



PROPOSED 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