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 9 February 2015.

Present: Dr J K Aronson (*Chairman*), Dr L Tsang (*Vice-chairman*), Dr M Ahmed, Mr D Mehta and Dr R Thorpe.
In attendance: Dr P Holland, Mr A Evans, Miss Catherine Pitt and Ms H Corns (part of the meeting)

Apologies for absence were received from Dr G P Moss.

INTRODUCTORY REMARKS

Welcome The Chairman welcomed members to the meeting.

Declaration of Interests No conflicts of interest were declared by members during the meeting.

Confidentiality The Chairman reminded all present of the confidential nature of the papers, discussion and minutes of the meeting.

I MINUTES

133 The minutes and summary minutes of the meeting held on 11 February 2013 were accepted.

II MATTERS ARISING FROM THE MINUTES

134 Attention was drawn to comments made by Dr Moss and Dr Thorpe on the papers distributed to members in February 2014.

Presentation of amino acid sequence
It was noted that amino acid sequences within *Ph. Eur.* monographs include the final H/OH, while those originating from BP and BAN entries do not, as for instance the sequence for Human glucagon (BAN). Dr Moss had commented that IUPAC/IUBMB rules do not use H and OH. While this was not ideal, it was the terminal entities in the sequence that were important, for instance '-Thr-NH_2'.

Alimemazine The use of the descriptor hemitartrate made it clear that the entry in the BAN book described a 2:1 ratio of alimemazine to tartrate.

Degradation of clobetasol; salmeterol impurity; ursodeoxycholic acid impurity Dr Moss's advice on the correct systematic names of the impurities listed above was accepted.

III REPORTS AND CORRESPONDENCE

135 **Data Integrity** The Secretariat gave a short presentation on 'Data Integrity'. There had been a Civil Service-wide drive towards risk management in relation to data integrity. It was explained that there had been a change in the security classification of papers distributed to members of the BP Commission and Expert Advisory Groups; 'RESTRICTED-PHARMACOPOEIA' had been replaced by 'OFFICIAL-SENSITIVE'. The rationale behind the proposal by the Secretary and Scientific Director to adopt e-working for EAG, Working Party, and Panel proceedings for a year was accepted by the group. It was agreed that if necessary the Secretariat would make papers for discussion at meetings available on the day of the meeting.

BP Website
Members were encouraged to register for access to the EAG NOM Forum.

136 **Membership Review** NOM (15)01
The BP Commission had reviewed the membership of EAGs, Panels, and Working Parties in December 2014. Corresponding members had been reduced from three to two and Miss Granell Villen would join EAG NOM, subject to Commission's approval in March 2015.

137 **British Approved Names 2012 Supplement No.4** NOM (15)03
New Entries 30 new entries and 9 amendments included in the draft supplement 4 were discussed. The new names in the draft of Supplement 4 had been included because there were licensed products available on the UK market. The Licence holders were invited to comment on the acceptability of the entries to be published in Supplement 4. Technical and editorial comments made are reported below.

Afatinib The entry in the draft Supplement 4 was accepted.

Albiglutide A proposal to adopt '*Glucagon-like peptide (GLP-1) receptor agonist (incretin mimetic): treatment of type II diabetes mellitus*' as the action and use statement was accepted. It was recommended that the action and use statements for other – *glutide* names should be harmonised with the agreed statement for albiglutide.

Alogliptin; Bedaquiline The draft entries were accepted.

Cabozantinib Dr Moss would be invited to confirm the entry in regard to the presentation of the BANM as 'Cabozantinib (*S*)-Malate'.

Canagliflozin; Ceftobiprole Medocaril The draft entries were accepted.

Delamanid A proposal to adopt an action and use statement of '*Treatment of multidrug-resistant tuberculosis*' was agreed. Members advised the Secretariat to review the action and use statements of other anti-tuberculosis drugs and their licensed indications to ensure consistency.

Dolutegravir; Elosulfase Alfa; Empagliflozin The draft entries were accepted.

Florbetaben A proposed action and use statement of '*Diagnostic aid; assessment of beta amyloid plaques in the brain in suspected Alzheimer's disease*' was agreed.

A recommendation to bring consistency and more information to the action and use statements for radiopharmaceutical entries in the BAN 2017 was approved by members.

Human Fibrinogen The draft entry was accepted.

Lurasidone It was agreed that the action and use statement for Lurasidone should be amended to read '*Dopamine D_2 and serotonin 5HT_2 receptor antagonist; antipsychotic drug'.* Members recommended that other 5HT receptor antagonists were checked for consistency.

Macitentan; Meldonium; Olodaterol The draft entries were accepted.

Peginterferon Beta-1a A query raised regarding whether 'n' should be given a defined range was deferred to Dr Moss for confirmation. While it would be useful to have the information, it was unlikely that the information would be readily available. It was not recorded in the INN or the USAN entries.

Pullulan; Riociguat; Siltuximab; Simeprevir; Sofosbuvir; Thrombin; Trametinib; Turoctocog Alfa The draft entries were accepted.

Umeclidium Bromide It was noted that the emphasis in the pronunciation should be placed on the first 'u' (u・*me*・kli・*di*・ne・um).

Vedolizumab; Vilanterol The draft entries were accepted.

Vortioxetine Dr Aronson agreed to review the action and use statement in light of the manufacturer's request for the draft entry to be amended as vortioxetine was not an SSRI.

Aciclovir; Denileukin Diftitox; Fluticasone; Macrogol; Mercaptamine; Pentosan Polysulfate Sodium; Sevelamer; Solifenacin; Sulfadimethoxine The draft revised entries were accepted.

