) (Veterinary) ABS(22)19
Enrofloxacin Concentrate for Oral Solution
Enrofloxacin Injection
Enrofloxacin Oral Solution
Enrofloxacin Oral Suspension
Enrofloxacin Tablets
Enrofloxacin Solution for Use in Drinking Water

The draft monographs would be included in a future publication, subject to resolution of any outstanding points.

555 ERYTHROMYCIN PREPARATIONS (Revised) ABS(22)20
Erythromycin and Zinc Acetate Lotion
Erythromycin Gastro-resistant Capsules
Erythromycin Gastro-resistant Tablets

The Erythromycin family of monographs had been revised in the BP 2021 to include updated methodology for dissolution, related substances and Assay based on a

laboratory assessment of the relevant Ph. Eur. drug substance related substance and Assay procedures.

Correspondence from a manufacturer had highlighted that the *erythromycin for impurity M identification EPCRS* was no longer available for sale and so users were unable to perform the related substance procedure as drafted.

Related substances A solution of *erythromycin for impurity M identification EPCRS* was specified in the Erythromycin drug substance monograph, but not in the other forms. Erythromycin was the drug substance in the Erythromycin and Zinc Acetate Lotion monograph and the Erythromycin Gastro-resistant Capsules and Tablets monographs and so these contained a limit for impurity M of 1.0% and a solution to identify it harmonised with the Ph. Eur. 9.0 drug substance monograph.

This solution was removed from the drug substance in the Ph. Eur. 10.4, and the limit for impurity M was reduced from 1.0 to 0.4% based on a review of batch data. 0.4% was the limit for any other impurity and it was therefore not required to specify impurity M in the monograph, hence why the standard to identify it had been discontinued.

The Secretariat noted that when the BP Laboratory had assessed the related substance procedure, they observed levels of impurity M of 0.44% in Gastro-resistant Capsules which were 2 years past their expiry. Impurity M was not detected in the Gastro-resistant Tablets or in the Erythromycin and Zinc Acetate Lotion products which included samples over 1.5 years past expiry.

Members agreed that the monographs should be revised to remove the specific limit for Impurity M in line with the Ph. Eur. and that the corresponding solution be omitted from the monograph, subject to comments from the public consultation.

556 TIGECYCLINE FOR INFUSION (Revised) ABS(22)21

The Tigecycline for Infusion monograph had first been published in the BP 2019 based on procedures provided by a donor manufacturer. It had then been updated in the BP 2022 to correct reference to reagents in line with the donor method as well as impurity identification.

Acidity The Secretariat had been notified that an application for a Tigecycline for Infusion product had justified an alternative pH range of 5.0 – 6.5 based on the composition of their formulation which was supported by development data. Members discussed how this could be accommodated in the monograph and agreed that a relaxation of the upper limit towards a neutral pH did not represent a safety risk. It was agreed that this was preferable to removing the test and losing control of acidity.

557 TETRACYCLINE PREPARATIONS (Revised) ABS(22)22

Tetracycline Capsules
Tetracycline Tablets

Members had previously agreed at the October 2021 meeting to update the Tetracycline Capsules and Tablets monographs, most significantly by adopting the Related Substances procedure from the USP Tetracycline Capsules monograph. This would provide greater control of known impurities representing a significant improvement from the published version.

Members had endorsed limits of 3.0% for impurity A, 1.0% for impurity D and 0.5% for impurity C for the purpose of public consultation with the unspecified impurities limit and reporting threshold drafted in line with ICH guidelines. Comments had been received from one manufacturer in response to the October to December 2021 consultation.

Identification Members had previously recommended moving away from the existing TLC procedure and adopting LC–UV/DAD for identification purposes, the suitability of which would be assessed by the BP Laboratory. The Secretariat highlighted that the USP monograph for Tetracycline Hydrochloride Capsules adopted this procedure. In light of pharmacopoeial use of LC-UV/DAD identification, members confirmed that the Laboratory assessment was no longer required.

Related substances The manufacturer had identified a number of areas for correction including peak identification solutions and a misalignment of limits for impurity B and C with the Ph. Eur. and the licensed specifications. Members confirmed changes to reflect these corrections.

