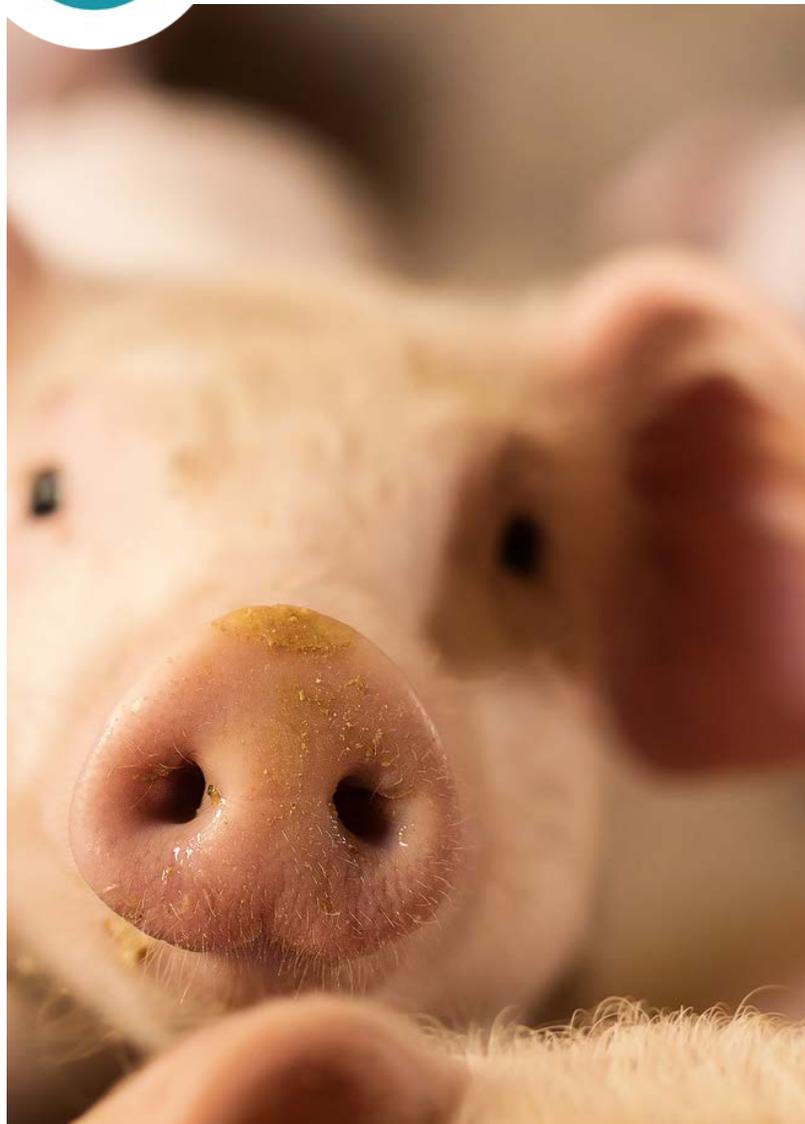


Brexit

Implications for companies

Rick Clayton
Technical Director
AnimalhealthEurope

EMA BREXIT Information day
20 April 2018, London



Stakeholder views

AnimalhealthEurope key messages

Brexit Barometer

Timing implications

Impact on keeping talent and R&D

Impact on Trade and Manufacturing

Impact on product registrations

Other costs

AnimalhealthEurope and Brexit

The call of the animal health industry

On 29 March 2019, the UK will leave the EU and thereby become a 'third country'. The UK's decision to leave the EU will engender many challenges also for the veterinary medicines industry.

AnimalhealthEurope¹ has flagged three areas for immediate focus: (1) ensuring continued access to the necessary veterinary medicines that safeguard animal health and welfare, (2) maintaining the collaboration in the field of transboundary diseases and (3) encouraging further innovation in the animal health sector by pursuing scientific cooperation.

We therefore ask the EU negotiators to consider the following elements:

1. **Ensure the availability of veterinary products for all animals**

- A call for a mechanism to allow UK to stay aligned and involved

To safeguard animal health and welfare, food safety and the well-being of animal owners, the continued availability of veterinary products is essential.

The animal health industry calls for a future arrangement allowing the UK to stay connected and engaged in the already existing EU regulatory network for medicines. The UK could follow the scientific discussions as well as the decision-making process and thus ensuring they take their decisions on these bases. Such a system should ensure that existing and new veterinary medicines registered in the EU are still accessible in the UK.

The UK seems willing to maintain alignment with the EU regulatory framework for medicines, for example, in terms of data requirements and timelines for considering new and variation applications. Such an approach should be supported as it provides a high likelihood of the same outcome (e.g. same studies required for a product development or same label content for a product). A common regulatory framework will avoid business disruption and will benefit the EU (e.g. increases the availability of products in smaller Member States and access to veterinary medicines for minor species). Lack of regulatory harmonisation post-Brexit will very likely impact the availability of animal health products.

