**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 10 February 2016.

**Present**: Dr J K Aronson (*Chairman*), Dr M Ahmed, Ms B Granell-Villen, Dr G P Moss, and Dr R Thorpe.
**In attendance**: Dr P Holland and Mr A Evans.
Apologies for absence were received from Mr D Mehta and Dr L Tsang.

## INTRODUCTORY REMARKS

**Welcome** The Chairman welcomed members to the meeting, in particular Ms Granell-Villen, who was attending her first meeting. Ms Granell-Villen is a clinical writer at the BNF.

**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

148 The minutes and summary minutes of the meeting held on 9 February 2015 were accepted, subject to a minor editorial amendment listed below.

**Minute 137.15** Replace Umeclidium Bromide by Umeclidinium Bromide.

## II MATTERS ARISING FROM THE MINUTES

149 **British Approved Names 2012, Supplement No. 4** This had been published in August 2015.

150 **British Approved Names 2017** The action and use statements for cancer-associated drugs would be reviewed by the Chairman before May 2016.

151 **Minute 137 Peginterferon Beta-1a** Dr Moss confirmed that entries for pegylated compounds listed in the BAN publication should include a definition (a defined range) of the average number of pegylated moieties (‘n’) linked to the active compound.

## III REPORTS AND CORRESPONDENCE

152 **Naming of Impurities for BP Monographs** NOM (16)01

A request for advice on naming impurities to be included in new and revised BP monographs that were the responsibility of the BP Commission Chemicals Expert Advisory Groups (EAGs) MC1, MC2 and MC3 had been sent to Dr Moss before the meeting. Dr Moss had provided systematic names for all the compounds except for the olanzapine impurities, for which further information was awaited from the manufacturer. It was agreed that the Secretariat will write again to the manufacturer to ask for the additional information that Dr Moss required, in order to provide the appropriate systematic names.

153 **Review of Action and Use Statements in BP Publications** NOM (16)2

**Lauromacrogol 400** The published action and use statement in the BP monograph for Lauromacrogol 400 was currently 'Non-ionic surfactant'. The Pharmacy (PCY) EAG Secretariat had requested extension of the statement to reflect the use of Lauromacrogol as a sclerosing agent. It was agreed to replace the published statement 'Non-ionic surfactant' by 'Non-ionic surfactant; sclerosant'.

**Sodium Benzoate Injection** EAG ULM was in the process of elaborating a new monograph for Sodium Benzoate Injection. There were currently no licensed products for children; it was an 'off-label' product prescribed by health-care specialists for the treatment of 'acute hyperammonaemia due to urea cycle disorder' in children. EAG NOM agreed with EAG ULM's decision to include this use in the draft BP monograph and to add another licensed indication, non-ketotic hyperglycinaemia.

**Sodium Bicarbonate Oral Solution** The proposal by ULM to amend the published action and use statement to reflect licensed and 'off-label' use was discussed. It was accepted to adopt 'Treatment of dyspepsia; treatment of uraemic acidosis and renal tubular acidosis'.

154 **British Approved Names 2017 New Entries** NOM (16)03

A revised list of new entries intended for inclusion in material for publication in the BAN 2017 was discussed. The document listing the new entries had been circulated to members for comment before the meeting. Comments received from Dr Aronson, Dr Moss, Mr Mehta, Dr Pickett (UK representative on Ph. Eur. Group of Experts on radioactive compounds) and MAHs were noted. Dr Pickett's comments were of particular note and were deemed helpful and were all accepted in principle. His suggested action and use statements will be formatted in the style used for BP publications.

29 new names had been identified for inclusion in the BAN 2017. Of these, 27 had already been published as rINNs and two, namely Colchicine and Technitium[$^{99m}$Tc] Tilmanocept, had not been assigned an INN. Both were the main active components in products marketed in the UK.

The revised draft document of new entries reflected the changes that had been suggested by members of EAG NOM on the first draft. The comments received from the MAHs had been reviewed by the Secretariat in consultation with EAG NOM and unless otherwise justified had been incorporated into the revised document.

In consultation with Dr Moss, the systematic names included in the new entries had been derived in accordance with IUPAC rules. Requests from some MAHs to amend some systematic names in accordance with CAS nomenclature or alternative nomenclatural systems were noted. Members accepted Dr Moss's advice to retain the convention of naming compounds within BP monographs and in the BAN according to IUPAC rules. The entries in the revised document were accepted for publication in the BAN 2017 except for those listed below, which required further changes.

**Afamelanotide** The action and use statement will be changed to *Alpha-melanocyte-stimulating hormone; treatment of erythropoietic protoporphyria*. The 3-letter-code of the terminal valine will be revised to show the 'terminal $-NH_2$' moiety.

**Eliglustat** The action and use statement will refer to Gaucher's disease and not Gaucher disease. The drug substance registered in Europe was the hemitartrate salt; a BANM for the hemihydrate will be added to the draft entry.

**Olaparib** It was agreed to remove the breast cancer indication, as had been advised by the MAH. The current licensed indication was restricted to 'use in the treatment of ovarian cancer'.

**Oritavancin** By analogy with vancomycin, which was a glycopeptide antibacterial, as was oritavancin, Dr Aronson's suggestion to show the pronunciation to evoke a hard 'k' (**Oritavancin** (rINN) o · ri · ta · *van* · sin to o · ri · ta · *van* · kin) was accepted.

**Technitium[$^{99m}$Tc] Tilmanocept** As requested by Dr Moss, the MAH will be asked to advise on whether the glucose in the mannose moiety is $\alpha$ or $\beta$. This should enable Dr Moss to provide the complete systematic name for the compound to be published in the BAN 2017.