Inclusion of a total impurities limit of 4.0% was endorsed by members, as no comments had been received on this during the consultation window.

Assay Members agreed that the system suitability should be removed on the basis that this would be assessed under Related substances, and in light of the Appendix III general requirements.

558 RIFAXIMIN TABLETS (Revised) ABS(22)23

A monograph for Rifaximin Tablets had first been published in the BP 2022 following a public consultation between April and June 2020 to which no comments had been received. The Secretariat had since been contacted by two manufacturers regarding issues with the UV quantification in the Dissolution.

Dissolution The Dissolution procedure proposed at the March 2020 meeting of this EAG had been sourced from an academic paper. In this paper a linearity study had been performed by first creating a Ringbom curve with concentrations ranging from 1 to 200 ug/mL, or 0.0001 – 0.02% w/v, prepared in a 50mM acetate buffer at pH 5.0 with 0.2% SLS. Based on the Ringbom curve, six concentrations between 15 – 50 ug/mL, or 0.0015 – 0.005% w/v, were chosen to evaluate linearity. The accuracy results indicated a target concentration of 30 ug/mL or 0.003% w/v.

Both manufacturers had reported issues with the drafted standard concentration of 0.02% w/v rifaximin EPCRS noting that it does not dissolve at that concentration and that it over absorbs with an absorbance of approximately 4.0. Both manufacturers recommend reducing the concentration by 10-fold as well as reducing the path length of the UV cell.

Based on the linear range and accuracy parameters used for validation in the analytical paper, a concentration of 0.003% w/v should have been specified for the sample and standard concentration. It was noted that the concentration of the 200mg tablet in the dissolution vessel was 0.022% w/v and so could have been diluted to this concentration. Members noted that the dissolution media should have included an instruction to adjust the pH to 5.0 and confirmed this should be included in the updated draft monograph for publication in the BP 2023 pending any comment from the manufacturers.

Regarding the dissolution conditions, one of the manufacturers noted that the FDA dissolution database stated alternative conditions and that they employed these conditions, which they had used to assess their product against competitors' formulations. It was noted that the concentration of sodium lauryl sulfate used in the FDA media increased with the higher strength tablet. Members recognised the value of the FDA dissolution database, but agreed that the corrected dissolution test should be published in this case based on the FDA procedure being strength dependent.

IV MONOGRAPHS FOR THE BP 2025+

559 DOXYCYCLINE PREPARATIONS (Revised) ABS(22)24

Doxycycline Capsules
Doxycycline Dispersible Tablets
Doxycycline Prolonged-release Capsules
Doxycycline Tablets

The Doxycycline family of monographs had last been reviewed by members at the February 2018 meeting prior to publication in the BP 2019. As part of the BP portfolio review, the Doxycycline Capsules monograph had been identified for modernisation due to the presence of a chemical identification test and non-Q based dissolution.

Following an assessment of the monograph family as a whole, it was noted that although the related substances and Assay procedures were in line with current expectations, a number of other tests would benefit from revisions.

Identification The Capsules monograph included a TLC identification and two colour tests, a reaction with sulphuric acid and the reaction of chlorides which were common with the Ph. Eur. drug substance monograph for the Hyclate. All other BP monographs relied on concordant retention in the Assay as well as a TLC procedure.

The USP contained a number of different means for identification across their product monographs including LC-DAD concordant spectra and retention time, Infrared and retention time and as well as TLC identification.

While it was considered preferable to include LC-DAD concordant spectra and retention time, the UV spectra of doxycycline obtained from the products was not known and so members agreed to retain the TLC procedure and remove the chemical colour tests from the Capsules monograph for the BP 2024. Members also requested that the BP Commission be asked to consider the general replacement of TLC with more current technology based on an assessment of environmental and cost factors.

Dissolution (Capsules and Dispersible Tablets) In 2019, a dissolution test had been introduced into the Capsules monograph. In the Dispersible Tablets monograph, the disintegration test had been removed and the existing dissolution test updated. As both of these monographs had been published prior to the BP 2008, policy at the time was to retain the legacy dissolution limits which was for a release of not less than 70% of the prescribed amount in 30 minutes for the Capsules and 45 minutes for the Dispersible Tablets. The Tablets monograph was new and so a limit of 75% (Q) in 45 minutes was agreed. Supplementary Chapter I E had been updated after publication of these monographs removing this limitation on application of "Q" values.

