Appendix B

Early Access to Medicines Scheme (EAMS) Consultation

The Medicines and Healthcare products Regulatory Agency (MHRA) have launched a UK wide consultation on the Early Access to Medicines Scheme, which if accepted will require amendments to the UK Human Medicines Regulations 2012.

The consultation (full details: https://www.gov.uk/government/consultations/early-access-to-medicines-scheme-eams-consultation) will be open for six weeks and runs until 11:45 pm on 17 September 2021. The response form can be accessed here: https://www.surveys.mhra.gov.uk/60decbb30f01ca5f644799e4.

The UK Early Access to Medicines Scheme (EAMS) is one of the ways through which a patient with a life threatening or seriously debilitating condition can gain access to a medicine before it has gained approval from the UK's medicines regulatory authority. The aim of this proposal is to ensure that EAMS remains an attractive option for patients, healthcare professionals and companies, so that cutting-edge therapies are available for patients where there is an unmet clinical need.

The aim is to make the legal basis for EAMS supply clear and minimise the burden on those supplying EAMS medicines and for those companies wishing to collect real-world data during the scheme. This will be delivered whilst continuing to ensure the safety of EAMS products through pharmacovigilance (safety monitoring), maximising patient access and benefit.

Full details of the proposals are available at the above link and all interested parties and stakeholders are encouraged to complete the survey and share their views. We would welcome that this information is shared with your colleagues encouraging them to respond to the consultation to enable a full range of views to be obtained. If you could please forward this email, rather than sharing the link directly, that would be most appreciated.

Thank you

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