FINAL DOCUMENT

Title: REQUIREMENTS OF MEDICAL DEVICE NOMENCLATURE SYSTEM FOR THE ASIAN HARMONIZATION WORKING PARTY

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Requirements of Medical Device Nomenclature System
for the Asian Harmonization Working Party (AHWP)

1. Charge:
   A. The charging mechanism shall be transparent and reasonable. Details of how the charges are calculated shall be given.
   B. The charge shall be on country/economy basis and proportional to the affordability.
   C. It shall be free of charge to all users including hospitals, manufacturers, importers, distributors and healthcare institutions etc.

2. Governance:
   A. AHWP shall have the say and power to manage when needed.

3. Database:
   A. AHWP shall have the updated copy of the database such that members could make their translations if so required.
   B. AHWP shall have the right to continue the use, distribution and development of the database should the provider bankrupts, fails to perform or breaches the agreement.

4. Response Time:
   A. Replies to questions from AHWP members shall be made within 1 week.
   B. Replies to requests for the creation of new codes shall be made within 2 weeks.

5. Developments:
   A. AHWP shall have the say and power to direct the future developments.

6. Further Use of the System:
   A. The charge shall have already covered other applications e.g. Unique Device Identification (UDI) in the future.

END