11 March 2021
EMA/CHMP/154036/2021 Rev.1
Human Medicines Evaluation Division

Hemoblast Bellows

Procedural steps and scientific information after initial consultation

Application number	Scope	Opinion/ Notification[1] issued on	Summary
II/0008/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II	25/02/2021	Change of notified body from BSI Group, UK to BSI Group The Netherlands B.V. Change of device manufacturer from Biom'up SA to Biom'up France SAS. To submit a 2nd step notification. To reconfirm the Scientific opinion granted under MDD (93/42/EEC) for the purpose of certification under MDR (MDR/2017/745). Submission of follow up measure linked to EMEA/H/D/002769/IB/001. Submission of Clinical Study report of study ETC2015-002, a prospective, randomized, controlled, multicentre,

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

			pivotal, clinical investigation evaluation the safety and efficacy of HEMOBLAST™ Bellows in cardiothoracic, abdominal and orthopaedic lower extremity surgeries (ETC2015-002) conducted on HEMOBLAST™ Bellows.
IB/0007	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	24/01/2020	To update the shelf life of the device to 24 months based on real time stability data.
II/0006/G	This was an application for a group of variations. Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	14/06/2019	To include a 2nd step notification procedure. Update to the 'Adventitious Agents Safety Evaluation' information to replace obsolete studies related to manufacturing steps and adventitious agents already reported in the dossier.
IB/0004/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB	23/10/2018	To include a 2nd step notification procedure. Minor change in manufacturing process of the finished product. Minor change to in process controls or limits applied during the manufacture of the finished product. Minor change to in process controls or limits applied during the manufacture of the finished product. Minor change in the test procedure of the finished product. Minor change to in-process tests or limits applied during the manufacture of the finished product
II/0003/G	This was an application for a group of variations. Minor changes to an ancillary medicinal substance -	26/04/2018	Changes in the manufacturing process of the active substance. Change in immediate packaging of the active substance Minor change in manufacturing process of the active substance.

	Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IB Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA		Change to in-process tests applied during the manufacture of the active substance. Change in test procedure for the immediate packaging of the active substance. Deletion of name of suppliers used for the primary packaging material for the active substance. Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Changes to in-process tests and limits applied during the manufacture of the finished product.
IA/0002	Minor changes to an ancillary medicinal substance - Post consultation procedure equivalent to IA	26/02/2018	To add a new specification parameter for a starting material used in the manufacturing process of the active substance.
II/0001/G	This was an application for a group of variations. Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II Minor changes to an ancillary medicinal substance -	10/11/2016	Change in immediate packaging of the finished product (biological medicinal product), changes in the composition (excipients) of the finished product, to change the material of the CE marked device, to extend the currently approved intended use and to replace a biological/immunological/immunochemical test method for the finished product.

	Post consultation procedure equivalent to IA Major changes to an ancillary medicinal substance - Post consultation procedure equivalent to II		