APPENDIX 5

GUIDELINE ON REGISTRATION OF GENERICS

1. DEFINITION
A generic product is a product that is essentially similar to a currently registered product in Malaysia. However, the term generic is not applicable to Biologics.

2. GENERIC APPLICATION
The following categories of product can be processed as generic application provided that it fulfils the definition of a generic product.

(i) Scheduled Poison
(known as Controlled Medicine/ Controlled Poison)
Products containing active ingredients as listed in the First Schedule under Poisons Act 1952.

(ii) Non-Scheduled Poison
(Known as “Over-the-Counter”, OTC)
Products containing active ingredients which are not listed in the First Schedule under Poisons Act 1952; and are excluding active ingredients which are categorized under health supplements or natural products or cosmetics.

(a) Full Evaluation
Other than listed at (b) Abridge Evaluation
(b) **Abridged Evaluation**

which include, but not limited to the following:

- Antiseptics/ skin disinfectants;
- Locally-acting lozenges/ pastilles;
- Topical analgesic/ counter-irritants;
- Topical nasal decongestants;
- Emollient/ demulcent/ skin protectants;
- Keratolytics;
- Anti-dandruff;
- Oral care;
- Anti-acne;
- Medicated plasters/ patch/ pad; and
- Topical antibacterial.

For medicinal gases classified as generic products, please refer to Directive No. 8, 2021 and [Guideline on Registration of Medicinal Gases](#).

**Reference:**

- Directive No. 8, 2021, [NPRA.600-1/9/13 (18): Direktif Berkenaan Pengukuhan Pelaksanaan Kawalan Regulatori Ke Atas Produk-Produk Gas Perubatan dan Penggunaan Guideline on Registration of Medicinal Gases (11 February 2021)](#)

### 3. **SUBMISSION OF APPLICATION**

Applicants are advised to refer to **Section A** ([5. Application Procedures](#)) of the DRGD for further explanation.
4. EVALUATION TIMELINE FOR GENERIC APPLICATION

Table 1: Evaluation Timeline for Generic Application

<table>
<thead>
<tr>
<th>No.</th>
<th>Product Category</th>
<th>Evaluation Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A)</td>
<td>Full Evaluation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generic (Schedule Poison)</td>
<td>210 working days</td>
</tr>
<tr>
<td></td>
<td>Generic (Non-Schedule Poison)</td>
<td>210 working days</td>
</tr>
<tr>
<td>(B)</td>
<td>Abridged Evaluation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generic (Non-Schedule Poison)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(i) Single active ingredient</td>
<td>116 working days</td>
</tr>
<tr>
<td></td>
<td>(ii) Two (2) or more active ingredients</td>
<td>136 working days</td>
</tr>
</tbody>
</table>

5. REQUIREMENTS FOR GENERIC APPLICATION

Please refer to the following Appendices supplemented together with the DRGD for further information, where applicable:

- **Appendix 9** Fees
- **Appendix 11** Regulatory Control of Active Pharmaceutical Ingredients (APIs)
- **Appendix 12** Priority Review
- **Appendix 13** Designation and Registration of Orphan Medicines
- **Appendix 14** Evaluation Routes
- **Appendix 15** Requirements for Full Evaluation and Abridged Evaluation
- **Appendix 16** Bioequivalence (BE) Requirements
- **Appendix 17** Product Names Not Permitted To Be Registered
- **Appendix 18** List of Permitted, Prohibited and Restricted Substances
- **Appendix 19** General Labelling Requirements
- **Appendix 19A** Prohibited Visual/ Graphics/ Statements on Label
- **Appendix 20** Specific Labelling Requirements
- **Appendix 21** Special Conditions for Registration of a Particular Product or Group of Products
6. REFERENCES FOR GENERIC APPLICATION

Applicants are also advised to refer to NPRA’s website for the latest registration requirements. In addition, other relevant and latest international guidelines e.g. by EMA, USFDA and ICH should also be referred to complement the ASEAN Guidelines and the DRGD as appropriate.

7. OTHERS

Classification of Products containing Glucosamine, Chondroitin and Methylsulphonylmethane (MSM)

<table>
<thead>
<tr>
<th>No.</th>
<th>Product</th>
<th>Product Category</th>
<th>Route of Evaluation</th>
<th>Condition on Product Indication</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Products containing Glucosamine</td>
<td>As single active ingredient</td>
<td>OTC</td>
<td>Full evaluation</td>
<td>As adjuvant therapy for osteoarthritis</td>
</tr>
<tr>
<td></td>
<td>As combination with Chondroitin and/ or MSM</td>
<td></td>
<td></td>
<td></td>
<td>Products containing glucosamine in combination with other health supplement ingredients are only allowed to be registered for therapeutic purposes and NOT allowed to be registered as Health Supplement Product.</td>
</tr>
</tbody>
</table>

Appendix 22: Educational Materials
Appendix 23: Patient Dispensing Pack for Pharmaceutical Products
Appendix 24: Appeal
Appendix 25: Guideline for the Submission of Protocol of Analysis (POA)
Appendix 26: Guideline for the Submission of Analytical Method Validation (AMV) Documents
Appendix 27: Inspection
Appendix 28: Explanatory Notes for Repackers
<table>
<thead>
<tr>
<th>No.</th>
<th>Product</th>
<th>Product Category</th>
<th>Route of Evaluation</th>
<th>Condition on Product Indication</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Products containing Chondroitin</td>
<td>As single ingredient OR In combination with other supplement ingredients</td>
<td>Health supplement</td>
<td>Abridged Evaluation</td>
<td>No therapeutic claims are allowed</td>
</tr>
<tr>
<td>3.</td>
<td>Products containing MSM</td>
<td>As single ingredient OR In combination with other supplement ingredients</td>
<td>Health supplement</td>
<td>Abridged Evaluation</td>
<td>No therapeutic claims are allowed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>As combination with Chondroitin</td>
<td>Health supplement</td>
<td>Abridged Evaluation</td>
<td>No therapeutic claims are allowed</td>
</tr>
</tbody>
</table>

References: Circulars

(i) *Bil. (66) dlm BPFK/02/5/1.3*
Prod**uk yang Mengandungi Glucosamine dan Chondroitin** (14 November 2006)

(ii) *Bil. (20) dlm.BPFK/PPP/01/03*
Prod**uk yang mengandungi Glucosamine, Chondroitin dan Methylsulfonylmethane (MSM)** (31 December 2008)