25 June 2015
EMA/CHMP/BPWP/316655/2014
Committee for Medicinal Products for Human Use (CHMP)

Overview of comments received on 'Guideline on core SmPC for plasma-derived fibrin sealant/ haemostatic products' (EMA/CHMP/BPWP/598816/2010 rev. 1)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	Plasma Protein Therapeutics Association (PPTA)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
N/A	N/A	N/A

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
137 - 139	1	Comment: The new proposed Guideline requests to include the following text for products recommended for use with pressurised gas fibrin sprayers: < To avoid the risk of potentially life-threatening air embolism {(Invented) name of the product} should be sprayed using pressurised CO_2 gas only.> The new proposed text does not correctly reflect the outcome of the referral procedure under Article 31 of Directive 2001/83/EC, procedure number EMEA/H/A-31/1337: In the course of the referral procedure under Article 31 of Directive 2001/83/EC, procedure number EMEA/H/A-31/1337, the CHMP has considered restricting spray application of fibrinogen-containing solutions for sealant authorised for administration by spray application to pressurised CO_2 gas only. **However, in their final opinion the CHMP agreed that the use of CO_2 should not be mandatory for all products subject to the referral for the spray application using a pressure regulator**. The specific products for which the use of CO_2 should not be mandatory are listed in Annex II "Scientific conclusions and grounds for variation to the terms of the Marketing Authorisations", page 22 (English text), of the European Commission decision EMEA/H/C/A31/1337 of the above mentioned referral procedure. The CHMP recommended changes to the Product Information of the products subject to the referral which are reflected in Annex III of the commission decision. In line with the scientific conclusions of the CHMP, mandatory use of CO_2 was not requested for all products subject to the	Partly accepted. Two situations are described in the core SmPC: • If no air or gas embolism cases have been reported • If air or gas embolism cases have been reported or if a known risk (air or gas embolism) has been identified.

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
		referral procedure. In line with the scientific conclusions from the CHMP we disagree with the proposed wording in lines 137 – 139 and propose the text changes described below. Also, we strongly recommend to amend “air embolism” to “air or gas embolism” in line with other sections of the SmPC (4.4, 4.8): Proposed change: *[For products recommended for use with pressurised gas fibrin sprayers include the following text, and if products are restricted to use of CO_2 gas only:]* <To avoid the risk of potentially life-threatening air embolism {(Invented) name of the product} should be sprayed using pressurised CO_2 gas only. > *[For products recommended for use with pressurised air or gas fibrin sprayers include the following text:]* <For spray application, see sections 4.4 and 6.6 for specific recommendations on the required pressure and distance from tissue per surgical procedure <and length of applicator tip>>. Reference: European Commission decision on the referral procedure under Article 31 of Directive 2001/83/EC, procedure number EMEA/H/A-31/1337, Annex II “Scientific conclusions and grounds for variation to the terms of the Marketing Authorisations”	

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151-153	1	Comment: We do not agree that spray application in endoscopic procedures is a contraindication: Medical devices specifically developed and designed for use in endoscopic procedures with spray application are available. These devices (pressure regulator & applicator) use pressurized gas for uniform spray delivery, **enabling a safe, aerosolized endoscopic spray application by reducing gas flow rate** and dynamically venting gas throughout the spray application. **The gas flow rate is reduced** (approximately 2 L/min), whereas open gas spray systems (NOT designed for endoscopic use) can have flow rates as high as 20 L/min." Proposed change (if any): [*For products recommended for use with pressurised gas fibrin sprayers include the following text:*] <Spray application of {(Invented) name of the product} with the {(Invented) name of the applicable spray device/system} should not be used in endoscopic procedures. For laparoscopy, see section 4.4.>	Not accepted. *Addition of an explanatory note:* *'Some products have been allowed to continue endoscopic use based on clinical experience and a sound benefit/risk evaluation.'*
370-371	1	Comment: The proposed statement in lines 370 and 371 does not apply to all fibrinogen-containing solutions for sealant authorised for administration by spray application – see comment above regarding lines 137 – 139 of the draft Core SmPC. Proposed change (if any): [For products restricted to the use of CO_2 gas only with spray application include the following text:] < To avoid the risk of life-threatening air or gas embolism {(Invented) name of the product} should only be sprayed using pressurised CO_2 (see table below)>	See above.