BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group: Antibiotics

SUMMARY MINUTES

A meeting of this Expert Advisory Group was held at 151 Buckingham Palace Road, London, SW1W 9SZ on Wednesday 21st September 2016.

Present: Dr R Horder *(Chairman),* Dr G Cook (*Vice-chairman*), Dr W Mann, Mr I Williams, Prof J Miller, Mr G Blake and Dr V Jaitely.

Apologies: Mr P Ellis, Mr E Flahive.

In attendance: Mr M Whaley, Mr P Crowley, Dr A Gardiner, Dr G Kemp, Mrs F Lee (BP Lab), Ms C Galdino (BP Lab) and Ms A Vasilaki (BP Lab). Dr F Swanson attended the meeting for the items discussed under minutes 335 and 336.

Dr G Cook, Dr Horder and Mr Blake declared interests in one or more agenda items and appropriate action was taken.

329 Introductory remarks

Welcome
The Chairman welcomed members to the meeting of Expert Advisory Group ABS: Antibiotics. A special welcome was extended to Mr Greg Blake, who was attending his first meeting as a new member, and to Mrs F Lee, Ms C Galdino and Ms A Vasilaki from the BP Laboratory.

Staff News
Mr Whaley had recently been promoted to Laboratory Service Manager following a restructure in the BP and Laboratory services team and as a result, along with Dr Gardiner, would be handing over Secretariat responsibilities to Mr Peter Crowley and Dr Gary Kemp. The Chairman and members expressed their gratitude for Mr Whaley's and Dr Gardiner's valuable contributions to the work of the group.

Confidentiality
Members were reminded of the sensitive nature of the papers and discussions.

Declaration of interests
Experts were reminded to declare any specific interests at the start of the relevant discussions during the meeting.

I MINUTES

330 The minutes of the meeting held on 8th February 2016 were confirmed.

II GENERAL MATTERS

331 General Matters **ABS(16)33**

Emergency evacuation procedure
Experts were reminded of the evacuation procedure in the event of a fire alarm.

BP Team Organogram
A new team organogram was provided to members for information

Freedom of Information
Experts were reminded that any FOI queries that they received from the media were to be referred to the Secretariat.

Membership
A copy of the current membership list was provided for information. Members were asked to inform the Secretariat if any of their details were incorrect and reminded to notify the Secretariat in the event of any future changes.

III MATTERS ARISING FROM THE MINUTES

332 Matters Arising from the minutes ABS(16)34

The following matters arising from the meeting held on 8th February 2016 were noted.

Norfloxacin Preparations (minute 229 refers) The Secretariat continued to seek information regarding the potential inclusion of a test for Related substances, and were in communication with a manufacturer. Information was yet to be received.

Amikacin Injection (minute 284 refers) Laboratory work examining the suitability of the Ph. Eur. method was still pending at the BP Laboratory. Results would be circulated to experts at the earliest opportunity.

Moxifloxacin Tablets (minute 315 refers) The draft monograph previously reviewed by the group had been used by the WHO to create a draft Moxifloxacin Tablets monograph for the International Pharmacopoeia. The draft was discussed at their meeting in May. The laboratory investigation on the monograph would be carried out collaboratively between the BP and the TGA (Therapeutic Goods Administration in Australia).

Azithromycin Preparations (minute 312 refers) Laboratory work examining the suitability of the Ph. Eur. method was still pending at the BP Laboratory. Results would be circulated to members at the earliest opportunity.

333 Work Programme ABS(16)35

The work programme had been updated since the previous meeting and was presented to the group.

A spreadsheet detailing Ph. Eur. revisions of ABS relevant monographs was presented.

Additions and Removals
At their July 2016 meeting the British Pharmacopoeia Commission had agreed to add Tobramycin and Dexamethasone Eye Drops, Marbofloxacin Powder for Injection, Rifampicin, Isoniazid and Pyrazinamide Tablets and Meropenem Injection/Infusion.

Two further monographs were initiated: Prolonged – release Doxycycline capsules and Rifabutin capsules.

Monographs in progress
Members noted the list of monographs from the work programme which were being worked on.

Proposed additions
None

334 Analytical Methods Evaluation Assessment ABS(16)36

A new procedure for evaluating whether analytical methods included in monographs required a laboratory assessment had been agreed by the British Pharmacopoeia Commission. It was provided to members for information.

