Department of Health & Social Care

Minutes – Advisory Committee on Borderline Substances

15 and 16 November 2021 | By teleconference owing to coronavirus measures

Attendees:

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Alison Smith (AS) - Chair
Stuart Lakin (SLk)
Rosemary Stennett (RS)
Stephen Lewis (SL)
[redacted]
Anne Daly (AD)
Andrea Hilton (AH)
Ghazala Yousuf (GY)
Emily Walters (EW)
[redacted]
Evelyn Ward (EWard)
Charlotte Ellerton (CE)
Ian R White (IRW)
Emma Emmerson (EE)

Apologies:

[redacted]
Amit Arora (AA)
Una Cuthbert (UC)
[redacted]

1. **Introductions and apologies**
   On Monday 15 November, there were apologies from Una Cuthbert and Amit Arora. On Tuesday 16 November there were also apologies from Emma Emmerson.

2. **Declaration of interests**
   AS read out the declaration of interests. The interests declared are at appendix A.

3. **Minutes of the 14th and 16th September 2021 meeting**
   The minutes were agreed and no amendments were raised.

4. **Business**

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a. Consultation on standard ready-to-drink adult ONS [redacted]

The Committee discussed an initial summary of responses from the ready-to-drink ONS consultation, which was circulated with the meeting papers, and the Committee's plans for drafting the consultation report.

SLk, GY, EE and EW volunteered to undertake the work on behalf of the Committee and work with the Secretariat to write the consultation report. The Committee will review and analyse the responses and then form recommendations, which will be published in the report. The report, including the recommendations, will be sent from the Committee to ministers as advice. Ministers can then take a decision on policy.

- [redacted] and [redacted] to contact SLk, GY, EE and EW to start making arrangements for starting the work.

b. Types of applications [redacted]

The Committee discussed new definitions for the different types of applications, which have been proposed by the joint ACBS-BSNA Working Group that is working to update the ACBS guidance and application form. The proposed definitions were circulated in Appendix 4 of the meeting papers.

The Committee recounted difficulties that type 1 applications had caused previously. Particularly regarding the evidence being presented in type 1 applications to substantiate the advantages claimed by manufacturers. Therefore, the Committee said that it would like the process for the type 1 route to be much more thorough than currently. As the nature of a type 1 product proposes the use of new or novel foods, substances and formulations, the Committee feels the requirements for, and expertise needed to review, each type 1 application would be better considered on a case-by-case basis. Overall, the Committee feels type 1 applications should include more evidence to support the product's claims of being clinically effective. This is important because type 1 products being the first of their kind pave the way for me-too products later entering the market.

The Committee considered the proposed definition for the type 1 route. It discussed whether the route had anything to do with similarities of formulas or if the route should be more concerned with the clinical outcomes afforded by any innovative product in comparison to existing products. As per the ongoing discussion, the Committee is of the opinion that the evidence of clinical outcomes needs to be compelling if it is to recommend any innovative products for listing. The Secretariat quoted the minutes of the ACBS-BSNA Working Group of 19 August 2021 in which a BSNA member speaking on the subject of evidence stated: *'established' means there is significant amounts of evidence whereas 'well-characterised' suggests there is some evidence but not a great deal…* and*…. it was unlikely that a new Type 1 product would be well-established.* For the reasons already explained, the Committee said that evidence needs to be conclusive.

On the definition for type 3 applications, the Committee said it is not appropriate for changes to the clinical or age indication of a product to be considered via this route and they should always be discussed at a meeting. When a product initially comes to the ACBS the application has to demonstrate that it is effective at managing the identified condition in the targeted patient population, and also that it is well-tolerated in that same population. Therefore, the evidence for an amendment to the clinical and/or age indication shouldn't be any different from that required upon initial application. It otherwise creates a risk that products are indicated for a condition or age without having undergone the necessary assessment – the committee was shown an example of a type 3 application received, but not yet reviewed, where a change to the clinical indication is proposed but no other product on the market is yet indicated for that condition so it would be the first of its kind and, therefore, ordinarily assessed as a type 1. The Committee agree such scenarios would be unacceptable.

