BVA notes that, while this consultation applies only to Great Britain, we must ensure that the benefits of better regulations of veterinary medicines must also be extended to Northern Ireland. Every effort must be made to ensure that any divergence from EU regulations does not exacerbate structural supply issues, or the availability of veterinary medicines in Northern Ireland.

Chapter 1 General

1. **Do you agree with the proposal for the VMD to be able to require information on request?** *(1.4-5)*

Agree in principle but have some concerns regarding reduced availability of medicines when products have supply issues.

8. **Do you agree with the proposed removal of the option have marketing authorisations for parallel import?** *(2.12-13)*

   Neutral. This may compound supply problems if imports have to be authorised to counter shortages, causing delay.

9. **Do you agree with the proposal of assessing applications for MAs and MRLs at the same time?***(2.14-15)*

   Agree

10. **Do you agree with the proposal for amending the current data protection periods?** *(2.16)*

    Disagree with decoupling the addition of species where the product is packaged separately. Products for minor species are already limited as it is not cost-effective for manufacturers to apply for separate MAs. This is placing an additional barrier to increasing the availability of authorised medicines for those species.

11. **Do you agree with the proposal for introducing flexibility into the assessment timeline?** *(2.17)*

    Agree

12. **Do you agree with the proposal for a UK-based local representative instead of the requirement for the MAH to be established in the UK?** *(2.18)*

    Agree

13.

Recommendation 12: The VMD should review the requirements for environmental impact assessment of companion animal parasiticide products.

19. **Do you agree with allowing electronic package information leaflets?** *(2.40)*

Agree However small animal vets are concerned about accessibility for pet owners (as opposed to professional keepers.) We would also like to see the GTIN number included as this facilitates cross-referencing and upload to the Medicines Hub.

20. **Do you agree with this approach to pharmacovigilance?** *(2.41-44)*

Agree, in particular the provision at 2.42 to allow urgent safety restrictions in the event of a risk to animal or human health.

21. **Do you agree with this approach for homeopathic remedies?** *(2.45-48)*

Neutral. Homeopathic remedies should be subject to the same efficacy requirements as other medicines.

22. **If all changes to Schedule 1 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?**

23. **We will make transitional arrangements to cover applications already being processed for (variation of) a marketing authorisation or registration or registration of a veterinary homeopathic remedy, changes in labelling or packaging requirements, and other new requirements, as appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.**

Chapter 3 Manufacture

24. **Do you agree with this approach for manufacturing authorisations?** *(3.3-5)*

Neutral

25. **Do you agree with this approach for specific manufacturing authorisations?** *(3.6-3.8)*

Neutral

26. **Do you agree with this approach for regulatory oversight of active substances?** *(3.9-10)*

Agree

27. **Do you agree with this approach for products manufactured under the cascade?** *(3.11-13)*

30. **We will make transitional arrangements to cover applications already being processed for a (variation of) a manufacturing authorisation and other new requirements, as appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.**

Chapter 4 Classification and Supply

31. **Do you agree with the proposed additions to the POM-V classification?** *(4.2-3)*

    We strongly agree. We would also like to see anthelmintics reclassified as POM-V, due to the increasing body of evidence that there is growing resistance to parasiticides. There is also emerging evidence of fluke resistance in humans which can be linked to overuse of parasiticides. Responsible provision of anthelmintics needs to sit alongside knowledge of pasture management and diagnostic data in the specific case, requiring these products to be more closely regulated thanst

administrative burden on pharmacies, we feel it is justified by the well-recognised and significant risk of prescription fraud to animal health and welfare, public health, and the environment.

37. Do you agree with this approach to audits, record-keeping and storage by retailers? *(4.14-5)*

    Agree

38. **Do you agre**

Chapter 5 The Cascade

44. Do you agree with this approach to ensuring appropriate use of the cascade?
(5.5)

We agree with the intentions of these changes, but some clarifications are