IV ITEMS FROM EAG ULM

335 Ceftazidime Injection ABS(16)37

The published monograph for Ceftazidime Injection described the dry powder formulation which was dissolved in Water for Injections before use. The Expert Advisory Group on Unlicensed Medicines had been asked to develop a monograph for a ready-to-use solution which is used in hospitals.

It was highlighted that the previous BP Commission policy, when formulations were available in several different presentations, had been to include the requirements for each presentation within one monograph (i.e. with separate requirements for the ready-to-use solution, sterile concentrate and/or dry powder formulation, as appropriate). Following discussions by the Pharmacy EAG and the BP Commission during 2010, a change in policy was introduced stating that new monographs for formulations that were available in more than one presentation should be prepared as stand-alone monographs, rather than as a sub-monograph of an Injection or Infusion monograph. This presented a potential problem since the title of the new monograph for the unlicensed formulation (Ceftazidime Injection) was the same as that of the published monograph for the licensed preparation.

The Secretariat was awaiting further information on the unlicensed formulation before the monograph could be finalised. The reason for bringing the matter to the attention of EAG ABS was to seek members' views on the following monograph title options.

Option 1 was to include a new ULM monograph for Ceftazidime Injection (ready-to-use solution) and revise the published ABS monograph to Ceftazidime for Injection specifying the dry powder formulation in line with the current BP policy for stand-alone monographs. This approach had the advantage of separating the requirements for the licensed and the unlicensed formulations, but could be confusing as the title of the published monograph would need to change.

Option 2 was to amend the current monograph for the dry powder formulation to include the requirements for the ready-to-use solution. This approach had the advantage that there would be no change to the title of the existing monograph. It would mean that the licensed and unlicensed formulations would be controlled within one monograph and would be out of step with the current policy.

Members confirmed their preference for revising the monograph title in line with the current BP policy (Option 1).

336 Tobramycin Sulfate ABS(16)38

The draft monograph would be included in a future publication, subject to receipt of further information.

V NEW AND REVISED MONOGRAPHS

337 Erythromycin Preparations ABS(16)39

EDQM had revised their five Erythromycin API monographs in Ph. Eur. 9.0 to include an improved LC method for related substances and Assay with new limits for impurities and for content. A significant change from the previous version of the monograph was a harmonised limit for 'any other impurity' (across all five monographs) that had been set at 0.4%.

Revision strategies were prepared for the 8 Erythromycin monographs which members were invited to comment on. It was hoped that the monograph revisions would be harmonised with the USP as part of their 'up to date' programme and the BP would lead this work.

Members agreed to the omission of the Erythromycin Estolate Capsules monograph due to lack of usage in the UK, subject to assessment of international usage.

Identification
Members suggested that the colorimetric tests used in identification test B should be replaced with concordant retention time in the Assay. Members noted that a change from chloroform to dichloromethane for the Infrared Identification test would be trivial but should be tested in the lab. Members expressed a preference for having an IR procedure as a primary Identification test with reference to a concordant Assay retention time as a secondary test.

Dissolution
Members suggested that a dissolution test should be included for the Gastro-resistant Tablets, the Ethyl Succinate Tablets and possibly for the Oral Suspension. It was also suggested to use isocratic LC methods for Assay and Dissolution tests to reduce the run time.

Related Substances
The LC Related Substances method from Ph. Eur. was drafted for all monographs and members agreed that it should be assessed by the Laboratory. Members thought the system suitability resolution of 0.8 was lower than would usually be specified; the Secretariat noted that this was harmonised with the Ph. Eur. parent monographs.

Members agreed that these monographs were suitable to progress through collaboration with the USP.

Assay
The LC assay method from Ph. Eur. was drafted for all monographs and members agreed that it should be assessed by the Laboratory.

338 Doxycycline Preparations - Revisions ABS(16)40
Dispersible Doxycycline Tablets
Doxycycline Capsules

Members had agreed at the February meeting of the EAG to revise the Doxycycline Capsules and Dispersible Doxycycline Tablets in line with the Ph. Eur. revisions following a request from a user to widen the limits in line with the Ph. Eur. revisions. The Secretariat had prepared the draft revised monographs for both products which were presented for comment.

Identification A
The TLC identification in both monographs had been editorially re-styled as they were previously in an old format. The technical content of the tests had not been altered.

