BVA response to the consultation on the importing, batch testing and batch releasing of veterinary medicines in Great Britain

Who we are

1. BVA is the national representative body for the veterinary profession in the United Kingdom and has over 19,000 members. Our primary aim is to represent, support and champion the interests of the veterinary profession in this country, and we therefore take a keen interest in all issues affecting the profession, including animal health and welfare, veterinary medicines, public health, regulatory issues and employment matters.

Option 1 – Medicines must be imported into a ManA site and be certified by a QP

6. Benefits

This option would give increased oversight over imports, although it is debatable how much value this adds for countries with similar standards.

7. Drawbacks

This option would add additional controls to imports from 27 new countries. This may have the effect of deterring manufacturers who have been importing to the UK without restrictions until now. The medicines haven't changed, the suppliers haven't changed, therefore we cannot see the benefit of subjecting them to additional checks that have hitherto been deemed unnecessary.

Adding checks to imports from EU countries, has the potential to complicate the process of finding a durable, long-term solution to the import of veterinary medicines to Northern Ireland. The more we diverge from EU standards, the harder it will be to find common ground.

This option removes any advantage from countries with comparable standards and practices, and adds unnecessary bureaucracy.

8. Impact on availability of Veterinary Medicines

There is potential for this option to slow supply lines, which is unnecessary for imports from countries with similar high standards. It may also increase the cost of medicines at a time when owners are struggling to afford vet bills.

It may limit the availability of medicines, particularly new, innovative, and specialist medicines, if European manufacturers decide to withdraw from the UK market due to the additional checks.

Option 2 – No additional requirements for medicines batch tested and released in exempt countries

9. Benefits

This option is a smaller change than Option 1. It reduces controls on a small number of countries, which we already recognise, through an MRA, have similar high standards to the UK.

This would maintain the current system for imports from EU countries, which are likely to form a large proportion of the market. Maintaining the current regime is likely to facilitate finding a durable, long-term solution to the import of veterinary medicines to Northern Ireland, as it will not have to find a way to incorporate checks for EU imports of veterinary medicines.

10. Drawbacks

This option would reduce oversight slightly, but only relates to a small number of countries with whom we have an agreement, and whose standards we are satisfied remain comparable to our own. This option would also create the need for regular meetings with these exempt countries to ensure standards are maintained, but would be less labour-intensive than the other options.

11. Impact on availability of Veterinary Medicines

This option reduces restrictions, and would therefore have either no impact, or a positive impact on supply. This would maintain availability of a full complement of veterinary medicines to treat and prevent diseases in animals.

Option 3 – The introduction of a market access scheme for wholesale dealers

12. Benefits

This would maintain access to UK markets for large EU pharmaceutical companies, but may be untenable for smaller businesses. It also retains oversight of imports from more countries, although again, the advantage of this is debatable for countries with similar standards.

13. Drawbacks

This would add much more bureaucracy for the wholesalers, and may push some smaller companies out of the UK market. Smaller companies, or those with lower market share may no longer believe it is viable. However, these may be the ones supplying more specialist and specific products not obtainable elsewhere.

14. Impact on availability of Veterinary Medicines

This option is likely to increase the costs of medicines, and may cause delays in the supply chain while checks and paperwork are completed. It may also delay the availability of cutting edge new veterinary medicines in the UK, if the producer does not already have an existing market here.

Additional points to consider

We have initially included countries in the EU on the CERS list. This is because we are aware that these countries have equivalent regulatory standards. However, whilst the Trade and Cooperation Agreement includes mutual recognition of Good Manufacturing Practice (GMP), batch testing is not included. We therefore propose conducting risk-based audits of batch testing laboratories in countries on the CERS list from time to time, to ensure these countries continue to have equivalent

regulatory standards.

15. What are the benefits of this approach?

This approach would ensure that unnecessary divergence does not impact on standards, and could facilitate the agreement of a durable, long-term solution for the import of veterinary medicines to Northern Ireland. It also retains some oversight of processes, without undue impact on imports.

16. What are the drawbacks of this approach?

The checks would need to be proportionate, and not impose an undue burden on laboratories, to avoid them withdrawing from the arrangement.

We will introduce a process that will allow other countries to apply to have its regulatory standards deemed 'equivalent'. This will include risk-based audits of laboratories. We will also introduce a process of removing a country from the CERS list should it fail to demonstrate continued equivalent regulatory standards.

17. What are the benefits of this approach?

This approach maintains checks and balances in the system, allowing reduced controls on individual batches. It would also ameliorate any issues caused by divergence from EU standards, potentially supporting a durable, long-term solution to the supply of veterinary medicines to Northern Ireland.

18. What are the drawbacks of this approach?

The process needs to be proportionate, particularly if the onus is on other countries to apply. Availability of veterinary medicines from a particular country may be more significant for the UK veterinary sector, than it is for the government of the supplying country, making us the demandeur in the situation.