The Committee asked the Secretariat to make the necessary changes to the definitions and to present them as final to the Working Group. The Committee asked that the Secretariat thank the BSNA and its members on its behalf for the many hours they have given to helping consider and work-up the new definitions.

S40 ❖ [redacted] to amend definitions and feedback final ACBS proposal to the working group.

c. Draft of the new application form [redacted]

The Committee reviewed the draft application form at appendix 5 of the meeting papers. The Committee were supportive of the draft but noted they could not really assess its usefulness until it was tested.

There were specific comments that the nutritionally complete table should ensure it expresses nutrients as a percentage of RNIs for all relevant groups, and that adults should be split into two age groups – 19-50 and 50+ as per UK reference nutrient intakes.

Throughout the meeting, the Committee also noted that the new application form should include a pro forma for acceptability studies so that relevant information is always provided. This will help to prevent instances of the Committee asking for more information and manufacturers having to redo studies.

S40 **d. Meeting date for November 2022** [redacted]

The Committee agreed to schedule a meeting for Tuesday 15 November 2022 and to hold the March 2022 meeting over two days on 14 and 15 March via Microsoft Teams.

❖ [redacted] to schedule the November 2022 meeting and reschedule the March 2022 meeting.

5. Product submissions

Product submissions were discussed. A record of this conversation is at appendix B.

Before and at the meeting, the ACBS Secretariat notified the Committee that one or both of AD and CE have a conflict of interest in all the metabolic products on the agenda.

However, given AD and CE are the only members with metabolic expertise on the Committee, they were required to review the relevant products despite their conflicts of interest.

To manage the conflicts as best as possible, the Secretariat did not have AD or CE jointly review any applications and instead paired them with other members for the purposes of the review process to increase impartiality and have appropriate challenge. The entire Committee also reviewed and discussed all the applications as per normal procedure and the decisions are those of the Committee and not individual members.

The Secretariat understands that such circumstances are likely to occur again in future and are probably unavoidable as there are so few metabolic dietitians and metabolic centres in the country and much work is conducted at Birmingham Children's Hospital and UCLH, which are AD and CE's places of work, respectively.

6. Submissions and price increases approved mid-term

A document providing a record of the submissions and price increases approved mid-term was circulated with the meeting papers. This was for information only.

7. Other Business

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[redacted]

Table of actions

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Action	Responsible
❖ [redacted] and [redacted] to contact SLk, GY, EE and EW to start making arrangements for starting the work.	[redacted]
❖ [redacted] to amend definitions and feedback final ACBS proposal to the working group.	[redacted]
❖ [redacted] to schedule the November 2022 meeting and reschedule the March 2022 meeting.	[redacted]
❖ AH, CE and AD agreed to draft a response [redacted]	AH/CE/AD

Appendix A – Declarations of interest

Name	Name of organisation	Nature of interest
Charlotte Ellerton	Vitaflo	I have agreed to speak at an educational event for dietitians in December 2021, hosted by Vitaflo. I will be paid a speaker's fee for this.
Anne Daly	Anne Daly	I have updated my declarations for a new study review. As before payments are directly to the hospital and not for personal gain
Anne Daly	Vitaflo/ APR / Promin/ Gaelen/ Nutricia	Vitaflo - Webinar on bone mineral density following use of GMP protein substitute APR - previous work in evaluating [redacted] Promin - evaluation of [redacted] Gaelen - evaluation of [redacted] Nutricia - evaluation of [redacted] Sept 21 part of an evaluation [redacted] Any monies/payments are not for personal gain and are given to the hospital
Emma Emmerson	Nutrinovo	Completed podcast around ACBS - received fee

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Appendix B – Product submissions

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* Resubmission