HELLENIC REPUBLIC
MINISTRY OF HEALTH

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Cholargos : 23-01-2026
Protocol Nr : 8490

Subject: Submission of variation requiring assessment- G.I.18

Marketing Authorization Holders of veterinary medicinal products with a marketing authorization granted in accordance with either the Directive 2001/82/3C or the Regulation (EC) No 726/2004, are required to update the product information until the ***29th January 2027***, as mandated by the article 152 of the Regulation (EU) 2019/6.

Therefore, Marketing Authorization Holders are strongly encouraged to proceed *immediately* to the submission of the VRA- G.I.18, in order to align the product information with the latest version of the QRD standards before the Regulation (EU) 2019/6 deadline.

For more guidance on the submission of the variation, please refer to the link:
<https://www.hma.eu/fileadmin/dateien/Veterinary_medicines/CMDv_Website/Procedural_guidance/Post_Marketing_Procedures/Variations/Guidance_on_the_submission_of_G.I.18_Variations_Requiring_Assessment.pdf>

The President of EOF

S. Sapounas

INTERNAL DISTRIBUTION

1. *President's office*
2. *Veterinary Medicines Assessment Section*