FREQUENTLY ASKED QUESTIONS (FAQs) REGARDING THE REQUIREMENTS OF DEOXYRIBONUCLEIC ACID (DNA) TESTING FOR BIOLOGICAL PRODUCTS THAT USE ANIMAL-DERIVED MATERIALS

1. **What product categories are involved?**
   All Biologic product categories that use materials/tools derived from animals throughout the manufacturing process, starting from the preparation of the active ingredients to the production of the final product.

2. **Which animals are referred to in these requirements?**
   For the time being, the involved animals are only Porcine and Canine.

3. **Is it necessary to include this DNA test in all registration applications for biologic products that use Porcine and Canine-derived materials/tools?**
   No. The DNA test only needs to be submitted as evidence if the product registration holders refuse to declare the animal source content on the label because they believe the animal's DNA is no longer present in the final product due to the purification processes involved in its manufacturing.

4. **When does this requirement take effect?**
   Following the decision from the 384th meeting of the Drug Control Authority, starting from May 24, 2023, all new Biologic product registration applications received for screening and existing products under evaluation for registration must meet these requirements.

5. **Where are the facilities that provide Porcine and Canine DNA testing services and accepted by NPRA?**
   NPRA does not limit it to specific facilities. Therefore, companies can appoint any facility or conduct it in-house, provided that the analytical protocol for the DNA test has been validated. DNA test evidence from any national regulatory agency is also accepted. However, it is important to note that any declaration without submitting the results of the DNA test is not acceptable.

6. **What types of DNA analysis tests need to be conducted?**
   No specific test is stipulated. However, tests using the Polymerase Chain Reaction (PCR) technique have been and can be accepted to date.

7. **If DNA testing has been conducted at the active substance (Drug Substance) level and Porcine and/or Canine DNA is not detected, is the same test required at the final product (Drug Product) level?**
   Not necessary if Porcine and/ or Canine-derived material(s)/ tool(s) are no longer involved in the manufacturing of the final product.

8. **If DNA testing has been conducted at the active substance (Drug Substance) level and Porcine and/or Canine DNA is detected, is the same test required at the final product (Drug Product) level?**
   Yes, if the product registration holder wants to prove that there is no longer any DNA of those animals in the final product content. If DNA testing is not conducted on the final product content, the product label must clearly state that the product contains materials derived from Porcine and/or Canine.

9. **If the product contains excipients derived from Porcine and/or Canine, is it necessary to conduct DNA testing for these animals at the final product stage?**
   Not necessary, and the product label must clearly state that the product contains materials derived from Porcine and/or Canine.

10. **Is DNA testing required for every batch imported into Malaysia?**
    No. The DNA test evidence only needs to be submitted during the screening or registration evaluation process.

11. **How many batches of products need to undergo DNA testing?**
    At least 1 batch for each product.

12. **Are registered Biologic products required to meet these requirements?**
    For registered Biologic products, these requirements are voluntary and can be made through a variation application. However, if deemed necessary, NPRA reserves the right to request DNA testing for registered products.