Dissolution limits in the licensed specifications ranged from 70% in 30 minutes to 85% in 15 minutes with a number applying 80% (Q) in 30 minutes. It was therefore agreed that a limit of 80% (Q) in 30 minutes be included in the draft Capsules and Dispersible Tablets monographs for public consultation with a view to reviewing responses at the February 2023 meeting of this EAG if necessary.

Absorbance A test for light absorbing impurities under the name Absorbance was included in the monographs of all pharmaceutical forms and the drug substance in addition to a HPLC related substance procedure.

When a HPLC procedure for 6-epidoxycycline and metacycline was first introduced into the monographs in 1994, the innovating manufacturer noted that there was no positive correlation between results from the HPLC procedure and the Light Absorbing Impurities test. As such it was necessary to retain the Light Absorbing Impurities test as it was thought to measure a component not determined by HPLC.

The related substances test in the drug substance monograph had then been improved in Ph. Eur. Supplement 8.4 providing control of 4 additional impurities (C-F) in addition to the Impurity A (6-epidoxycycline) and Impurity B (metacycline). During the Pharmeuropa stage for this monograph, the Belgian NPA proposed that the light-absorbing Impurities could be deleted since all related substances were determined by means of liquid chromatography, but a decision was taken to maintain the test under the different heading (Absorbance).

It was noted that the use of the absorbance/ light-absorbing impurities test were expected to be discussed at a future Ph. Eur. Group 7 meeting and the outcomes would be brought back to this EAG for further consideration.

Loss on drying In line with previous decisions of this EAG regarding the relevance of tests for water, the Secretariat had considered removal of this test from the family of monographs. It was noted that the Capsules and Tablets monographs which contain the Hyclate form of doxycycline, had a limit of 8.5% whereas the Dispersible Tablets and Prolonged-release Capsules monographs, which contain the monohydrate form, had limits of 6% and 5% respectively. It was noted that for the drug substance, the water specifications were 1.4 – 2.8% for the Hyclate and 3.6 – 4.6% for the Monohydrate.

Although the water content appeared to be formulation dependent, it was agreed that this test be retained as it was defined in ICH Q6A.

560 METRONIDAZOLE PREPARATIONS ABS(22)25
Metronidazole Cream (New)
Metronidazole Gel (Revised)
Metronidazole Infusion (Revised)
Metronidazole Tablets (Revised)
Metronidazole Oral Suspension (Revised)
Metronidazole Suppositories (Revised)
Metronidazole Vaginal Gel (New)

The Metronidazole family of monographs had not been updated for a considerable period, the last update being replacement of the TLC related substances test in some monographs with a LC procedure harmonised with the Ph. Eur. They were a highly used family of monographs and so had been prioritised for revision.

The draft monographs for the Cream and Vaginal Gel would be included in a future publication, subject to resolution of any outstanding points.

Content The Suppositories and Gel monographs included a content of 92.5 – 107.5% but members confirmed that 95.0 – 105.0% would be suitable in the suppositories monograph based on licensed specifications. For the Gel products, a range of content limits had been approved but it was agreed 95.0 – 105.0% should be initially investigated. The Infusion monograph contained a limit of 95.0 – 110.0% but all other monographs were published with a 95.0 – 105.0% content statement.

Identification The Secretariat noted that Infrared was used as the primary means of identification in all published monographs with the exception of the Gel. The spectra were the sole means of identification in the Infusion, Suppositories and Oral Suspension monographs.

The Gel monograph had been published in 1998 but no work had been conducted to develop an infrared procedure. It was noted from the specifications that manufacturers referred to identification by HPLC indicating concordant retention time in the Assay. It was proposed that the BP Laboratory should assess the suitability of an infrared identification procedure, and that if this was not successful, to investigate suitability of a LC-DAD identification based on the proposed LC Assay, which it was noted was the approach the USP take for the majority of their product monographs.