For example, a lack of harmonisation will hinder the ability of companies to use a common label for two or more countries with a common language. The prime example is UK and Ireland: the Irish market is small, and it risks losing product if the packaging cost cannot be combined with the UK market, as some products may fall below a volume threshold which makes them sustainable. Moreover, maintaining the existing regulatory harmonisation will also ensure that data requirements for new product developments and line extensions will not differ between the EU and the UK, thus avoiding a negative impact on R&D programs and development costs.

¹ AnimalhealthEurope represents the views of its diverse membership which spans across the European continent, and which includes the UK's National Office for Animal Health (NOAH).

AnimalhealthEurope key messages

- **Stay aligned**
 - UK should stay aligned with EU rules and EU should allow UK to stay connected
 - Impact on: availability of medicines; UK-Ireland joint labelling
- **Transition period**
 - Political agreement to 21 month transition period; but no certainty
 - Should be extended until suitable MRAs are in place (e.g. inspections)
- **Trade agreement**
 - UK-EU to remain sustainable trade partners; minimise trade costs and delays
- **Linked surveillance**
 - Animal disease do not respect borders
 - UK should stay in EU surveillance programmes (EARS-Net, Eudravigilance, ESVAC)
- **Maintain talent**
 - Support EU leadership in R&D; continue mutual exchange of scientific talent

UK: “We will also want to explore with the EU, the terms on which the UK could remain part of EU agencies”

EC : “No way”
“MR not possible in FTA”
“Only if UK joined the EEA”

“Nothing is agreed until everything is agreed”

Industry key messages

- **Stay aligned**
 - UK should stay aligned with EU rules
 - EU should allow UK to stay connected in EU Regulatory Network
 - Impact on: availability of medicines; UK-Ireland joint labelling
- **Transition period**
 - Political agreement to 21 month transition period; **no certainty**
 - Will also apply to Animal Health industry in all aspects, allowing for an extra and valuable ‘preparedness’ time
 - Should be extended until suitable MRAs are in place (e.g. inspections)

AnimalhealthEurope Brexit Barometer

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BREXIT BAROMETER

ABSTRACT

In the context of AnimalhealthEurope's Brexit strategy, we conducted a survey* to measure the level of optimism amongst our membership on key topic areas and the overall future of the industry in light of the UK's exit from the EU.

The animal health industry is seeking to understand how its members perceive the impacts of Brexit on their business.

A 'Comparative Focus' compares UK and Europe findings and concludes that the overall sentiment is similar.

*This barometer is inspired by the NOAH (the UK National Office of Animal Health) Brexit Barometers (See [NOAH Brexit Barometer 1 - Summer 2017](#) & [NOAH Brexit Barometer 2 - Winter 2017-2018](#) available on their Website: www.noah.co.uk)

Most concern

➤ Problems expected

- Bringing products to market in UK
- Impact on UK trade and exports
- Impact on post-licencing controls

