## Appendix 2 – Type of nutritional application

Please seek advice from the ACBS Secretariat if you are unsure about which application route to use after reading this guidance.

**Type 1**
New formulation which the applicant perceives to have well characterised and substantiated advantages in terms of nutritional composition and patient tolerance / acceptability.

**Type 2**
A product similar to a product that is listed on Part XV of the Drug Tariff and that could be considered a suitable alternative to that product.

**Type 3**
A product listed on Part XV of the Drug Tariff to which changes are proposed.

Permitted changes include those to:

- Product formulation insofar as it is not significantly altered*
- Product name
- Storage
- Preparation or reconstitution instructions
- Packaging or labelling, other than changes that do not need to be notified to the Committee as described below.
- A manufacturing process which has an impact on the product composition
- Pack size, including the addition of new pack sizes
- The addition of new flavours

Non-permitted changes include those where:

- The price is changing. Price changes are considered separately to other changes. Changes to anything other than the price should be made using the appropriate application route, and price changes need to be made in accordance with the ACBS pricing policy.
- A new product is being introduced other than new pack sizes and new flavours of existing products, which are permitted changes. For example, it is not permissible to apply for a name and formulation change to a product and then to keep the product in its existing form and add a product with a different name and formulation – that would be introducing a new product. New products should be submitted via the type 1 or type 2 routes.
- Significant alterations* to the product are proposed such that it would no longer be recognised as the product and/or formulation that was previously approved. In this case the Committee considers that a significantly altered* product is a new product and should, therefore, be treated as such. New products should be submitted via the type 1 or type 2 routes.

- There is a proposed change to the clinical and/or age indication. Changes of this nature must be submitted via another appropriate route and follow the requirements of that route.

Changes that do not need to be approved by the Committee include those to:

- Shelf life
- Manufacturing location, provided the new location complies with UK standards and legislation
- Required by legislation
- The contact details and country of origin on product labels and packaging, and the dimensions of labels and packaging provided it does not change the quantity or the prescribing unit or the use of the product.
- the listing of ingredients constituting less than 2 % of the finished product (as per Retained Regulation (EU) No 1169/2011) provided it will not affect efficacy, tolerability or acceptability.
- The addition or removal of recycling or sustainability symbols.
- The age indication where it is being narrowed from that which is already approved. For example, if a product has previously demonstrated that it is effective and has been approved for use in *children from 1 year to 5 years of age* then the applicant does not need to seek approval to narrow that indication to *children from 1 year to 3 years of age*. However, it is necessary to notify the Secretariat so that it can arrange for the relevant change to be made to publications and prescribing systems where the product is mentioned.
- The clinical indication where the clinical terminology used in the approved indication is regarded by healthcare professionals as having changed but the meaning of the indication remains the same. For example, the clinical terminology being changed from *renal disease* to *kidney disease*. However, it is necessary to notify the Secretariat so that it can arrange for the relevant change to be made to publications and prescribing systems where the product is mentioned.

**Notes**

1. If you are intending to change many products at the same time, you should first seek advice from the ACBS Secretariat.
2. The Committee reserves the right to table any type 3 application at an ACBS meeting and will do so at the next meeting where there is availability on the agenda. In this case, it will inform the applicant of the reason(s) for wanting to consider the application at a meeting and invite the applicant to provide supporting information ahead of the meeting.
3. *The Committee recognises the difficulty in defining, and the subjectivity of, the terms ‘significantly altered’ and ‘well-established advantages’ or variations on those terms. Nevertheless, the Committee must be the decision maker of whether a product is significantly altered or evidence is well-established and, therefore, reserves the right to make such determinations.
4. The Committee and Secretariat reserve the right to stop processing an application if it considers that the applicant has submitted the wrong type of application. In this case,

the reasons will be explained and an alternative application route will be recommended. The applicant must then make a new submission and restart the process.