European Animal Research Association

Health and Social Care Committee

Impact of a No-deal Brexit on health and social care inquiry – submission

Impact of a No-deal Brexit on animal science used for the development of human and veterinary medicines in the UK

1. About EARA

1.1 The European Animal Research Association (EARA)[1] is a pan-European organisation that communicates and advocates in support of biomedical research using animals, by providing accurate and evidence-based information. We aim to educate the public on the benefits of animal research, partner with research stakeholders, and promote the creation and development of national networks. EARA was created by academic institutions, associations and the life science industry to provide a European platform for the public and other external stakeholders to be informed and learn about animal research, its benefits and its limitations. Being a European-wide organisation, EARA will encourage the creation and development of national networks and bring co-ordination between them. The association has more than 70 member organisations across 15 countries.

1.2 The mission of EARA is to:

- Better inform and educate audiences on the continued need for, and benefits of, the humane use of animals in biomedical research.
- Co-ordinate national and international efforts to create a favourable climate for animal research by addressing EU and national political decision and opinion makers.
- Lead pan-European initiatives to counter pressure on the laboratory animals supply chain and the licence to use laboratory animals in research.
- Support the efforts of animal research facilities to access the goods and services needed to discover and develop new medicines and treatments for humans and animals.

[1] http://eara.eu/en/

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1.3 EARA has brought together a group of organisations under a Brexit Taskforce, that supports and represents the interests of European biomedical research using animals. The Taskforce comprises the following organisations: EARA, AnimalHealth Europe, Charles River Laboratories, Covance, Ellegaard Göttingen Minipigs, Envigo, GSK, Marshall BIoResources, UK National Office of Animal Health and Understanding Animal Research.

2. Implications of a No-deal Brexit on the life sciences sector

2.1 The importance of animal models used in biomedical and veterinary research and drug development

Animals are used in biomedical and veterinary research, to advance scientific understanding, to develop solutions to medical problems, to protect the safety of people, animals and the environment, and as models to study disease.

The use of animals in research in the UK is highly regulated, with ethical reviews at institutional level, of the potential benefits weighed against the harms to the animals. There are also three separate licences from the Home Office that are required for each study (for the establishment, the project and the individual researcher). Animals need to be used to find out what happens in the whole living body, which is far more complex than the sum of its parts. It is very difficult, and in most cases simply not yet possible, to develop non-animal methods to replace the use of living animals completely.

Animal research is still a vital part of drug development. A candidate drug is initially tested in isolated cells, tissue slices or organs. Studies in living animals show whether the drug works the same way inside the body as it did in the artificial environment of the laboratory. They also indicate how the drug affects the interactions between different cells and organs of the body. By law, a potential drug can only be studied in human trials once it appears to be effective and passes initial safety screening in animals.

2.2 The importance of sustainable options to transport research animals

Much attention has focused on the unresolved consequences for UK-based research and the development of human and veterinary medicines in a No-deal Brexit scenario. Critical to the continuing success of this sector will be the timely and efficient transport, both imports to and exports from the UK, of purpose-bred research animals (including frozen embryos and sperm), biological samples from research animals, medical and pharmaceutical supplies, plus supplies of specialised animal feed and research diets.

Research and drug development in the UK for the benefit of both humans and animals is dependent upon ongoing access to research animals, often with the need for shipment from the continent of Europe or elsewhere in the world. Current challenges include the embargo by British Airways, other airlines and maritime companies on the transport of research animals - these challenges could be exacerbated significantly by a No-deal Brexit.

Without the ability to move research animals from one country, or continent, to another, or from a breeder or supplier, to a research institution, crucial scientific research to discover new treatments may be disrupted. Purpose-bred animals (including fish and amphibians) sourced from unique breeding facilities which are exported from and imported into the UK, often possess specialised anatomical, genetic and physiological features. Research work is often conducted in global partnerships and enables researchers in the UK to access genetically unique strains and species thus enhancing scientific collaboration. This international collaboration also reduces the potential risk of over-breeding commonly used strains.

Under the current policy restrictions of airlines, handling agents, airports and maritime companies in the UK on the transportation and handling of specific research animals (dogs, non-human primates (NHPs) and mini-pigs, in particular) for biomedical research, the sector is unable to use scheduled passenger or cargo airlines, or maritime providers, to bring those species into the UK.

