EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

New veterinary regulation (NVR): impact on IT/Telematics

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An agency of the European Union

Telematics requirements from NVR

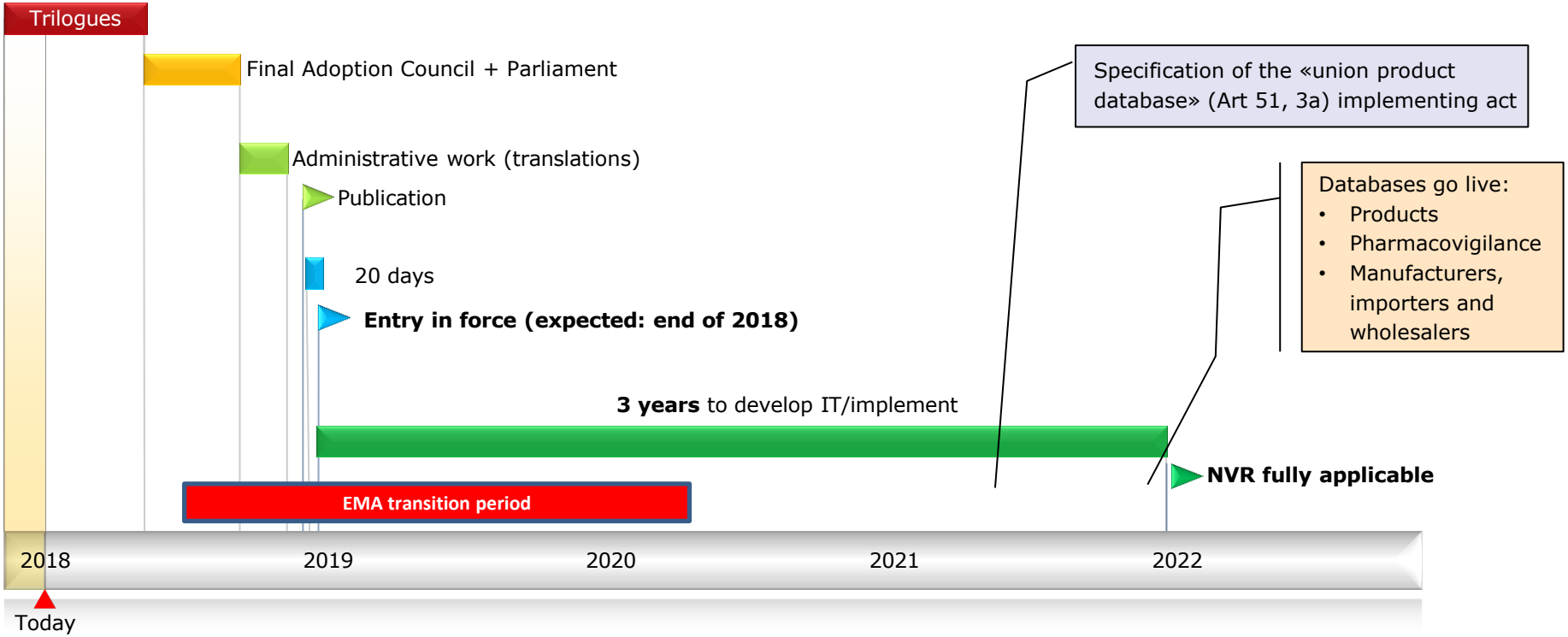
3 Union databases:

- Product database
- Pharmacovigilance database
- Manufacturing/wholesale distribution and inspections database

Plus: IT tools and business processes for new requirements in monitoring of antimicrobial resistance

1 Update on NVR implications; June 2018

NVR: timeline



Implications

Financial resources:

- Much higher cost than originally anticipated (first draft of NVR and related EC impact assessment)

Human resources:

- Union product database (NVR specifications) build and data transfer requires significant resources from EMA and NCAs – plus adaptation of PhV and Inspections databases to new requirements

Timelines:

- Implementation coincides with relocation and business continuity period due to Brexit

Risks arising if IT solutions are not implemented in time

Higher workload

- Increase in SPC harmonisation referrals
- Variations not requiring assessment allowing submission (CESSP) and direct update of relevant data in the *Union Product DB* by MAH
- *Required systems: Union Product DB*

Threat to scientific quality/safety oversight

- PSURs stop - reliable & scientifically sound signal management required
- *Required systems: Union Product DB, PhV system, sales data collection*

Limited visibility to available medicines and suppliers/retailers

- General public access to product and PhV data
- *Required systems: Union Product DB, PhV system, MS websites on authorised online retailers*

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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Background slides: IT systems/requirements arising from NVR

EU-level (EC/EMA)	Member States
MRL database (*to be developed/managed by EC*)	Individual websites: information on **online retailers**
EMA: **Union Product Database (UPD)** (utilising SPOR, CRM, and publishing technologies) **Common PhV system** (EVVet3 integration to ADR Human) **Manufacturers, Wholesalers, Importers Inspections database** (reuse EudraGMP until replaced by CRM)	*Explore opportunities to re-use national IT systems, e. g.* ***sales database*** *from one member state, extend to all products, license to other MS?*

Expectations is that IT systems will reduce administrative burdens, enable reliable pharmacovigilance, and provide visibility of available veterinary medicines to users and suppliers.

Background slides: Risks & Issues

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Risk	Likelihood	Severity	Mitigation
Insufficient funding and resources to develop new/ modified business capabilities.	High	High	• Prioritise development activities • Align to human processes in order to facilitate re-use and to minimise delivery risk • Consider **fees/funding & additional staff?**
Insufficient funding and resources to operate new/ modified business capabilities. NCAs will have increased administrative burden to submit product data to the Union Product DB. CAP workload is anticipated to increase.	High	High	• Align to human processes in order to facilitate re-use and to minimise operational overhead • **Consider fees** to compensate the work done by the NCAs and EMA to ensure operation of the legislation
The legislation implementation period is overlapping with the **EMA relocation**	High	High	• **Reducing functionality** to fit with something that is compatible with legislative timelines.
Legislation **timelines are set from the outset** without consideration of implementation effort	High	High	• Prioritise development activities • Take a risk based, **minimal viable product** approach • Align to human processes in order to facilitate re-use and to minimise delivery risk
The general **public does not** utilise information on medicines and availability, thus preventing addressing the goals of the NVR (single market, availability of medicines)	High	High	• Short term: **facelift EudraPharm-Vet**; engage with the European veterinarians (“marketing campaigns”); use SEO to improve visibility on the internet • Long term: replace EudraPharm-Vet with a medicines portal; provide multi-lingual access to the digital services