BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group (EAG): Nomenclature (NOM)

SUMMARY MINUTES

A meeting of the Expert Advisory Group on Nomenclature was held at 151 Buckingham Palace Road, Victoria, London SW1W 9SZ on 14 February 2018.

Present: Dr G P Moss *(acting chair)*, Ms A McFarlane, Mr D Mehta, Dr R Thorpe.

In attendance: Mr A Evans, Dr K Radi and Mr L Elanganathan.

Apologies for absence were received from Dr J K Aronson and Dr L Tsang.

INTRODUCTORY REMARKS

Welcome The Chairman welcomed members to the meeting.

Declaration of Interests No conflicts of interest were declared.

Confidentiality The papers, discussion, and minutes of the meeting were noted to be confidential.

I MINUTES

The minutes and summary minutes of the meeting held on 14 February 2017 were accepted with a minor typographical error.

II MATTERS ARISING FROM THE MINUTES

175 **Impurities** The recommended names for the impurities discussed at the previous meeting had been published in the BP 2018.

176 **Action and use** The recommended statements for EAG ULM discussed at the previous EAG meeting had been published in the BP 2018.

177 **British Approved Names 2017 Supplement 1** This had been published in August 2017.

III ITEMS FOR THE BRITISH PHARMACOPOEIA 2019

178 **Naming of Impurities for BP Monographs**

Advice was requested on naming impurities to be included in new and revised BP monographs that were due to be published in the BP 2019. The names to be used were agreed for inclusion in the monographs for Salmeterol Inhalation Powder, pre-metered, Galantamine Tablets, Galantamine Oral Solution, Galantamine Prolonged-released Capsules, Amlodipine Tablets, Fluticasone and Salmeterol Pressurised Inhalation, Fluticasone and Salmeterol Suspension. Names were agreed post meeting for the monographs for Vardenafil Tablets, Vardenafil Orodispersible Tablets and Tigecycline for Infusion.

179 **Action and Use Statements for BP monographs**

Ketamine Nasal Spray EAG ULM had elaborated a new monograph for publication in the BP 2019, as this product was used for a different indication other than an “Intravenous general anaesthetic”. Members agreed a shorter, more open statement “Anaesthetic” to be included for this monograph.

Ferric Chloride Injection EAG ULM had elaborated a new monograph for publication in the BP 2019. There was currently no entry for Ferric Chloride in the BAN. Members questioned whether ferric chloride was to be used as a nutrient or as a therapeutic agent for anaemia. The unlicenced use for this material was for parenteral nutrition only, therefore the proposed statement “Used in Parenteral Nutrition Solutions” was agreed.

Potassium Acetate Sterile Concentrate EAG ULM had elaborated a new monograph for publication in the BP 2019. There was currently no entry for Potassium Acetate in the BAN. As this was also to be used only in parenteral nutrition, members agreed to include “Used in Parenteral Nutrition Solutions” as the Action and use statement.

IV ITEMS FOR THE BRITISH APPROVED NAMES PUBLICATION

180 **British Approved Names 2017, Supplement 2**
New Entries

A revised list of new entries intended for inclusion in material for publication in the Supplement was discussed. 22 new names had been identified for inclusion in the Supplement. The agreed entries would be published in the Supplement and sent to the BPC for final approval.

181 **Co-dydramol**

The Secretariat informed members, that two new strengths of co-dydramol had been granted by MHRA, with different ratios of dihydrocodeine tartrate and paracetamol. MHRA had published a drug alert to indicate that Co-dydramol should be prescribed with strength noted. It was noted that the current BAN definition provided a fixed ratio for products using the name Co-dydramol. Based on the joint Licensing Division and BP assessment of the risk to patient safety in changing the definition of the BAN to permit various strengths of the individual complonents in available products, the recommendation to amend the BAN definition was accepted by members. Members agreed that the new definition should be published in the BAN 2017 supplement 2 and the BP 2019.

182 **WHO, INN updates**
Latest pINN and rINN lists

The new pINN and rINN lists had been made available since the last meeting of the EAG were noted.
The Executive Report from the 61st and 62nd INN Consultation were provided for information.

