## The International Association

## of Generic & Innewative Manufacturers

## Rules of the Association & Rules of Membership.

- 1. IAGIM is a non-profit Research Association, a division of the LOCUM *International GROUP*, a limited liability Research Association mandated to Pharmaceutical Drug Research & Development, including publishing the Association's prescribed publications, maintaining Drug Development Archives on the World Wide Web and levying annual membership subscription fees (membership *per* annum 2003-2004 \$600 per annum).
- 2. The Secretary of IAGIM is wholly responsible for the administration of, annual membership fees, the Association Rules, any member dispute/disagreements, administration costs, fines or penalties levy to members where the secretary deems the association rules have been clearly breached.
- 3. The position of Secretary shall be honorary free of any salary, disbursements, payments or gratuities either from the Association or its Members. Administrative decisions of the Secretary shall be final and binding (ex officio). The Association is subject to annual auditing. Unused income shall be distributed into the Association's secretarial account for ongoing research and development or administration purposes in the forthcoming fiscal year. Members shall view notices placed on the Association's web site from time-to-time. Special notices shall be place in the association's IAGIM-ONLINE center.
- 4. All parties entering into pharmaceutical or biopharmaceutical joint venture development programs, technology transfer contracts or technology transfer documentation (TTD) shall be accredited members of LA.G.I.M. and shall abide in full by the Association's rules as published, on the date of acceptance by the Association as an fully paid-up member. No member, or a member's legal representative associated with the company, firm or an affiliated group or similar or related industry or entity may litigate or sue or enter into any litigation or legal action or actions deemed adverse by the Secretary, either directly or indirectly to any association office bearer, staff person, administrator, executor or the Association itself or any affiliated firm, company or entity, including any member of the LI Group, Locum Press or Locum publishers affiliated directly or indirectly with IAGIM, Locum, LIG, or Locum International in any country, or via any third party or any entity during the entire duration of their membership.
- 5. Contracting members, subject to R-T-Go<sup>TM</sup> know-how transactions, shall continue annual membership with the Association for the duration of a minimum period of 3 consecutive years from the date of the *initial* contract/project 'start date'. Additional R-T-Go<sup>TM</sup> purchases shall extend the membership period from this <u>new</u> purchase date by an additional full three (3) years and so continue membership, with each new purchase. During this period the Association provides free <u>email</u> know-how technology and consultations on the EULA R-T-Go<sup>TM</sup> Technology. Association data is Copyright©2003 and is not for resale, retransmission, emailing or transfer.
- 6. Companies, multinational corporations universities and affiliations, shall strictly honor all the Association's Journal & Handbook Publication's Copyrights©2003 with payments to the Copyright Clearance Center (CCC) