









HPRA webinar on requirements for veterinary medicines for pets that qualify for registration under Article 5(6) of Regulation 2019/6

Closing remarks

14 May 2021





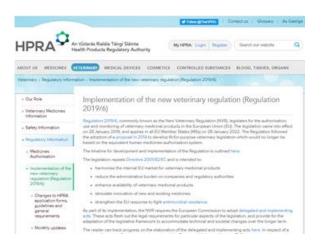
Conclusion

- Article 5(6) of Regulation 2019/6 allows MS to grant exemptions from the requirement for a MA for products intended for certain pets,
- New national legislation will provide for a registration system from Jan 2022,
- HPRA will draft data requirement and procedural guidance,
- After Jan 2022, no new product can be brought to the Irish market without being either authorised or registered with the HPRA.



Stay informed

• <u>http://www.hpra.ie/homepage/veterinary</u>



• <u>https://www.ema.europa.eu/en/veterinary-medicines-regulatory-information</u>





Follow up questions

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New Veterinary Regulation Webinar

On 31 March 2021, the HPRA held a webinar to provide information about how the New Veterinary Regulation affects marketing authorisation holders and veterinary manufacturers.

The webinar aimed to:

- · raise awareness of upcoming changes impacting the regulation of veterinary medicinal products;
- focus on aspects of the new Regulation directly affecting how marketing authorisation holders engage with the regulatory system;
- · outline the next steps in the implementation pathway;
- · inform stakeholders about where to find relevant information.

A recording of the webinar is available below, in addition to copies of the presentation slides and a Q&A document providing responses to questions raised in the webinar.

Video Recording

Please note that the video below is only available to view if you have selected the relevant preferences in the cookie settings for our website. The video is also available to view on our YouTube account. On YouTube, time stamps are available in the description box, which allow you to skip to specific sections of the video.



Presentations

Please download copies of the presentation slides using the links below.

Webinar welcome and overview





Thank you





> www.hpra.ie