183 **Invented Names**

MHRA Naming Activities It was noted that the BP Secretariat continued to provide advice to stakeholders on suggested names before submission of MAAs. The BP continued to have significant input into the policy for naming of medicines and represented MHRA at the EMA Names Review Group.

184 **Any other business**

Spilt Standard Terms
The Secretariat informed EAG NOM members about decisions made by EAG PCY and BPC regarding split Standard Terms (BPC 174, November 2017 PCY 490, Sep 2017). With the exception of monographs for parenteral medicines, all specific monographs would now be named using the standard term as written.

185 **Date of Meeting**
12 February 2019

Abbreviation/Synonym	Name
AAN	Australian Approved Names
ATC	Anatomical Therapeutic Classification
ANDPB	Advisory Non-Departmental Public Bodies
AOAC	Association of Analytical Chemists International
API	Active Pharmaceutical Ingredient
BAN	British Approved Name
BANM	British Approved Name Modified
BHomP	British Homoeopathic Pharmacopoeia
BNF	British National Formulary
BP	British Pharmacopoeia
BP (Vet)	British Pharmacopoeia (Veterinary)
BPC	British Pharmacopoeia Commission
BPCRS	British Pharmacopoeia Chemical Reference Substance
BPL	Blood Products Laboratory
BRP	Biological Reference Preparation
BS	British Standard
BSP	Biological Standardisation Programme
CEP	Certification Procedure for the European Directorate for the Quality of Medicines
CHM	Commission on Human Medicines
CP	Centralised Procedure
CRS	Chemical Reference Substance
DCP	Decentralised Procedure
EAG	Expert Advisory Group
EDQM	European Directorate for the Quality of Medicines and Healthcare
EMA -NRG	European Medicines Agency Names Review Group
EPBRP	European Pharmacopoeia Biological Reference Preparation
EPC	European Pharmacopoeia Commission
EPCRS	European Pharmacopoeia Chemical Reference Substance
EU	European Union
FIP	International Pharmaceutical Federation
FOI	Freedom of Information
GC	Gas chromatography
GP	General Practitioner
GSL	General Sale List
HAB	German Homoeopathic Pharmacopoeia
HKCMMS	Hong Kong Chinese Materia Medica Standards
ICH	International Conference on Harmonisation
INNM	International Nonproprietary Name Modified
IUPAC	International Union of Pure and Applied Chemistry
IUBMB	International Union of Biochemistry and Molecular Biology
NOM	Nomenclature
pINN	Proposed International Nonproprietary Name
rINN	Recommended International Nonproprietary Name
ISO	International Organisation for Standardisation
JAN	Japanese Accepted Names
JP	Japanese Pharmacopoeia

LC	Liquid chromatography
LD	Licensing Division
LGC	Laboratory of the Government Chemist, Teddington
LR	BP Laboratory Report
MAIL	The MHRA updating service for medicines
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MC1	Medicinal Chemicals 1
MC2	Medicinal Chemicals 2
MC3	Medicinal Chemicals 3
MHRA	Medicines and Healthcare products Regulatory Agency
MRP	Mutual Recognition Procedure
NIBSC	National Institute for Biological Standards and Control
NOAH	National Office of Animal Health
NPA	National Pharmacopoeial Authority
NPSA	National Patient Safety Agency
OMCL	Official Medicines Control Laboratory
OTC	Over the counter
PCY	Pharmacy
Ph. Eur.	European Pharmacopoeia
QA	Quality assurance
QC	Quality control
RAD	Radiopharmaceuticals
RS	Related substances
SSRI	Selective serotonin reuptake inhibitor
TGA	Therapeutic Goods Administration, Australia
TLC	Thin-layer chromatography
UK	United Kingdom
UKD	United Kingdom Delegation [to the European Pharmacopoeia]
ULM	Unlicensed Medicines
USAN	United States Adopted Names
USP	United States Pharmacopeia
WHO	World Health Organization