Conseil de
l'Union européenne

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NOTE

Origine:	la présidence
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N° doc. Cion:	COM (2022) 76
Objet:	Proposition de RÈGLEMENT DU PARLEMENT EUROPÉEN ET DU CONSEIL établissant des règles transitoires pour l'emballage et l'étiquetage des médicaments vétérinaires autorisés conformément à la directive 2001/82/CE et au règlement (CE) n° 726/2004 (COM(2022)76) - Résumé de la consultation publique - information de la Commission

Les délégations trouveront en annexe, pour information, le résumé de la consultation publique préparée par la Commission.

Ref. Ares(2022)4006723 - 30/05/2022

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director-General

Brussels
SANTE/E5/AL/ci (2022)3891882

Dear Ambassador, dear Honourable Member,

From 3 March to 28 April, the Commission carried out a public consultation on a proposal for a Regulation of the European Parliament and of the Council laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004 (COM (2022) 76). Attached you find for your information a summary of the response received during this consultation.

Yours sincerely,

[e-signed]
Sandra GALLINA

Enclosure: 1

c.c.: Mr N. Ponçon, Chair of the Council Working Party
(nicolas.poncon@diplomatie.gouv.fr)
Secretary General
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Ms C. Bury, Mr K. Berend, Ms E. Zamora Escribano, Ms A. Long
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HE Mr Philippe Léglise-Costa
Ambassador to the Permanent Representation of France to the European Union

Mr Pascal Canfin, Member of the European Parliament
Chair of the Committee on the Environment, Public Health and Food Safety
European Parliament

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Electronically signed on 30/05/2022 14:50 (UTC+02) in accordance with Article 11 of Commission Decision (EU) 2021/2121

Summary of Feedback

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised in accordance with Directive 2001/82/EC and Regulation (EC) No 726/2004 (COM(2022)76)

The above Commission proposal was published for feedback on the Better Regulation Portal from 3 March to 28 April 2022. One comment was received from BPI (*German Pharmaceutical Industry Association*).

BPI welcomed the Commission's proposal insofar as it allows marketing authorisation holders to place veterinary medicinal products that comply with the previous legislation on packaging and labelling on the market until 29 January 2027.

BPI also put forward a number of proposals to amend the text.

First, BPI considered that the proposal should cover registrations of homeopathic products. In this regard, the Council and European Parliament have introduced an amendment to the Commission's proposal in order to clarify that indeed the proposal applies to registrations of homeopathic products.

Second, BPI considered that there should be a transitional period for authorisation of antimicrobial veterinary medicinal products intended for animals exclusively kept as pets. However, it should be noted that the Commission's proposal addresses a very specific concern in relation to compliance with packaging and labelling rules. Any changes to Regulation (EU) 2019/6 in relation to authorisation of specific types of products in specific circumstances would go far beyond the scope of this proposal.