Most optimism

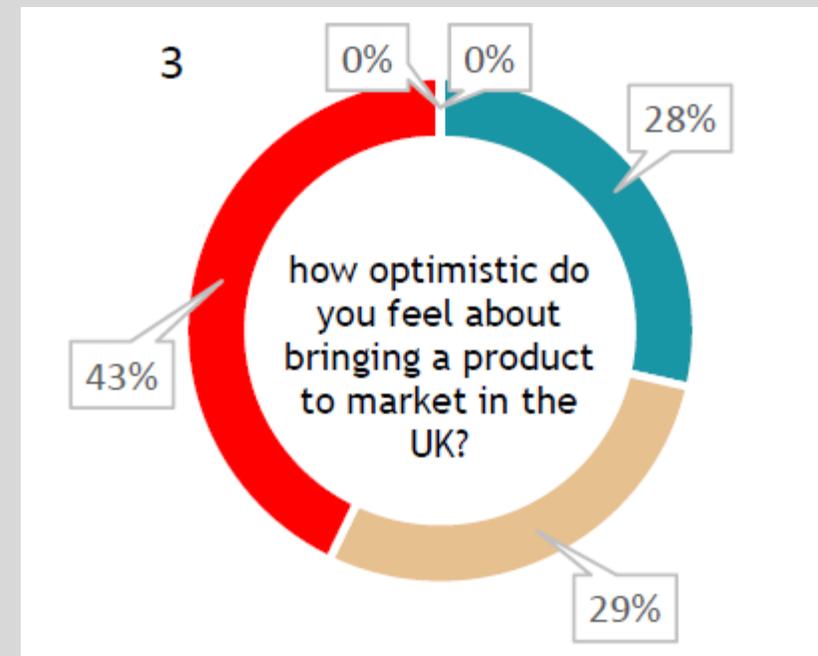
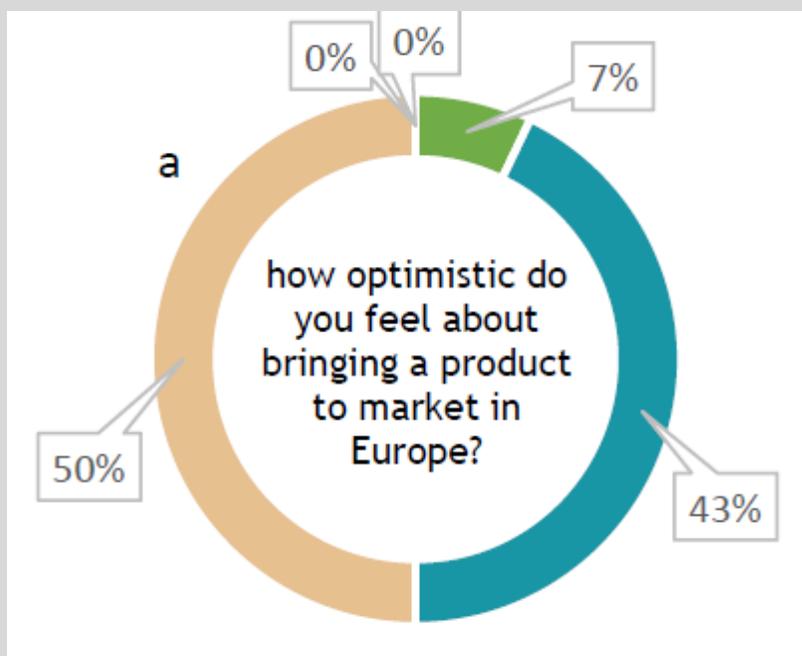
➤ No problems expected

- R&D in the animal health sector
- Public health and food production
- Animal health and welfare

AnimalhealthEurope Brexit Barometer

- bringing products to market

- Very optimistic
- Optimistic
- In the middle
- Pessimistic
- Very pessimistic



Timing implications



- **New EU Regulation on VMPs**
 - Adopted Q1 - Q2 2019?
 - Becomes applicable 3 years later (2022)
- **UK Withdrawal Bill to 'download' EU legislation**
 - EU legislation must be applicable on 29 March 2019
 - Risk of divergences post-Brexit
 - Opportunity to diverge / adapt to national situation



Keeping Talent

- **Impact on access to top scientists in EU pool**
 - Applied research underpins the industry
- **Impact on access to veterinary services**
 - Fewer vets in UK = fewer prescriptions

Impact on R&D

- **Diversion of resources to Brexit fire fighting**
 - Regulatory staff buried under Brexit admin burden
- **Impact on product registration**
 - Impact on product launch plans



Impact on trade

- Need to stay aligned with EU/int'l rules
- No tariffs on life science products
- But increase in documentation and costs
- Border control bottlenecks and delays?
- Unknown additional costs
- Trade deals - an unknown, timing?
- Land-bridge to Ireland - impact on Irish business (none expected)

Impact on manufacturing

- Cost of imported materials
- Cost of duplicated manu. site inspections
- Relocation of manufacturing to EU?
- Relocation of batch release to EU (legal requirement)
 - Relocation/replacement of Qualified Person (legal entity)
 - Relocation of testing facilities
- Assumption: in general UK authority will wish to avoid duplication
- MRA with EU?



Impact on products

- **Existing authorised products**
 - UK licence remains in place, but regulatory admin
 - all registration routes (CP/DCP/MRP)
 - Update packaging at next print run?
 - Risk of divergence of SPCs over time
- **New products**
 - Parallel regulatory assessment EU + UK?
 - all registration routes; UK will try to stay aligned
 - Delayed product entry to UK?
 - Novel therapies and access to leading scientists?

Other cost of doing business

- **Pharmacovigilance**
 - Relocation of legal responsible person (QPPV)
 - UK to recognise EU QPPV?
 - Access to EU pharmacovigilance IT structures
 - Database and signal management systems
- **IT systems**
 - Will UK have access to key EU systems (MRA)?
 - Will UK replacement systems be ready on time?

Conclusions

- **Business uncertainty; no clarity on final arrangement**
 - Industry seeks a final scenario close to current conditions or similar agreements (e.g. EEA / EFTA).
- **Major impact**
 - impact on business becoming clearer
 - planning for hard exit
 - keeping talent, R&D, product registrations, manufacturing, pharmacovigilance and IT structures
- **Optimism, and looking for opportunities**

A warm, golden-toned photograph of a person's hands gently petting a white dog's head. The dog's eyes are closed, and the overall mood is peaceful and affectionate.

Thank you!

 @animalhealthEU

 WeCare.petsEurope

www.animalhealtheurope.eu