Absorbance (Light absorbing impurities)
The Ph. Eur. revisions included renaming the light absorbing impurities test as an 'absorbance' test (the methodology and limits had not changed). The tests had therefore been renamed in the BP revisions in the interest of harmonisation.

Disintegration
Members agreed to delete the test for Disintegration from the Dispersible Doxycycline Tablets monograph as it was covered by the requirements in the Tablets General Monograph.

Dissolution
The Secretariat had investigated the Doxycycline Capsules monograph history and found that it did not contain a dissolution test because a consensus between manufacturers regarding dissolution conditions was not be reached at the time of the monograph development. During the latest consultation, a validated method had been provided by a manufacturer and had been included in the draft monograph. Members noted that the procedure provided by the manufacturer used quantification at 345nm which was thought to be a second maxima. Members confirmed that they had a preference for 276nm in line with the Dispersible Tablets.

The UV dissolution method in the published Dispersible Doxycycline Tablets monograph had been editorially re-styled.

As both monographs were first published prior to the BP 2008, they referenced Appendix XII B1 which provides standard criteria of not less than 70% of label claim in 45 minutes. These limits were not provided in the monograph as per BP policy.

Members stated a preference for inclusion of Q values based on the innovator licensed specifications in monographs published prior to the BP 2008. A member mentioned that the latest draft guideline from the QWP stated that for immediate release tablets, Q criteria of 85% release in 15 minutes should apply.

Related substances
In both monographs, the new LC method from the Ph. Eur. parent monographs had been included in the draft. This method identified and controlled impurities A, B, C, and F. The existing sample preparation had been retained as the dispersible tablets/ capsules were previously dissolved in 0.01M HCl which was very similar to the 1 g/L hydrogen chloride R used in the APIs.

The existing method used 6 epidoxycycline BPCRS and metacycline BPCRS for the

system suitability requirement and for the identification/quantification of these impurities (impurities A and B). No other impurities were identified by the method. The Ph. Eur. revision used doxycycline for system suitability EPCRS to identify impurities A, B, C and F and for a system suitability requirement. Members discussed producing a similar BPCRS to support these monographs but concluded it would be more efficient to use the EPCRS. Members noted that the 6 epidoxycycline BPCRS was not used by any other monograph and so could be omitted following publication of the revision.

The specific impurity limits included in the draft monographs were based on the limits included in the parent monographs. The any other impurity and disregard limits were based on the guidelines for semi-synthetic antibiotics (the parent API monographs also appeared to incorporate these guidelines).

Assay
The Related substances LC method had been included as the Assay in both monographs, as per the parent monographs. Additionally, the sample preparation had been harmonised with the Related Substances. The declared content of doxycycline given with the doxycycline hyclate BPCRS would be used for quantification as both products were labelled in terms of doxycycline.

339 Doxycycline Preparations - New Monographs ABS(16)41
Doxycycline Tablets
Prolonged-release Doxycycline Capsules

The draft monograph would be included in a future publication, subject to receipt of further information.

340 Ciclosporin Preparations ABS(16)42
Ciclosporin Capsules
Ciclosporin Oral Solution

The new Ciclosporin Capsules draft monograph would be included in a future publication, subject to receipt of further information.

Laboratory work has been completed on the Ciclosporin preparations (revision to the oral solution monographs and new capsules monograph) and the reports were presented. The methods drafted were found to be suitable with modifications. Draft monographs were presented to the group.

An addendum to the Laboratory Report relating to the proposed system suitability test had been posted on the BP Website Forum.

Unidentified peaks were present in both preparations which may be due to excipients – manufacturers would be asked to comment on the peaks as part of the monograph consultation.

Identification
The TLC method from the current Ciclosporin Oral Solution was retained.

Related Substances
The system suitability EPCRS standard had been found to be unsuitable as a means of demonstrating suitable resolution between peaks when injected using the manufacturers HPLC conditions. The Laboratory had developed a system suitability test by heating ciclosporin in sodium hydroxide in an enclosed vessel. Members questioned

the use of the phrase “closed oven-proof vessel”. The Secretariat agreed to consider the terminology.

Members indicated that the system suitability resolution requirement of 1.0 was low and that using a peak to valley ratio would be preferable; the Laboratory agreed to provide the necessary data. Members questioned whether the hydrolysis product could be ciclosporin G and the Secretariat agreed to investigate.

Assay
Members questioned whether it was possible to shorten the LC method by using an isocratic gradient. It was agreed that since the gradient method was validated and used by the manufacturer, it would be retained.

