

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 2017.

Present: Dr J K Aronson (*Chairman*), Dr M Ahmed, Dr G P Moss, and Mr D Mehta.

In attendance: Mr A Evans and Mr L Elanganathan.

Apologies for absence were received from Mr Dr R Thorpe 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

165 The minutes and summary minutes of the meeting held on 10 February 2016 were accepted.

II MATTERS ARISING FROM THE MINUTES

166 **British Approved Names 2017** This had been published in August 2016.

167 **British Approved Names 2017** The review of the Action and use statements for cancer-associated drugs had been completed and included in the publication.

III ITEMS FOR THE BRITISH PHARMACOPOEIA 2018

168 Naming of Impurities for BP Monographs

A request for advice on naming impurities to be included in new and revised BP monographs that were due to be published in the BP 2018. The names to be used were agreed for inclusion in the monographs for Enalapril Tablets, Indapamide Tablets, Indapamide Prolonged-Release Tablets, Ketoprofen Gel, and Phenindione Tablets

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

Hydroquinone The Action and use statement was required for a new BP API monograph to help control a ULM product 'Tretinoin, Hydrocortisone and Hydroquinone Cream'. Members agreed that the statement should be '*Depigmenting agent*'.

Tretinoin, Hydrocortisone and Hydroquinone Cream EAG ULM had elaborated a new monograph for publication in the BP 2018. As this product was used for a different indication than the more usual 'use' for the individual components, a new statement was required for this monograph. Members agreed the statement should be '*Vitamin A analogue (retinoid) + Corticosteroid + Depigmenting agent*'.

IV ITEMS FOR THE BRITISH APPROVED NAMES PUBLICATION

170 **British Approved Names 2017, Supplement 1: New Entries**

A revised list of new entries intended for inclusion in material for publication in the Supplement was discussed. 46 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.

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

The new pINN and rINN lists that had been made available since the last meeting of the EAG were noted.

The Executive Report from the 61st and 62nd INN Consultations were provided for information.

172 **WHO, INN updates: Naming of Biological Medicines**

Biological qualifiers Members were informed of the latest developments of the Biological qualification scheme.

International Nonproprietary Names (INN) for biological and biotechnological substances (a review) The publication from WHO was provided to the EAG for information.

173 **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.

164 **Date of Meeting in 2017**
Wednesday, 14 February.

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
INN	International Nonproprietary Name
INN	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 Pharmacopoeia
WHO	World Health Organization