Imports from outside the EU into the UK have first to land at an EU international airport. Here, they are processed by the EU Border Inspection Post (BIP). Once cleared by the BIP and customs checks, they are accepted into the EU customs union and are able to be shipped into the UK without the need to pass through another BIP in the UK. Post Brexit, the BIPs in the EU would no longer have the responsibility to carry out the current checks to ensure that EU import conditions have been met, since the animals are only 'transiting' the EU airport. If this system is agreed, such animals will still need to pass through the EU BIPs – but remain in a 'bonded area' pending their transhipment to the UK. Any increase to transport times would, undoubtedly, have a negative effect on animal welfare, and would significantly increase handling costs. DEFRA will need significant new resourcing to enable the new checks required for entry into the UK.

2.3. The requirement for the timely movement of biological samples

Research is also dependent upon the ability to import and export biological samples (blood, tissues, organs, etc.) quickly for analysis, peer review, or return of samples to research sponsors (allowing for further studies). For global drug development, with collaboration between labs in different countries, multiple sample shipments are regualarly required because of the specialisation of laboratories, equipment, experts, and the fact that research must take place where the study-specific protocols have been validated to government standards.

Currently, there are no governmental restrictions on the movement of biological samples (i.e. tissues, blood samples and other histopathological samples) from NHPs (monkeys) and other animals within the EU, neither are there any regulatory approvals that must be obtained. In a no-deal situation, at the moment when the UK becomes a third country vis-à-vis the EU27 and in the absence of any transitional or co-operation arrangement, movements of samples would require compliance with customs formalities and export health certificates (EHCs) for each individual shipment for all animal species and the issuance of several Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permits for every sample from monkeys.

In addition, the movement of biological samples is extremely time-sensitive and the studies themselves take place within strict timeframes to enable timely regulatory approvals.

Brexit will bring even greater challenges for imports/exports, raising the importance and urgency of identifying and implementing the most efficient and seamless ways to maintain continuity of movement.

3. What planning and, or reassurances are required in a No-deal Brexit scenario to avoid disruptions to animal science and drug innovation for the development of human and veterinary medicines in the UK?

3.1 UK airports should permit the landing of research animals, so that the necessary checks on health and compliance with UK import regulations can be performed in the UK. We require a timely decision over the future position and operation of BIPs in the UK to determine if suitable Defra-approved BIPs can be found and that they will handle our imports.

Special requirements and consideration of the valuable contribution of monkeys, dogs and minipigs to science are needed to ensure their rapid transit into the UK. These movements should be facilitated and not subject to any additional bureaucracy.

Government support is also needed to help encourage service providers to transport live research animals directly to and from the UK to reduce transport time and thus improve animal welfare.

3.1 TRACES and Balai Directive

It is imperative that such imports from EU states into the UK, as well as UK exports of these animals to EU member states, can be entered into the Trade Control and Expert System (TRACES) online system. Should the UK lose access to TRACES then it is imperative that DEFRA prioritise a new system. Without this in place the smooth transit of laboratory animals and related products into and across the EU will be seriously impaired.

There should also be continuing recognition and acceptance by the UK of Council Directive 92/65/EEC (Balai Directive) to support imports of research animals to the UK from the EU27; the UK should also seek to be registered on the existing EU-approved third countries list under the Balai Directive, thus reducing the potential imposition of damaging licence costs and customs duties.

The feasibility of live research animals being 'bonded', when imported into the UK or exported from the UK, if transiting within the EU, must also be explored.

3.2 There needs to be a system established for simplified procedures for the import and export of biological samples from research animals. For example, the introduction of a single permit to cover different types of samples (e.g., liquid and tissue) as is done in Germany, the U.S. and elsewhere.

Government support is also needed to ensure sufficient options are available to transport samples to and from the UK in order to reduce transport time.

3.3 CITES

Action should be taken by the UK to reduce the regulatory burden, including the use of simplified procedures and electronic permitting for CITES and possible facilitations for Authorised Economic Operators (AEOs). For example, introducing a CITES application

process allowing for single entry of data (i.e. data is entered by applicants on a permit form that can be reviewed and completed by authorities). This will reduce the administrative burden on authorities and eliminate the issuance of (and need to return) erroneous permits. Writeable PDF formats could be used until such a time as a more automated electronic system is developed for UK CITES permitting.

In the event of a No-deal Brexit, the UK should cease applying stricter EU measures requiring the issuance of import permits for CITES Appendix II species.

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