BRITISH PHARMACOPOEIA COMMISSION

Expert Advisory Group NOM: Nomenclature

SUMMARY MINUTES

A meeting of the Expert Advisory Group on Nomenclature was held at 10 South Colonnade, Canary Wharf, London, E14 4PU on Tuesday 12th February 2019.

Present: Dr J K Aronson (*Chair*), Ms A McFarlane, Dr G P Moss and Dr R Thorpe.

In attendance: Mr A Evans and Dr F J Swanson.

Dr Ka-Wai Wan (MHRA Licensing Division) attended the meeting for the item recorded under Minute 192.

An apology for absence was received from Mr D Mehta.

186 **Introductory Remarks**

Welcome The Chair welcomed Dr Wan to the meeting and also Dr Swanson from the Secretariat.

Declaration of Interests Members were reminded of the need to declare specific interests as they arose during the meeting.

Travel and Expenses Members were reminded that expense should be sent to Mr Brian Delahunty at the Secretariat.

I MINUTES

187 The minutes of the meeting held on 14th February 2018 were confirmed.

II MATTERS ARISING FROM THE MINUTES

188 The following matter arising from the meeting held on 14th February 2018 was noted.

Minute 178 – Naming of Impurities for BP monographs It was pointed out that there was an anomaly between the spelling of galantamine in the titles of the future formulation monographs (galan**t**amine) and in the trivial and systematic names of the associated impurities (galan**th**amine). It was confirmed that the previously agreed names were correct since "galan**t**amine" was the INN for the active substance, whereas "galan**th**amine" was the spelling recommended by IUPAC (and included for the impurities).

III ITEMS FOR THE BRITISH PHARMACOPOEIA 2020

189 **IUPAC Names for New Impurities** NOM(19)3

A list of 13 proposed IUPAC names relating to impurities in monographs intended for publication in the British Pharmacopoeia 2020 was provided.

The recommendations would be drawn to the attention of the relevant EAG Secretariats for inclusion in the individual monographs. There were a number of entries where additional information was required before the entries could be finalised.

190 **New Action and Use Statements** NOM(19)4

The Expert Advisory Group on Unlicensed Medicines (ULM) was developing a monograph for Calcium Carbonate Oral Suspension. Members were reminded that the usual practice for including action and use statements in BP formulation monographs was to include the statement from the corresponding BAN entry. In the case of unlicensed medicines, which may be used for a different indication than licensed products containing the same active ingredient, the BAN entry was not always appropriate. The oral suspension was used in the treatment of phosphate binding in renal failure and hyper-phosphataemia. The BAN entry for sevelamer included the following statement: "*Phosphate binder; treatment of hyperphosphataemia*" and members agreed that this statement was also suitable for inclusion in the draft monograph for Calcium Carbonate Oral Suspension.

IV BRITISH APPROVED NAMES 2017

191 **British Approved Names 2017: Supplement No. 3** NOM(19)5

A revised version of Supplement No. 3 was provided for confirmation. The original version, circulated by correspondence, had been updated to reflect comments received from members. The draft entries were mainly recommended INNs which were being formally adopted as BANs for products that were now licensed in the UK. The text had been prepared based on the corresponding INN entries and taking note of existing BAN pronunciations and action and use statements for similar substances.

Members confirmed that the draft entries were acceptable, subject to minor changes noted at the meeting and to additional corrections to the pronunciation and chemical names that would be provided outside the meeting. The revised Supplement would be presented to the British Pharmacopoeia Commission at their meeting in March and would be published at the same time as the BP 2020.

V ALERTS AND REPORTS

192 **Liposomal Formulated Medicines** NOM(19)6

Introduction Products prepared using active pharmaceutical ingredients encapsulated with liposomes released the drug substance over a longer time than conventional-release formulations of the same strength. This could lead to a patient receiving a fatal dose of a particular drug if the wrong formulation was administered.

MHRA Presentation Dr Wan gave a presentation entitled '*Generic' Liposomal Product Naming Proposal*. This highlighted the current difficulty of distinguishing between liposomal and non-liposomal formulations using the current naming conventions and a proposal to develop a BAN for the liposomal formulations.

The key issue was that although the strength of the active ingredient in conventional and liposomal products was the same, the release of the active pharmaceutical ingredient from the formulations was not the same. A prescriber would generally state the required strength in terms of the amount of amphotericin, for example, but would not include the full name of the product and so either liposomal or non-liposomal products could legally be dispensed. Even with the stringent labelling requirements for non-liposomal Amphotericin, which stated that Amphotericin products were not interchangeable, errors had occurred.

Discussion It was agreed that there was a need to reference liposomal within the product name. Further liposomal products would become available in the future and it was important

for the BP/MHRA to reach an unequivocal position. The problem was exacerbated by the existence of pegylated liposomal products which also had a different posology than conventional products.

Members agreed that the entry for Amphotericin in British Approved Names 2017 should be amended to include “Liposomal Amphotericin B” by means of Supplement No. 3”. Similar entries relating to liposomal (and “pegylated liposomal”) forms of Daunorubicin Hydrochloride and Doxorubicin Hydrochloride would also be added. Formal approval for this approach would be sought from the British Pharmacopoeia Commission at their next meeting (minute 191 refers).

VI INN: INFORMATION FROM WHO

193 **INN Reports** NOM(19)7

The Executive Summaries from the 65th and 66th INN Consultations were provided for information.

Mr Evans would be attending the 68th INN Consultation which would be held between 2nd and 5th April in Geneva.

VII INVENTED NAMES

194 **Invented Names** NOM(19)8

Members were informed that a total of 850 invented names had been assessed by the Secretariat during 2018, the majority of which were for products going through the Centralised Procedure.

The BP had retained the policy leadership for the naming of medicines for the MHRA and the Secretariat continued to provide advice to stakeholders prior to the submission of a Marketing Authorisation Application and to represent the MHRA at the European Medicines Agency Naming Review Group.

VIII ANY OTHER BUSINESS

195 **MHRA Guideline for the Naming of Medicinal Products and Braille Requirements for Name on Label** The current guideline was being revised and comments from members on the updated document would be welcomed.

196 **Date of next meeting** To be advised.