341 Minocycline Capsules ABS(16)43

The draft monograph would be included in a future publication, subject to receipt of further information.

342 Minocycline Preparation Revisions ABS(16)44
Minocycline Tablets
Minocycline Prolonged-release Capsules

The two published BP minocycline monographs had been revised using the revised Ph. Eur. parent monograph; members’ comments were welcomed on the drafts. The Laboratory assessment indicated that the monographs required Laboratory work and it was suggested that the three minocycline monographs were worked on by the lab as a single project.

Content
The limits were tightened to 95.0 – 105.0% in line with licensed product specifications. There were no comments from members.

Identification
Members suggested Laboratory evaluation of the Infrared method which was based on the Ph. Eur. parent monograph.

Dissolution
The method for the tablets monograph was drafted using the USP Minocycline Hydrochloride Tablets monograph. Members agreed that it should be adopted with UV as the quantification method.

Related Substances
A method with limits based on the Ph. Eur. parent monograph was drafted. As with the capsules, members endorsed using the minocycline for system suitability EPCRS. Members agreed that the method should be evaluated in the lab.

Assay
The method wasarmonised with the Related Substances. Members agreed that the method should be evaluated in the Laboratory.

Members suggested building evidence for/against method evaluation assessment of lab work if there are no issues found. Members also noted that specifying excipients used for coatings would be useful when displaying data about excipients.

343 Ceftiofur Hydrochloride Suspension For Injection ABS(16)45

The draft monograph would be included in a future publication, subject to receipt of further information.

344 Doxorubicin Preparations ABS(16)46
Sterile Doxorubicin Concentrate
Doxorubicin for Infusion

It had previously been agreed that the Doxorubicin Injection monograph should be revised in order to create two separate monographs - Sterile Doxorubicin Concentrate and Doxorubicin Infusion. The drafts had been prepared and members were asked to comment on them.

Advice sought from EAG PCY suggested changing the name of the monograph "Doxorubicin For Infusion" to "Doxorubicin For Infusion or Injection", since administration was common through both routes.

Sterile Doxorubicin Concentrate

Definition
Contained a statement indicating the monograph would not apply to pegylated liposomal products, which was endorsed by members.

Content
Limits of 95.0-105.0% were agreed by members.

Bacterial Endotoxin Test
The test was removed in line with BP policy for the BET in new monographs.

Related Substances
The drafted limits from the existing monograph were agreed.

Doxorubicin for Infusion

Title
Members agreed to EAG PCY advice to change the monograph name to "Doxorubicin For Infusion or Injection".

Post Meeting Note - following a check of current BP policy, the title had remained as "Doxorubicin for infusion", but "Doxorubicin for injection" had been included as a subsidiary title.

Content
Limits of 90.0-110.0% were agreed by members.

Bacterial Endotoxin Test
The test was retained in line with BP policy.

Acidity
Although a stakeholder has previously requested revision of the limits, data was not provided to support the revision and so the existing limits had been retained. The suitability of the limits would be investigated as part of the public consultation.

Related Substances
The drafted limits from the existing monograph were agreed.

VI MONOGRAPHS IN PROGRESS

345 Colistimethate Sodium For Injection ABS(16)47

At the previous meeting the group had been presented with a proposal for the revision of the monograph which had been received from a manufacturer.

It had been highlighted that there were no excipients in the formulated product which were likely to cause an issue and the group had agreed that the revision to the BP injection monograph could be based on the proposed revision of the Ph. Eur. API monograph.

The Secretariat had performed an analytical methods evaluation assessment as agreed at the previous meeting. Validation data had been provided by the manufacturer and provided to members following finalisation of the meeting papers. Members discussed the assessment and agreed that no additional laboratory assessment was required to support this monograph.

Identification A
As agreed at the previous meeting the existing identification tests: A (TLC), B (chemical reaction) and C (Sulfates), had been replaced with a test for concordant retention time in the Composition test.

Identification B
The published Identification test D (sodium test) had been retained in the amended draft revision.

Loss on Drying
As agreed, the limit proposed by the manufacturer of ‘not more than 7.0%’ was included in the draft revision.

Bacterial Endotoxins
The test for bacterial endotoxins had been removed from the monograph. Members previously agreed that this test would be performed as per the general monograph for Parenteral Preparations.

