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European Directorate for the
Quality of Medicines & Healthcare
Council of Europe
Ph. Eur. Commission
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Brussels, 5 May 2021

Object: Request to remove the PMSG (eCG) monograph from the European Pharmacopoeia

Dear Members of the European Pharmacopoeia Commission,

A delegation of animal welfare organisations and Eurogroup for Animals - a pan-European animal advocacy organisation based in Brussels, Belgium - would like to express their support to a request submitted to the European Pharmacopoeia Commission on 21st January 2021 by Mr Schäffer, a lawyer representing the Animal Welfare Foundation (AWF) and Tierschutzbund Zürich (TSB), asking to **cancel the monograph “gonadotropin, equine serum, for veterinary use” from the European Pharmacopoeia.**

PMSG (pregnant mare serum gonadotropin), also called eCG (equine chorionic gonadotropin), is a hormone extracted from the blood of pregnant mares. It is used as an active ingredient in medicinal products administered to farmed animals in order to increase their fertility, and **not for health purposes**. A number of **authorised synthetic medicinal products are available** on the pharmaceutical market which makes PMSG (eCG) dispensable. It is important to note that achieving good reproductive results is also possible to some extent with informed management techniques such as adjusting feeding plans to the reproductive cycle¹.

The extraction of PMSG (eCG) raises serious animal health and welfare concerns. Furthermore, upholding intensive animal farming practices, during which PMSG (eCG) is used, goes against the European Commission's Green Deal objectives, such as the shift to a more plant-based diet outlined in the Farm to Fork strategy. For all these reasons, we respectfully ask the European Pharmacopoeia Commission to cancel the monograph “gonadotropin, equine serum, for veterinary use” from the European Pharmacopoeia.

¹ Nutrition in Cattle Reproduction By Jonathan Statham, By, Statham, J. Apr 2015. (n.d.). *Nutrition in Cattle Reproduction - Management and Nutrition*. Veterinary Manual.
<https://www.msdevetmanual.com/management-and-nutrition/management-of-reproduction-cattle/nutrition-in-cattle-reproduction>.

Conditions of production in third countries

Despite repeated evidence of mistreatment²³ and the attempts by pharmaceutical industry to improve the situation⁴, PMSG (eCG) continues to be sourced in a cruel way, mostly from Uruguay and Argentina. In so-called “blood farms” run specially for the production of PMSG, pregnant mares have up to 10 litres of blood extracted per week; their foals are systematically aborted twice a year, and the mares are most often left without veterinary care. Mares are often emaciated and suffer severe abuse from their handlers.

The blood plasma and the active substance used to be exported to the EU on a large scale and are still imported today by some companies to be processed and marketed as a veterinary medicinal product. After several EU-based pharmaceutical companies stopped importing PMSG from South America on animal welfare grounds, the largest producing company (Syntex, based in Argentina and Uruguay) is currently re-entering the EU market with a final PMSG (eCG) product, supported by a German company that is acting as applicant and using a decentralised authorisation procedure in seven EU Member States.

PMSG production classified as “animal experimentation” in the EU

Until September 2019, the European Commission and the German Federal Government had no knowledge of a PMSG (eCG) production within Germany. Yet, a farm had been producing PMSG (eCG) for 40 years without approval from the competent authority. After media exposure in December 2019, the State Office of Thuringia allowed the activity to continue within the framework of an “animal experiment”.

However, this EU-based production of PMSG (eCG) is in breach of the EU directive on the protection of animals used for scientific purposes (EU Directive 2010/63/EU), which is based on the principle of the “3Rs” - Replacement, Reduction and Refinement. Both the German and EU legislation require animal experiments – including the manufacture of pharmaceuticals – to be “indispensable”. Such “procedures” can thus only be approved if there are no alternatives available. The Recitals no. 11 and 12 in the upper mentioned directive clearly state that “*when choosing methods, the principles of replacement, reduction and refinement should be implemented through a strict hierarchy of the requirement to use alternative methods*” and “*the use of animals (...) should therefore only be considered where a non-animal alternative is unavailable.*” In the case of PMSG, numerous synthetic alternatives, and other natural methods, exist. It is important to note that, although the state of Thuringia has allowed this production to continue, the collection of blood from pregnant mares is generally prohibited in Germany according to “Guidelines on the collection, storage, transport and administration of blood and blood products in the veterinary field”. On this German farm, 16 litres of

² Süddeutsche Zeitung, 29.9.2015: www.sueddeutsche.de/wirtschaft/handel-grausamer-bluttransfer-1.2668283

³ NGOs denounced these abuses over the past 6 years, see AWF|TSB documentary film (2018): www.youtube.com/watch?v=Rc1rhfMVI08&t=12s

⁴ Several EU-based companies stopped importing PMSG (eCG) from South America based on animal welfare concerns, see Ceva’s statement (2018): www.cevavousrepond.com

blood are extracted per week from each mare. This is about twice as much as the guidelines allow for non-pregnant horses every 30 days. According to veterinary experts⁵, several health risks exist with the blood collection as practiced on the German stud.

Conclusion

Bearing in mind the above and all the evidence available to date, we call on the European Pharmacopoeia Commission to remove the monograph “*gonadotropin, equine serum, for veterinary use*” from the European Pharmacopoeia. While its production generates immense animal health and welfare concerns, this substance can be replaced by synthetic alternatives and management techniques. Furthermore, it does not fulfil any essential purpose in the EU and breaches EU law. The use of PMSG (eCG) contradicts the wider objectives set by the European Green Deal of moving towards sustainable food production systems and improving animal welfare. It would be an important step from the Members of the European Pharmacopoeia Commission to act in compliance with the demands of the European citizens⁶⁷ and to prevent cruelly produced PMSG (eCG), whether obtained in third countries or in the EU, from being placed on the EU market.

Yours sincerely,

Stephanie Ghislain, Eurogroup for Animals
Frederieke Schouten, Dier&Recht
Sonny Richichi, IHP Italian Horse Protection Onlus
Andrea Mihali, Deutscher Tierschutzbund
Roza Roussou, IPPOTHESIS, Panhellenic Equine Welfare Society
Brian Gillen, DSPCA
Pierre Sultana, Four Paws
Ann Degreef, GAIA
Heidi Kivekäs, Animalia ry
Ghislain Zuccolo, Welfarm
Sonja Meadows, Animals’ Angels Inc.
Anita Krajnc, Animal Save Movement
Azul Cardozo, Montevideo Horse Save
Alejandra García, Fundación Franz Weber
Sinikka Crosland, Canadian Horse Defence Coalition
Åsa Hagelstedt, Djurskyddet Sverige/Animal Welfare Sweden
Maria Lindqvist, SEY Animal Welfare Finland
Paul McGlone, Animal Action Hellas & Greek Animal Welfare Fund

⁵ Expert opinion of Prof. Dr Heidrun Gehlen, Free University Berlin, Clinic for Horses, General Surgery and Radiology (attached)

⁶ Petition No 0076/2019 by Manuela Giacomini (Italy), on behalf of Animal Welfare Foundation, on blood farms and Pregnant Mare’s Serum Gonadotropin (PMSG)
<https://www.europarl.europa.eu/petitions/en/petition/content/0076%252F2019/html/Petition-No-0076%252F2019-by-Manuela-Giacomini-%2528Italy%2529%252C-on-behalf-of-Animal-Welfare-Foundation%252C-on-blood-farms-and-Pregnant-Mare%25E2%2580%2599s-Serum-Gonadotropin-%2528PMSG%2529>

⁷ Petition “Stop the pregnant horse blood trade!” https://secure.avaaz.org/campaign/en/horse_blood_loc/