



Renewals

and the implementation of Veterinary Medicines Regulation (EU) 2019/6

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

May 2022



Renewals - under the 'old' Directive 2001/82



Renewals, Transfers & Withdrawals

Renewal application

Marketing authorisations are valid for five years from the date of first issue. For the authorisation to remain valid, it must be renewed at the end of this five-year period. Following this renewal, the authorisation remains valid for an indefinite period (unless a further renewal is deemed necessary by the HPRA on grounds of public or animal safety).

Renewal applications must be submitted to the HPRA at least six months before the expiry of the authorisation.



Veterinary Medicines Regulation (EU) 2019/6

7.1.2019

EN

Official Journal of the European Union

L 4/43

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on veterinary medicinal products and repealing Directive 2001/82/EC

(Text with EEA relevance)

Section 1

General provisions

Article 5

Marketing authorisations

1. A veterinary medicinal product shall be placed on the market only when a competent authority or the Commission, as applicable, has granted a marketing authorisation for that product in accordance with Article 44, 47, 49, 52, 53 or 54.

2. A marketing authorisation for a veterinary medicinal product shall be valid for an unlimited period of time.



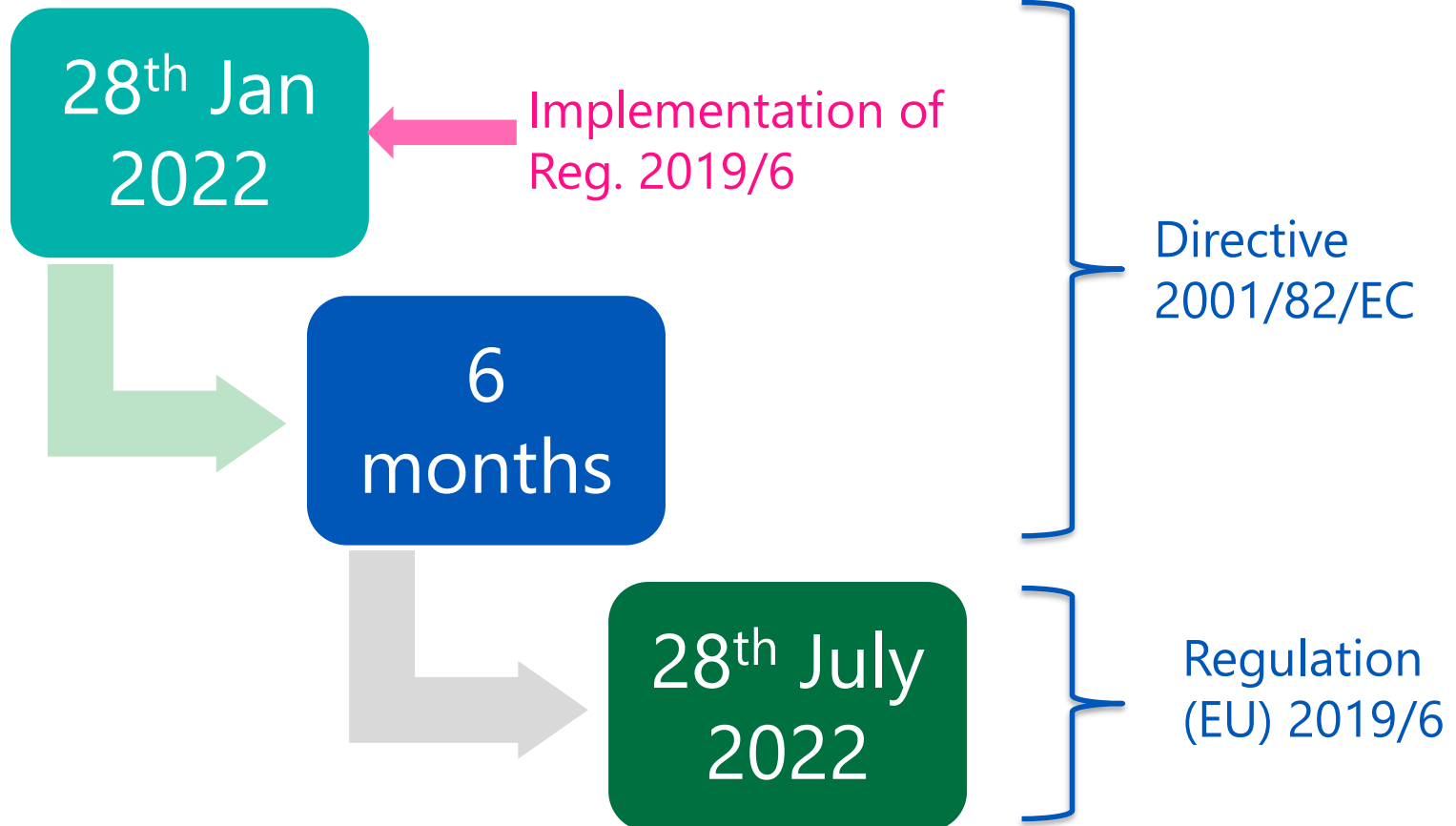
Regulation (EU) 2019/6

Article 5(2) of Regulation 2019/6 –
The validity of a MA of a VMP is
unlimited

- a provision for a renewal under exceptional cases will be retained; however, it is expected that this will occur very infrequently.