It was further noted that the Tablets monograph contains two chemical tests which the Members confirmed should be omitted.

Dissolution (Tablets and Oral Suspension) It was proposed that the dissolution test from the USP monograph for Tablets be included in the BP Tablets monograph. The specifications listed a range of acceptance criteria from 60% in 45 minutes to 80% (Q) in 15 minutes with the USP specifying (85%) Q in 60 minutes. A limit of 75% (Q) in 45 minutes was endorsed by members for inclusion in the draft monograph with a view that the BP Laboratory assess the suitability of the procedure and limit prior to consulting manufacturers.

No pharmacopoeial procedure existed for the Oral Suspension but a journal article had been published containing a procedure. It was noted that one of the manufacturers of this product included an acceptance criterion of 75% (Q) in 30 minutes in their specifications. The Secretariat proposed that the BP Laboratory investigate the suitability of this procedure for use in the BP Oral Suspension monograph.

Members noted that Metronidazole was a BCS Class 1 compound as such a more rapid dissolution limit would be appropriate. It was agreed that 80% (Q) in 30 minutes would be more appropriate. It was also noted that it would be useful to work with the USP to develop harmonisation across the pharmacopoeias due to the high usage.

Acidity (Gel, Infusion, Oral suspension) Published monographs for Gel, Infusion, and Oral Suspension products contained a test for Acidity with limits of 4.5 – 6.0, 4.5 – 6.0 and 5.0 – 6.5 respectively. Members confirmed the limits should be widened to 4.5 – 7 for the Gel and Infusion products and 4.7 – 6.7 for the Oral Suspension to reflect licensed specifications but queried if it was feasible to determine the pH of a Gel, which it was agreed the laboratory should assess.

Related substances All published monographs with the exception of the Oral Suspension included a related substances test controlling Ph. Eur. impurity A (2-Methyl-

5-nitroimidazole). A TLC procedure was included in the Gel monograph and a LC procedure was used in all other monographs.

The Ph. Eur. LC procedure for metronidazole was very similar to that included in the BP monographs, subject to some minor differences including column length and BP instruction on adjusting sensitivity. Notably, the Ph. Eur. included limits for any other impurity and total impurities. For Metronidazole benzoate however, a gradient LC procedure was described capable of controlling metronidazole, 2-Methyl-5-nitroimidazole and an additional impurity (benzoic acid) specific to the benzoate form.

The USP employed a slightly different procedure using a methanol water mobile phase in contrast to the buffered mobile phase used in the BP and Ph. Eur. Like the Ph. Eur., the USP include a limit for impurity A as well as any other impurities and total impurities.

It was agreed that the existing LC procedure, which was harmonised with the Ph. Eur., should be included in all product monographs with additional limits for any other impurity and total impurities in line with the licensed specifications. Members also agreed that the laboratory assess the suitability of this procedure for the revised Gel and Oral Suspension monographs.

Nitrite (Infusion and Gel only) A test for Nitrite was included in the Infusion and Gel monographs only, with quantification based absorbance at 524nm. It was noted that specifications for these products include a range of limits for Nitrites but that the published limit of < 50 ppm was with respect to the product and not the active substance. Members noted that Nitrite is produced as a degradant in solutions of metronidazole, particularly on sterilisation and so it was noted that the test may also be required for the Oral Suspension monograph.

Metronidazole (Oral suspension only) A test for determining free metronidazole was included in the Oral Suspension monograph, but it was noted that this would not be required should the Ph. Eur. related substances procedure be included, as this method was capable of controlling levels of impurity A (Metronidazole).

Assay The Gel and Oral Suspension monographs currently included an LC procedure, the Tablets and Suppositories include a titration and the Infusion a UV absorbance procedure. It was agreed that the BP Laboratory assess the suitability of the USP Assay procedure and the BP Assay for use in all monographs other than the Gel and Oral Suspension.

V FOR INFORMATION

561 RENAMING OF EAG: ANTIBIOTICS ABS(22)26

At the November 2021 meeting of the BP Commission, members endorsed the recommendation to expand the remit of EAG: ABS to include antifungals, antivirals, antiprotozoals and anthelmintics, covering the entirety of BNF Chapter 5. This resulted in the transfer of over 70 monographs, mainly from EAG: MC1, creating an enhanced work programme for EAG: ABS.

