New Process for Handling the SPC

HPRA webinar – Update on the implementation of Regulation 2019/6 in Ireland

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Processing of the SPC by the HPRA

- As of 16 February 2022, the manner in which the HPRA processes the Summary of Product Characteristics (SPC) at the end of procedures (both new marketing authorisation and variation procedures) changed.
- With the objective of:
  - Establishing a process that is simple and efficient, and
  - Ensuring consistency with documents published in the Union Product Database (UPD),

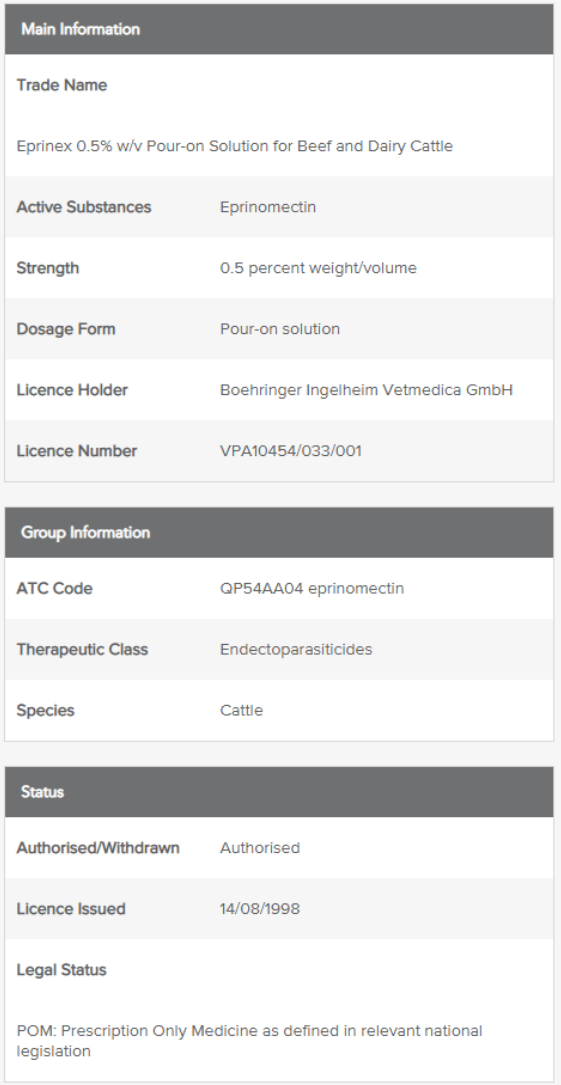
  the HPRA will take the SPC document as agreed at the end of procedure (EoP) and publish it directly on the product listing on the HPRA website, without any manipulation or handling of the document.
- All relevant national-specific information will be published on the website together with the link to the EoP SPC.

National specific information will be published in the 'product profile' on the website:

- Name of the veterinary medicinal product (SPC, section 1)
- Name (and address) of the MAH (SPC, section 6).
- Marketing Authorisation Number (SPC, section 7)
- Date of first authorisation (SPC, section 8),
- Date of last revision of the SPC (SPC, section 9) – to be captured in the list of decisions to be published alongside the SPC and the PuAR.
- Classification of VMPs (SPC, section 10)

Trade Name	Licence Number & Holder	Documents
Eprinex 0.5% w/v Pour-on Solution for Beef and Dairy Cattle 0.5 percent weight/volume Pour-on solution Compare	VPA10454/033/001 Authorised: 14/08/1998 Boehringer Ingelheim Vetmedica GmbH	SPC

Product profile on HPRA website



Main Information	
Trade Name	
Eprinex 0.5% w/v Pour-on Solution for Beef and Dairy Cattle	
Active Substances	Eprinomectin
Strength	0.5 percent weight/volume
Dosage Form	Pour-on solution
Licence Holder	Boehringer Ingelheim Vetmedica GmbH
Licence Number	VPA10454/033/001

Group Information	
ATC Code	QP54AA04 eprinomectin
Therapeutic Class	Endectoparasiticides
Species	Cattle

Status	
Authorised/Withdrawn	Authorised
Licence Issued	14/08/1998
Legal Status	
POM: Prescription Only Medicine as defined in relevant national legislation	

New Applications authorised by way of National/MR/DC/SR procedure

Where QRD version 9.0 applies, the following sections of the SPC should be left blank:
6 (Name of the Marketing Authorisation Holder),
7 (Marketing Authorisation Number),
8 (Date of first Authorisation),
9 (Date of the last Revision of the SPC).

For any new marketing authorisation applications being reviewed under Directive 2001/82/EC, where QRD version 8.2 applies, the following sections of the SPC should be left blank:
7 (Marketing Authorisation Holder),
8 (Marketing Authorisation Number),
9 (Date of first Authorisation/Renewal of the Authorisation),
10 (Date of Revision of the text).

VRA/VNRA's authorised by way of National/MR/DC/SR procedure

For **variations to existing marketing authorisations** that result in revisions to the SPC, again the HPRA will take the SPC document as agreed at EoP and publish it directly on the HPRA website.

In order to avoid incorrect information being published to the website, the applicant should ensure that the relevant sections of the SPC that house national-specific information remain blank.

Points to note:

- For all procedures resulting in updates to the SPC, the MAH is responsible for ensuring that the most up-to-date versions of the SPC, incorporating all agreed revisions, are provided to the HPRA at EoP.
- Information on the handling of concurrent variations can be found in the BPG's for VRA's & VNRA's.
- Any inaccuracies in the published SPC should be notified to the HPRA immediately, if identified, so that the necessary corrective action can be taken.

Issuing of new MAA, Renewals & Transfers

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- HPRA will no longer issue the authorised SPC (neither electronically nor in hard copy) as part of the authorisation documentation
- The authorisation document (which details the product name, the MAH name and address, the VPA number, the date of first authorisation and period of validity of the authorisation), advises that the terms of the marketing authorisation, including the SPC and legal status, are as specified in the list of authorised veterinary medicinal products on the HPRA website.

Summary

- The new simplified processes are expected to significantly reduce administration input, reduce the need for QC checks, facilitate interaction with the union product database and result in faster publication of updated SPC documents.
- Responsibility for updating and 'controlling' the product information (PI) is with the MAH.
- National specific information to be left blank on the SPC for all procedures.
- The HPRA will take and publish the EoP SPC, noting that relevant national specific information will be published in the 'product profile' on the website.
- MAH to ensure the RMS is in receipt of the most recent SPC to include any changes authorised since submission of ongoing procedures (in line with relevant BPGs).

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Thank you

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