Composition
The UPLC procedure provided by the manufacturer had been included in the draft monograph. Members noted that it was unusual to include system suitability criteria for retention time shifts and column efficiency but the Secretariat highlighted they had been specifically specified by the manufacturer. It was agreed that the Secretariat would contact the manufacturer to justify their inclusion.

Related Substances
A procedure harmonised with the Composition test had been included in the draft monograph as agreed. A member confirmed that the drug substance limits were appropriate for inclusion in the drug product monograph and that these limits were supported by a large volume of stability data. Members expressed concerns however as to how impurities could be identified given the large amount of peaks related to the composition of the drug substance.

346 Benzoyl Peroxide And Clindamycin Gel ABS(16)48

The draft monograph would be included in a future publication, subject to receipt of further information.

347 Tigecycline For Injection ABS(16)49

The draft monograph would be included in a future publication, subject to receipt of further information.

348 Fusidic Acid & Sodium Fusidate Preparations ABS(16)50
Fusidic Acid Cream
Fusidic Acid Oral Suspension
Fusidic Acid Eye Drops
Sodium Fusidate Cream

The Secretariat updated members on university work which had been carried out on the fusidic acid/sodium fusidate product monographs. Members were impressed with the overall quality of the reports but had some concerns over the clarity of which mobile phase composition was used. Members endorsed sourcing an MSc project to carry out the remaining lab work and requested the final reports to be circulated.

349 Marbofloxacin Preparations ABS(16)51
Marbofloxacin Tablets
Marbofloxacin Injection
Marbofloxacin Powder for Injection

The draft monograph would be included in a future publication, subject to receipt of further information.

350 Clindamycin Tablets for Veterinary Use ABS(16)52

The draft monograph would be included in a future publication, subject to receipt of further information.

351 Moxidectin Preparations ABS(16)53

The paper was presented primarily for information. The Secretariat had received no response from manufacturers in order to finalise revisions to the monographs.

Members agreed that if the monograph had been out for public consultation and there were no comments, it could be published in the BP 2018.

VII REPORTS AND CORRESPONDANCE

352 Bacterial Endotoxins ABS(16)54

Members were reminded that at the February 2016 meeting the Secretariat reported that they had been in contact with manufacturers of Amikacin Injection, Colistimethate Injection and Flucloxacillin Injection to request data which could be provided to the Ph. Eur. Secretariat to allow them consider the revision of the parent monographs to remove the test for Pyrogens. The following progress had been made since this meeting and members' advice was sought on how to proceed further.

Amikacin Sulfate
Responses had been received from the two Amikacin Injection product manufacturers. One manufacturer indicated that they carried out the BET test on Amikacin base and therefore would be unable to provide assistance. Another manufacturer had declined to support the request for revision.

Colistimethate Sodium
As noted in February, the manufacturer had provided data directly to EDQM to support their request that the revision of the Colistimethate Sodium monograph includes replacement of the test for pyrogens with a bacterial endotoxin test. This request was discussed at the 10th meeting of the BET working party who rejected the revision, concluding that more independent data from different sources was required.

Flucloxacillin Sodium
Previously, when manufacturers had been contacted for replacement procedures for the test for Pyrogens, two of the four manufacturers supplied the same method validation package, which had been sent to EDQM. The Working Party on Bacterial endotoxins rejected the revision as they *"had not considered the data sufficient to support a change as no comparative data on pyrogen testing had been provided"*.

The validation package in both cases had been supplied by the same API manufacturer. A review of the available products revealed that all contain API from this manufacturer, and therefore would all be likely to provide the same validation package on request.

Members discussed the test for Pyrogens and highlighted that it would be covered by the general requirements in Substances for Pharmaceutical Use. Additionally, a member noted that Pyrogens are not likely to be formed in the fermentation process used for Amikacin or Flucloxacillin Sodium and so the test was not required.

The Secretariat agreed to seek clarification from the BET Working Party on what information would be required to replace this test.

353 Clarithromycin Granules for Suspension ABS(16)55

At the previous meeting the group had been presented with an updated draft monograph based on practical work performed at the BP Laboratory. Members were content that an updated draft monograph could be circulated to stakeholders for comment and prepared for publication in the BP2017.

The Secretariat highlighted the following comments and subsequent revisions to the draft monograph arising from the stakeholder consultation. All revisions had been agreed by the Chair and Vice-Chair.

Content
A manufacturer had requested that the limits of the monograph should be 90.0% - 115.0% citing concerns with bottle fill weight variations, homogeneity and the minor overages needed in some countries to fulfil extractable volume requirements.