It was noted that the group retained responsibility for some monograph families of fermentation products and semi-synthetics, for example Tacrolimus and Ciclosporin, that did not fall under BNF Chapter 5. The reason these had been previously assigned to the group was because they fall under the remit of European Group 7.

The Chair of the BP Commission had recommended that the group's name be reconsidered to better reflect the products it covered. Based on the alignment of the group's responsibilities with BNF Chapter 5 title: Infections, and the naming format of other EAGs, members endorsed the Secretariat's proposal for the EAG to be renamed Anti-infective medicines, abbreviated to AIM.

562 OUT OF STOCK BPCRS REVIEW ABS(22)27

Members reviewed the 2 out-of-stock BPCRS for monographs relevant to EAG: ABS which the Laboratory expected to be bring back in stock shortly. No specific concerns were raised, and members thanked the Laboratory for their continued high level of service.

563 WORK PROGRAMME ABS(22)28

The Secretariat presented an overview of the work programme noting for the BP 2024 there were 19 new monographs and 16 major revisions planned, of which there was a reasonable risk that 4 revisions would missing the publication deadlines.

It was noted that significant progress had been made with the prioritised list of monograph projects originating from the portfolio review with two monograph families published in the BP 2023 and a further 6 planned for the BP 2024. Work was progressing on 4 more monograph families for publication in later editions.

The work of the Laboratory was also recognised with 3 out of the 5 planned projects for the 2022/23 work plan completed. It was noted that the Laboratory had a significant number of EAG ABS requisitions available to them should space open up for them to take on additional projects, and that prioritisation of the Laboratory work plan continued to be based on product usage data while ensuring veterinary monographs continue to be supported.

564 BRITISH PHARMACOPOEIA MATTERS ABS(22)29

BP activities The BP was seeking views from stakeholders on the value of continuing to include the following production statement in monographs for drug substances and formulated preparations containing mesilates, following discussion at BPC. The deadline for comment was 30th September 2022.

The ATMP working party had released two pieces of best practice guidance, for Flow Cytometry and Vector Copy Number.

A BP monograph for Atorvastatin Tablets was published in the BP 2023, which was the first to feature a test where AQbD principles were applied during monograph development. Users would be able to find details on the experimental work on the BP website in the 'more resources' section on the monograph.

BPC and EAG membership 4 new BPC members had been appointed for a 4 year term from 1 May 2022: Edward Bush, Carlo Giartosio, Sean Jones, and James Rickard.

Following the extension of the BPC Chair's term until October 2022, the position had been re-advertised and 9 applications received.

Dr Anna Marie Brady had been appointed to role of vice-Chair of BPC, as Prof. Alastair Davidson had stepped down from this position when he reached the end of his BPC term.

BP and Lab Services team - staff changes A number of staff changes within the BP Secretariat were flagged for members information.

VI 565 EUROPEAN PHARMACOPOEIA ABS(22)30

Group of Experts 7 – Antibiotic An informal report of the 171st meeting of Group 7 (May ’22) had been provided by the UK expert for information.

Pharmeuropa The Secretariat thanked members for their continuing support for the work of the UK delegation to the European Pharmacopoeia.

Since the February 2022 meeting, monographs had been posted for review on Pharmeuropa 34.2 and 34.3. It was noted that several of the proposed revised monographs falling under the remit of EAG ABS were expected to impact related BP monographs including the Trimethoprim and Oxytetracycline families.

The Secretariat noted that the deadline for comments on Oxytetracycline Hydrochloride and Oxytetracycline Dihydrate was the 30th September and any comments would be gratefully received.

European Commission It was noted that the 173rd European Pharmacopoeia Commission meeting have been held remotely in June 2022. The 174th Session would be held in November 2022.

VII ANY OTHER BUSINESS

566 The national mourning for the passing of Queen Elizabeth II was noted and as a mark of their respect, members held a minute’s silence.

VIII NEXT MEETING

567 The date of the next meeting was confirmed as the 22nd February 2023.