



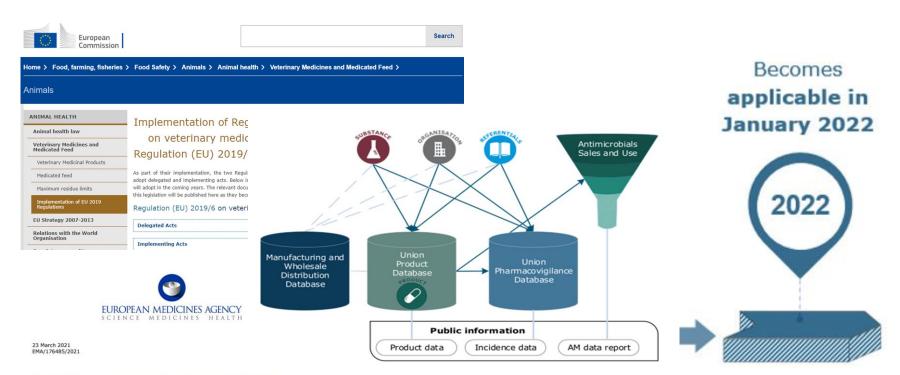
HPRA Webinar on Regulation 2019/6

Closing remarks

31st March 2021



Conclusion



Draft QRD veterinary annotated product information template $\nu.9$

| Draft agreed by CVMP for release for consultation | 17 March 2021 |
|---|---------------|
| Draft agreed by CMDv for release for consultation | 18 March 2021 |
| Start of public consultation | 29 March 2021 |
| End of consultation (deadline for comments) | 14 May 2021 |





Conclusion

- Know your responsibilities under Regulation 2019/6.
- Stay informed.
- Have your say.
- Review and prepare to update internal processes, where necessary.

Becomes applicable in January 2022







Stay informed

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

| HPRA 🗘 🗧 | n tilderåe Ralala Talogi Slänte altih Producte Regulatory Authority | | | |
|--|---|--|--|--|
| MOUT UR MEDICINES | TELEVIST MEDICAL DEVICES CONNETICS CONTROLLED SUBSTANCES BLOOD, TISUES, ORGANS | | | |
| Vetermany - Regulatory Inform | ators - Instanceduation of the new veterinery regulation (Regulation 2016-0) | | | |
| + Cur Role | Implementation of the new veterinary regulation (Regulation 2019/6). | | | |
| Safety Information | | | | |
| Repulsiony Information Medicines | | | | |
| Authorization | The legislation repeats Overtive 200/821C and is intended to: | | | |
| Inchementation of the new veterinery requireton (Regulation 20166) | Namona the internal EU market for veterinery medicinal products | | | |
| | reduce the administrative burden on companies and regulatory authorities | | | |
| | anhance availability of vetermary medicinal products | | | |
| Changes to HPRA epotestion forms, guidelines and general requirements | stimulate involution of new and existing medicines | | | |
| | attemption the EU response to light entimositival resistance. | | | |
| | As part of its implementation, the NVII requirements for particular spectra of the legislation of adopt delegation and provide for the adoption of the legislation of the legislation of the legislation of the legislation, and provide for the adoption of the legislation of the legislation of the legislation of the legislation of the legislation. | | | |
| + Monthly updates | The reader can lined, progress on the elaboration of the delegated and implementing acts here. In respect of a | | | |

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



 <u>https://ec.europa.eu/food/animals/health/veterinary-</u> medicines-and-medicated-feed/imp-regs-2019_en

| European Commission | 1 | Searc |
|--|--|---|
| ome > Food, farming, fisheri | es > Food Safety > Animals > Animal health > Veterinary Medicines and Med | dicated Feed > |
| | | |
| ANDHAL REALTH | Implementation of Regulation (EU) 2019/6 on veterinary medicinal products and | Share |
| Animal bealth lesr | | |
| Veterinary Modicines and Medicated Feed | | QUECK LINKS |
| Veterinary Hedicinal Products | Regulation (EU) 2019/4 on medicated feed As part of their indemendation, the text hypothesis index the Kongoun Commission to address the control sector of the sector of th | Scheropean Food Salety Authority abia ((FSA) |
| Hedicated feed | | 💩 European Hadicinas Apency |
| Hadmum residue limits | | Franks and find audits and analysis |
| Implamentation of EU 2019 Regulations | Regulation (EU) 2019/6 on veterinary medicinal products | P Trade Control & Expert System (TRACES) |
| EU Strategy 2007-2013 | Delegated Acts | of Dealey all per- |
| Relations with the World Organisation | Implementing Acts | V Setter Taking for Sale: Food |





Thank you





> www.hpra.ie