Timeline





HPRA approach - MA's to expire after July 2022

Where the validity of a MA falls on or after the 28 July 2022 the HPRA will provide MAHs with updated documents with unlimited validity of the MA



Pending renewals

Performed by the HPRA.

No documentation required.

Involves the removal of the date of expiry of the validity of the MA (licence), and the replacement of it with an unlimited MA.

The HPRA will provide the MAH a document that reflects this change.

No other changes will be made to the MA.

When? Updated documents for pending renewals will be provided to MAHs for MAs with an expiry after 28 July 2022





Renewals – MRP/DCP

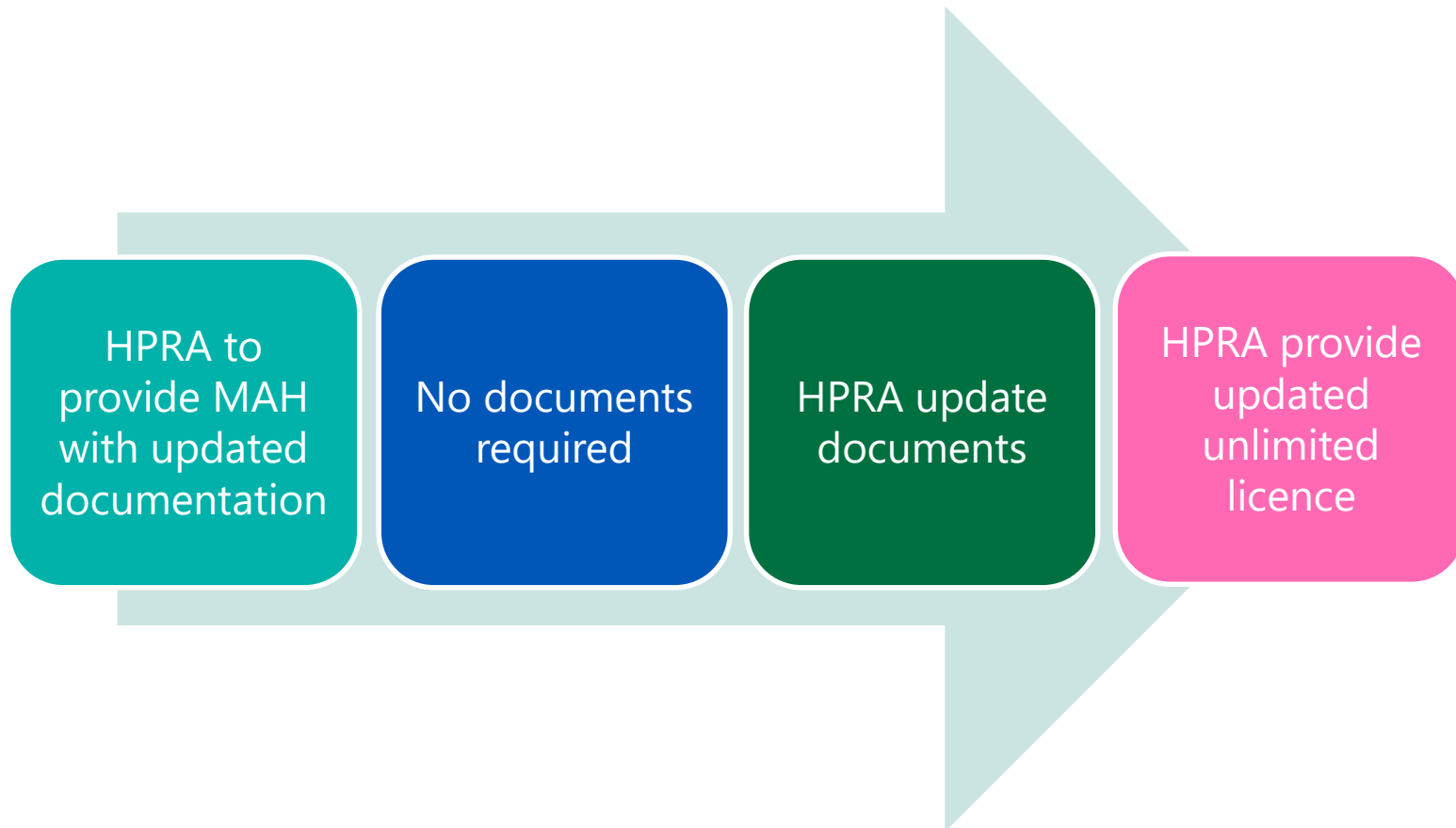
Renewals are handled nationally, HPRA has no role as RMS.

Each MS in a procedure must decide how they are to handle the national licence.

If a product is not renewed in any CMS, the MAH should notify the RMS so that CMS can be removed from the list of CMS.



Pending renewals - summary





HPRA approach

- The HPRA website will be updated with the approach

www.hpra.ie





Contact

Questions?

Please send them to vetinfo@hpra.ie





Thank you