No changes were made to the published limit of 90.0 – 110.0% based on the Group's decision at the February meeting and the results obtained by the BP Laboratory.

Related Substances
A manufacturer raised concerns for the homogeneity of the granules used to prepare

samples and so the preparation details were updated to include an instruction to finely powder the granules.

The correction factor for impurity B had been amended following consultation with the manufacturer and the limits had been aligned with the Ph. Eur. drug substance monograph as the Impurity E limit was highlighted to be tighter than for the API.

354 Mupirocin Ointment ABS(16)56

Correspondence from a user highlighted an error in the system suitability requirement for the TLC ID test. Members were asked to assess the evidence and advise on whether the monograph should be changed.

Identification
The TLC Identification test system suitability criterion stated “the chromatogram obtained with solution (3) shows at least two clearly separated spots at lower Rf values than the spot due to mupirocin”. Solution (3) is a solution of Mupirocin lithium that has been allowed to stand for 20 hours in 0.2M HCl, generating hydrolysis impurities. The user stated that despite two attempts, their TLC chromatograms showed one spot with a higher Rf value than the spot due to mupirocin and no lower running spots.

Members agreed that the system suitability test was not required for the TLC and could be removed, since a test for the TLC plates is included in the reagent section of the BP.

355 Vancomycin Infusion ABS(16)57

At the February 2016 meeting, members had been presented with a request and supporting stability data from a manufacturer to widen the limits of the Clarity of solution test from not more than 0.1 to not more than 0.2. Members felt that widening the limits would cause undue concern to patients. They requested that the Secretariat investigate the licensed specification of the product to determine if it was in line with their request.

Following the meeting, a member determined that the product in question had a registered specification of 0.1 and therefore did not support the request for revision. the member noted however that the manufacturer had submitted a variation application to widen the limit, and the assessor had asked them to put their request to the British Pharmacopoeia.

The origin of the test in the monograph was investigated and it was found that it was based on the Ph. Eur. parent monograph which contained the same limit of 0.1. As mentioned at the previous meeting, this monograph was currently being revised to include an improved Related substance procedure. The Secretariat had suggested that the manufacturer submit a request for revision of Vancomycin Hydrochloride to the EDQM.

Members agreed that once the revision is finalised, the new method is assessed with a view to updating the Vancomycin product monographs and that the clarity of solution specifications could be reviewed as part of this process.

356 Co-Amoxiclav Injection ABS(16)58

The Related substances method of the Co-amoxiclav Injection monograph specified that the user identify and limit ‘α-penicilloic acid’. A user had requested the structure of this substance which was not included in the monograph.

The Secretariat had contacted the manufacturer, who had provided the method, and received the structure of this molecule which was the same as impurity D in the Ph. Eur. Amoxicillin Sodium monograph.

Members agreed with the Secretariat proposal to include reference to the Ph. Eur. impurity D in the monograph for Co-Amoxiclav Injection, but suggested that the Secretariat ensured that impurity D remained the same following the Amoxicillin monograph revision.

357 Publications **ABS(16)59**

Members were informed of the publication of the BP 2017 and details of revised and new ABS monographs included in the BP 2017.

358 International Collaboration **ABS(16)60**

USP
The BP had entered into a prospective harmonisation programme for monograph revision with the USP. Six monographs/families of monographs have been chosen, of which Nystatin (five monographs) and Erythromycin (six monographs) are the responsibility of EAG ABS. The BP will be leading on the Erythromycin revisions (discussed earlier in these papers) and the USP will be leading on the Nystatin revisions.

Indian Pharmacopoeia
Collaboration with the Indian pharmacopoeia was in the early stages. The Indian Pharmacopoeia had expressed an interest in working together on the Doxycycline Dispersible tablets monograph. They have since published this monograph, and the BP had agreed to examine whether it will be useful to the planned revision discussed in these papers.

International Pharmacopoeia
Members were informed that the BP was working with the IP on the development of Moxifloxacin Tablets and Rifabutin Capsules monographs. The sole manufacture of the latter product has been contacted.

VIII EUROPEAN PHARMACOPOEIA

359 European Matters **ABS(16)61**

Members were informed of Group 7 Meetings and reminded that a new member was still being sought.

360 Any Other Business

None

361 Date of next meeting

Wednesday 8th February 2017