**Thiocolchicoside** It was understood from Sanofi that Thiocolchicoside containing products were not marketed in the UK, but a Sanofi licensed product is on the French market for use as muscle relaxant.

155 **British Approved Names 2017** NOM (16)04
**Review of Radiopharmaceutical names**

As had been agreed by EAG NOM at its meeting in February 2015 advice had been sought from Dr Pickett, the UK representative on Ph. Eur. Group of Experts on radioactive compounds, to review the entries for radiopharmaceutical substances in the BAN.

Dr Pickett's comprehensive list of comments and notes explaining the rationale of his decisions was presented. Members acknowledged Dr Pickett's contributions and agreed to adopt his suggestions, truncating some of his

proposed action and use statements to align with the format used for the BAN publication. Dr Pickett's comments on the appropriate use of square brackets and round parentheses for the isotope symbol for the radiolabel when used within a name was deemed to be helpful. He had advised that square brackets should be used immediately in front of the radiolabelled entity to show that no radiopharmaceutical is ever 100% carrier free and that some atoms of the natural element would be present. Different rules were applied to the presentation of the radiolabel when it was used in connection with the title of a preparation or non-pure chemistry. Dr Moss commented that there was an alternative school of thought, which was that the only atoms monitored in a radiopharmaceutical preparation were the labelled atoms and that round parentheses could be used to relay this information. Members joined the Chairman in acknowledging Dr Pickett's contributions to preparing the BAN 2017 publication. A formal letter of acknowledgement of contributions will be sent by the Chairman.

156 **British Approved Names 2017** NOM (16) 05
**Appendix A - Draft Revised Text**

The BAN publication included basic information on the systematic naming of organic compounds within Appendix A. Dr Moss had reviewed the Appendix A text included in the BAN 2012 to ensure harmonisation of the BP text with the up-to-date information in the IUPAC publication 'Nomenclature of Organic Chemistry' (the Blue book). The draft revised text was presented and was accepted for publication in the BAN 2017. Dr Moss undertook to provide the ISBN for the IUPAC document on 'Nomenclature of Inorganic Chemistry: IUPAC Recommendations'. The Secretariat will finalise the draft text in consultation with Dr Moss.

157 **British Approved Names 2017** NOM (16) 06
**Differences between BANs and other national nonproprietary names**

As had been agreed by EAG NOM at its meeting in February 2015 the Secretariat had sought and received information from national nomenclature and pharmacopoeial authorities, which can be used to list national names that differ from the BANs for the same active substances, as for instance paracetamol (BAN); acetaminophen (USAN). The Secretariat will prepare a list in conjunction with EAG NOM with the view of including it as a new appendix in the BAN 2017. The appendix will show differences between BANs and USANs, BANs and JANs, BANs and AANs and also BANs and INNs.

## IV BP NOMENCLATURAL ISSUES

158 **Proposed Changes to Monograph Titles** NOM (16) 07

Mr Evans informed members that as a result of a new EDQM policy on hydrates, the descriptor 'anhydrous' will be deleted from the title of 25 *Ph. Eur.* monographs and that the change would be implemented by means of the Ph. Eur. 9$^{th}$ Edition. Members will be informed of any impact on the BAN publication at the earliest opportunity.

159 **WHO Biological Qualifiier** NOM (16) 8

Members had been kept informed of developments of the WHO Biological Qualifier (BQ) proposals and also of the stakeholder consultation by the US FDA 'Draft guidance for Industry on nonproprietary naming of biological products'. The WHO BQ proposals had been finalised at the meeting of the INN Committee in October 2015. WHO had decided to carry out an impact assessment of the BQ on health-care systems in Member States. A copy of the document on 'Biological Qualifier Impact Assess study (Request for proposals)' was presented. Documents on 'Prescribing Practices for Biosimilars: questionnaire survey findings from physicians in Argentina, Brazil, Colombia and Mexico' and 'Prescribing similar biotherapeutic products in Latin America' were provided for information.

It was noted that both WHO and the FDA acknowledged that it was in the interests of patient safety for the two organisations to work together on developing harmonised guidance for biological substances and biological products. The BP Secretariat will continue to keep EAG NOM updated on developments of the WHO BQ scheme.

160 **International Nonproprietary Names** NOM (16) 09

Copies of the executive summaries of the 59$^{th}$ and the 60$^{th}$ Consultation on INN for Pharmaceutical Substances were presented. A 'Report on Biological Qualifier Front meeting for INN stakeholders' held in June 2015 at the WHO head offices in Geneva was also presented. Members were reminded that rINN/pINN lists were available on the WHO Mednet database.

161 **Invented Names** NOM (16) 10

**European Medicines Agency (EMA) - Names Review Group (NRG) Activities** A report giving the number of invented names assessed by the BP Secretariat through National, MRP, DCP, and CP for 2015 was 1450.

**MHRA Naming Activities** It was noted that the BP Secretariat continued to provide advice to stakeholders on suggested names before submission of MAAs.

The MHRA had reviewed the requirements for the naming of antiepileptic drugs, and the changes were reflected in the 'MHRA Guideline for the Naming of Medicinal Products and Braille Requirements for Name on Label'. The MHRA was currently considering a review of the national policy on the naming of prolonged-release oral dose medications. It was anticipated that MHRA Guideline will be published for stakeholder comments after this review.

163 **Any Other Business**

Mr Evans informed members that the US FDA had made the 'Phonetic and Orthographic Computer Analysis (POCA)' tool freely available online to industry. The POCA software programme could be used to identify possible conflicts of drug names within the database. The database for POCA did not address similarity of names in script.

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

**Annex 1**

| 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 |

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|---|---|
| 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 |