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Janssen's Response to the Appraisal Consultation Document

Anaemia (cancer-treatment induced) erythropoiesis-stimulating agents [ID541]

Please find below Janssen's response to the Appraisal Consultation Document (ACD) for anaemia (cancer-treatment induced) erythropoiesis-stimulating agents [ID541] issued in April 2014. We are pleased to have an opportunity to provide our comments and are supportive of NICE's initial positive recommendation.

We wish to highlight two key points in relation to the appraisal:

1. **The Committee's conclusion that the wholesale prices were the most relevant prices to the NHS and therefore the appropriate prices on which to base its decision. (Section 4.3.10 of the ACD)**

We do not support the use of wholesale prices in the NICE MTA process. We support the use of BNF list prices, as is usual practice within the NICE technology appraisal process.

2. **The current absence of any pharmacovigilance requirements in the ACD**

We wish to ensure that Section 1 of the guidance produced during this MTA contains appropriate wording in line with the recommendations made by the ABPI on brand named prescribing to support pharmacovigilance requirements and the use of other standardised wording for biosimilar medicines.

The ABPI recommendation is as follows:

When referencing the originator biological medicine and it's biosimilar medicines, it is appropriate to use the name of the active drug substance. However when any individual medicine is being referred to then the brand name should be used because substitutability and interchangeability cannot be assumed. This is extremely important in order to support consistent implementation by the NHS of EU and MHRA requirements for pharmacovigilance and monitoring of biological medicines, including biosimilar medicines, as set out in the ABPI's position paper on biosimilar medicines. The brand names of all biological medicines, including biosimilar medicines should be used in all guidance and guidelines documents and evidence summaries issued by NICE.