Appendix 8: The scheduling of product applications to an ACBS meeting agenda

Applications are allocated a place on the agenda of an ACBS meeting according to the following order of priority and rules.

Order of priority

1. Products already listed in Part XV that the Committee has called for review and, where applicable, any applications for new products that could contribute to the review.
   This is where the Committee has concerns or questions over the safety or efficacy of a listed product and it has called the product for review. It is possible that a new product application may be submitted that could contribute to the review. In that instance, it is necessary to review both the existing and new products at the same time to ensure consistency. This priority is also reserved for type 3 applications that the Committee has decided need to be discussed at a meeting.
   Expected frequency of use: Rare. Reviews, including those of type 3 applications, are rarely called by the Committee.

2. Products that can help to address a shortage.
   Where a shortage exists, applications for products that could address the shortage are given priority. The Department of Health and Social Care (DHSC) has knowledge of supply issues to advise whether an application should be prioritised under this heading. The National Supply Disruption Response team at DHSC defines a shortage as when the supply of a product is disrupted and there is insufficient availability or access to suitable alternative products, treatments or therapies to prevent that disruption from having a potentially material negative impact on patient safety and/or health.
   Expected frequency of use: Rare.

3. Type 1 products and products for the management of Inherited Metabolic Disorders (IMD)
   This prioritises innovation and patients. The type 1 route is specifically for innovative products that have well substantiated advantages for patient care and are not similar to others on the Part XV market. Products indicated for IMD are also prioritised to increase the range of options for clinicians to manage the conditions of these particularly vulnerable patients. Where a product is both a type 1 and for IMD it will be prioritised above others in this category. Otherwise, products in this category will be scheduled in the order they are received.
   Expected frequency of use: Regular. Few type 1 applications are submitted but the Committee regularly reviews applications for IMD products.

4. All other applications.
   Scheduled on a first-come-first-served basis.

Rules

1. There is no limit on the number of applications that can be on the agenda for a meeting. However, the Secretariat will determine how many applications can be accommodated on each agenda based on the number of committee members available to review products and other items on the agenda.

2. All applications on an agenda are reviewed by the Committee in its entirety at a meeting. In advance of each meeting, the Secretariat usually groups members into twos or threes and assigns each group 2-3 applications to report on to the Committee. Therefore, for certain products where members with particular skills are needed, there will be a limit to how many can reasonably be reviewed. This is predominantly the case in the review of applications for inherited metabolic disorders and paediatrics. For example, if the Committee has two paediatric specialists it is only reasonable that if they were to review different applications that they could review a maximum of two to three each, depending on the complexity of the applications and the other committee work they had on. In this instance, the agenda could only accommodate 4-6 paediatric products.

3. If an application cannot be accommodated on an agenda, it will be added to a queue for the next agenda according to the order of priority and these rules.

4. The Secretariat will monitor the effectiveness of this initiative and may take steps if necessary to prevent repeat de-prioritisation of applications.