Zanamivir The draft revised entries were accepted (zanamivir (BAN) and zanamivir hydrate (BANM)).

138 **British Approved Names 2017** NOM (15)04

Work on consolidating text for the BAN 2017 was continuing. Members were invited to inform the Secretariat of any additional changes to those noted at the meeting in February 2012, which should be considered for inclusion in the BAN 2017. It was noted that one of the first tasks would be a review of action and use statements for cancer-associated drugs. Other suggestions included those listed below.

(i) Cross-referencing BANs with USANs, as this was perceived to provide an added value to the BAN publication and would be useful to stakeholders, and, unless otherwise justified, replacing the descriptor '*antibiotic*' by '*antibacterial*'.

139 **Review of Radiopharmaceutical Names For BAN 2017** NOM (13)05

The Secretariat would work with Dr Pickett, to review BAN entries for radiopharmaceutical substances. His suggested amendments of Ioflupane [^{123}I], Tetrofosmin and Florbetavir (^{18}F) were accepted and would be reflected in the BAN 2017.

140 **Sulfur Spelling: MHRA Communication** NOM (15)06

It was noted that the MHRA had asked MAHs to vary all licences to ensure consistent spelling across national and centralised products.

141 **Monograph Titles** NOM (15)07

BP monograph titles would be reviewed by EAG PCY in consultation with EAG NOM.

Standard Term An issue under consideration was referencing of the pharmaceutical form (standard term) in monographs for pharmaceutical preparations. For instance, amending the title of a monograph where the standard term was split around the rINN (e.g. the combination of the standard term 'chewable tablets + INNs). Instead of adopting 'Chewable Ascorbic Acid Tablets', the title of the BP monograph would be 'Ascorbic Acid Chewable Tablets'. The matter would be given further consideration.

Attention was drawn to the Secretariat's proposal to review the appropriateness of established traditional pharmacognosy names, such as Kaolin Mixture with published *Ph. Eur.* standard terms. The consensus was that the cost of any such review would outweigh any benefits to industry.

Expression of Strength It was noted that the expression of content within BP monographs was being carefully considered, and advice would be sought from EAG NOM where required. It had been suggested that content statements should be expressed with reference to the base. Consensus from the discussion was that it was not always practicable to have the content statement expressed in the form of the base as this may lead to the undesirable practice of having content statements expressed as decimals. It was far more important to address the needs of the prescriber and the patient, rather than focussing on an expression in the form of the base; the patient must be able to understand the meaning of the content expressed on the label.

142 **Pharmaceutical Form: Scalp Application** NOM (13)08

Members considered the most appropriate use of the standard term 'cutaneous solution' for labelling products traditionally described as Scalp Applications. Cutaneous solution was perceived as an emulsion/dispersion; a multiphase oil-aqueous system. The scalp solution was more of a dispersion which by definition involved more than 2 different phases. Traditionally patients in the UK were familiar with the intended use of scalp application and there did not appear to be justification to label scalp applications as cutaneous applications.

143 **Naming of Impurities for BP Monographs** NOM (15)09

Advice on the nomenclature of a list of impurities, to be included in new monographs for the BP2016 had been received. The 19 monographs affected would be revised at the earliest opportunity.

144 **Zanamivir (BAN)** NOM (15)10

The modified entry for zanamivir to include the BANM zanamivir hydrate was noted.

145 **Medication Errors** NOM (15)11

Co-names Concern had been expressed by a GP regarding possible allergic reactions to penicillins, because of inadvertent administration to patients in the form of a co-product. It was accepted that there should be adequate education of patients and prescribers, in order to safeguard the public from penicillin related medication errors. The MHRA would continue to educate prescribers and patients alike in respect to the composition of co-products. It was accepted that no other actions needed to be initiated by the MHRA at this time. A response on the lines of the agreed outcome had already been sent to the GP.

146 **INN Information** NOM (15)12

Topics within the Executive summaries of the 57th and the 58th Consultation on INN for Pharmaceutical Substances were drawn to the attention of members, in particular the consultation document on Biological Qualifiers (BQ).

147 **Invented Names** NOM (15)13

A report giving the number of invented names assessed in the past 12 months was presented for information. 1700 invented name requests had been assessed by the BP Secretariat from the EMA, MHRA and MAH for products being considered for licensing through the National Mutual Recognition Procedure (MRP), the Decentralised Procedure (DCP), and the Centralised Procedure.

The MHRA guidance on the naming of medicines, published in January 2010, had received positive comments from the pharmaceutical industry. A revised draft document was presented, and members were invited to send any comments they might have on its technical contents to the Secretariat.

It was noted that the BP Secretariat continued to provide advice to stakeholders on the acceptability of suggested invented names before submission of a Marketing Authorisation application.

Any Other Business

None.

Date of Meeting in 2016

Wednesday 10 February.

Annex 1

Abbreviation/Synonym	Name
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	Pharmacopoeia of the People's Republic of China
CRS	Chemical Reference Substance
EAG	Expert Advisory Group
EDQM	European Directorate for the Quality of Medicines and Healthcare
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
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
MAH	Marketing Authorisation Holder
MC2	Medicinal Chemicals 2
MHRA	Medicines and Healthcare products Regulatory Agency
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
Ph. Eur.	European Pharmacopoeia
QA	Quality assurance
QC	Quality control
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]
USAN	United States Adopted Names
USP	United States Pharmacopeia
WHO	World Health Organization