Confidentiality Level D

# Provisions for Voluntary Registration of Quality and Safety Data etc.

1. Objective
   These detailed rules stipulate the rules concerning “Data, etc. Concerning Quality and Safety” that are voluntarily registered with this society by its members to demonstrate that their antibacterial products, antifungal products, antiviral products, industrial sterilization coating materials, or antibacterial agents satisfy the requirements of the “Voluntary Specifications for Quality and Safety” by voluntary management.

2. Definitions of Terms
   Term 3 of the “Provisions Concerning Labeling, Terminology etc.” shall apply.

3. Data for Submission
   (1) For antibacterial agent manufacturers etc. (generic designation for manufacturers, vendors, and importers of antibacterial agents):
   “Admission/Voluntary Registration Data Sheet Concerning Quality and Safety I (Antibacterial Agents),” filled in with necessary matters, shall be submitted to the Secretariat.
   (2) For antibacterial product manufacturers etc. (generic designation for manufacturers, vendors, and importers of antibacterial products):
   For each set of equivalent antibacterial products, “Admission/Voluntary Registration Data Sheet Concerning Quality and Safety II (Antibacterial Products),” filled in with necessary matters, shall be submitted to the Secretariat.
   (3) For antifungal product manufacturers etc. (generic designation for manufacturers, vendors, and importers of antifungal products)
   For each set of equivalent antifungal products, "Admission/Voluntary Registration Data Sheet Concerning Quality and Safety III (Antifungal Products)," filled in with necessary matters, shall be submitted to the Secretariat.
   (4) For antiviral product manufacturers, etc. (generic designation for manufacturers, vendors, and importers of antiviral products)
   For each set of equivalent antiviral products, “Admission/Voluntary Registration Data Sheet Concerning Quality and Safety V (Antiviral Products),” filled in with necessary matters, shall be submitted to the Secretariat.
   (5) For industrial sterilization coating material manufacturers, etc. (generic designation for manufacturers, vendors, and importers of antiviral products)
   For each set of the equivalent sterilization coating material, “Admission/Voluntary Registration Data Sheet Concerning Quality and Safety VI (Sterilization Coating Materials),” filled in with the necessary matters, shall be submitted to the Secretariat.
   (6) A copy of test result certificate for an antibacterial product
   For an antibacterial product, a copy of the JNLA logo-bearing test result certificate according to Term 4 of the "Voluntary Specifications for Quality and Safety" shall be submitted to the Secretariat. If the determination is made using a test method other than that specified in Term 5 of JIS Z 2801(2000), a test result certificate not bearing the JNLA logo shall be submitted to the Secretariat.
   (7) A copy of test result certificate for an antiviral product
   For an antiviral product, a copy of the test report issued by a test institution, as described in Term 6 of the "Voluntary Specifications for Quality and Safety", shall be submitted to the Secretariat.
   (8) A copy of test result certificate for an industrial sterilization coating material
   For an industrial sterilization coating material, a copy of the test report issued by a test

institution, as described in Term 7 of the "Voluntary Specifications for Quality and Safety", shall be submitted to the Secretariat.

(9) Material safety data sheet (SDS)

An antibacterial agent manufacturer etc. shall submit a SDS providing information on the physicochemical properties and handling instructions etc. of the antibacterial agent to the Secretariat.

(10) A case where the agents are designated as priority assessment chemical substance

For the products which contain chemical substances designated as priority assessment chemical substances (Article 2-5 of Chemical Substances Examination Law) by the New Chemical Substances Examination Law amended on May 20, 2009, the failure information on the products using such agents must be submitted every six months after registration.

4. Acceptance of Voluntary Registration

The Secretariat shall accept the application for voluntary registration, provided that the "Admission/Voluntary Registration Data Sheet Concerning Quality and Safety I (Antibacterial Agents), II (Antibacterial Products), III (Antifungal Products), V (Antiviral Products), or VI (Industrial Sterilization Coating Materials)" provides the necessary matters, and that a document according to Term 3 is submitted, and the Secretariat shall notify this fact to the voluntary registration applicant (member).

5. Indication of the SIAA Brand Mark

For an antibacterial product (and a set of the equivalent antibacterial products), antibacterial agent, antifungal product (and a set of equivalent antifungal products), antiviral product (and a set of equivalent antiviral products), and industrial sterilization coating material (and equivalent industrial sterilization coating materials) described in the “Notification of Voluntary Registration Acceptance,” the SIAA brand mark may be indicated with the application for its use. For details, see the “Labeling and Terminology Provisions” and “SIAA Brand Mark Management and Operation Provisions.”

6. Information Disclosure

This society shall disclose information on the voluntarily registered “Admission/Voluntary Registration Data Sheet Concerning Quality and Safety I (Antibacterial Agents), II (Antibacterial Products), III (Antifungal Products), V (Antiviral Products), and VI (Industrial Sterilization Coating Materials).” Concerning the method of information disclosure, etc., provisions shall follow those established by the “Website Management and Operation Provisions.”

7. Storage of Documents Relating to Voluntary Registration

Each member shall store all documents relating to the voluntary registration (including electronic media etc.) for its product for 10 years after termination of the sale of the product.

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(The registration of industrial sterilization coating materials shall be operated on or after April 1, 2022)