AfA Baxter AG

Submission number: KA600552-65

Communication number: AFA-C-2114510478-49-01/F

Substance: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated

Use name: *Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (as a detergent) for virus inactivation via S/D (Solvent/Detergent) treatment in recombinant and plasma-derived medicinal products*

Answers to SEAC question – Confidential version

Please provide an update of Table 4 in the AoA and SEA document ('Overview of active substances (medicinal products) and sites in scope if this AfA') taking into account the (future) manufacturing of CoVIg-19 hyperimmune. Please provide confidential and public versions of this table.

Table 4: Overview of active substances (medicinal products) and sites in scope if this AfA

Production Site	Substance class	Active substance	Trade name
Lessines, Belgium	Plasma-derived products****	Immune Globulin Subcutaneous (Human), 20 % Solution	Cuvitru
		Immune Globulin Infusion 10 % (human) with Recombinant Human Hyaluronidase	Gammagard S/D
		Human normal immune globulin infusion (human) 10 %	HyQvia
		Immune Globulin Infusion (Human) 10 %	Gammagard Liquid/ Kiovig / CoVIg-19 hyperimmune
Vienna, Austria [redacted]	Plasma-derived products	Human coagulation factor VIII/Human von Willebrand Factor (VWF) complex concentrate	Immunate
		Sealer protein solution: aprotinin (synthetic), Factor XIII, Fibrinogen; Thrombin solution: thrombin (human), calcium chloride dihydrate	Tisseel*
		Sealer Protein solution: human fibrinogen (as clottable protein), aprotinin (synthetic); Thrombin solution: thrombin (human), calcium chloride	Artiss*
		Gelatin matrix component: gelatin matrix (bovine or porcine); Thrombin component: thrombin (human), calcium chloride solution	Floseal Haemostatic Matrix*
Vienna, Austria [redacted]	Plasma-derived product	Immune Globulin Infusion (Human) 10 %	CoVIg-19 hyperimmune
Orth, Austria	Recombinant products	Factor VIII gene therapy	F-VIII GT project**
		[redacted]	[redacted]**
		Future commercial products***	

* Baxter products manufactured by Takeda;

** Development products manufactured by Takeda;

*** Orth is planned to be used as CMO for third-party development and commercial products and/or for Takeda commercial products

**** Products listed are representatives of plasma-derived therapies using the same process conditions and volumes manufactured on the same production lines.

Please note that, if the CoVIg-19 hyperimmune development drug becomes commercial, the production line ([redacted]) in Lessines would not need to be modified for its commercial production as Takeda would simply swap one of the products currently manufactured over this line with CoVIg-19 hyperimmune. Therefore, the RMMs described in the CSR for Lessines to not change for manufacturing CoVIg-19 hyperimmune.

Please note that the scope of this AfA is valid for the active substances (see Table 4) manufactured with OPnEO but is not limited to the trade names under which these are sold. Further information on these medicinal products can be found in A.4 Treatment areas.