Frequently Asked Questions (FAQs): Appendix 19 General Labelling Requirements for Products Containing Animal-Derived Materials

1. **Why was this FAQ issued?**

   The requirement to declare animal-derived materials has been in place since 2007. However, implementation challenges arose following circulars issued in 2023 and 2024. This updated FAQ reflects the new circular NPRA.600-1/9/12 (31) dated 16 March 2026, which clearly distinguishes between requirements for Drug Substance and Drug Product.

   With the issuance of this new guidance, the previous circulars NPRA.600-1/9/12 (20) and NPRA.600-1/9/12 (25) are officially revoked.

2. **What is the key change introduced by the 2026 circular?**

   The key change is the shift from mandatory DNA testing to a risk-based scientific justification for the Drug Substance, while maintaining strict labelling for the Drug Product:

   - Drug Substance: Scientific justification (e.g., validation of purification) is now acceptable to demonstrate the removal of animal-derived materials.
   - Drug Product: If animal-derived materials (including excipients, preservatives, capsules) are present in the final formulation, declaration on the label is mandatory regardless of test results.

3. **Does this apply to all product categories?**

   Yes. This requirement applies to both pharmaceutical, health supplement and natural products undergoing new registration or variation applications. Reassessment of currently registered product labels is not required unless a variation or other relevant event triggers label changes.

4. **Does the requirement apply to all animal species?**

   Yes. The scope includes all animal species, including but not limited to porcine and canine sources.

5. **Is there a grace period for registered products to comply with these requirements?**

   As this is an existing policy, no grace period is applicable. The effective date is immediate (16 March 2026) for all new product registration applications and products currently under evaluation. For registered products, updates can be made via a variation application (MiV-PA2: Change of drug product labelling in accordance with country-specific labelling requirements) for pharmaceutical products or (MaV-2: Change of product labelling subject to labelling requirements as per DRGD) for Natural and Health Supplement Products when label changes are triggered.

6. **Are there any exemptions for specific materials?**

   Yes. Clause 17 of Appendix 19 does not apply to low-risk materials including:

   - Lactose and milk derivatives.
   - Beeswax in ointments.
   - Inks derived from insects (e.g., shellac).

7. **Is DNA testing mandatory to confirm the presence of animal-derived elements in the drug substance for biologic products?**
   No. Validated DNA testing is no longer the only way to confirm the absence of animal-derived elements used during Drug Substance manufacturing. NPRA now accepts the following scientific justifications:
   - A Manufacturer's Declaration based on manufacturing principles.
   - A detailed description of purification processes (e.g., chromatography, filtration) designed to remove such materials.
   - Relevant process validation or product development data.

8. **Can negative DNA or analytical test results at Drug Product stage exempt a product from declaring animal-derived excipients?**
   No. If an animal-derived material is a component of the final product (e.g., porcine hydrolyzed gelatine used as an excipient), it must be declared. Analytical testing cannot be used to waive mandatory labelling requirements.

   If a company conducts DNA testing and wishes to include the result for transparency, the following exact wording is permitted on the outer carton as supplementary information:
   "[ANIMAL SOURCE] ORIGIN. DNA of [animal source] was not detected in the final product."
   Example: "PORCINE ORIGIN. No traces of porcine DNA found in the final product."

9. **Is declaration required if animal-derived materials are used in the primary packaging?**
   No. The scope of evaluation and declaration no longer includes animal-derived materials used in primary packaging. This alignment follows international practices by the WHO, EMA, and US FDA.

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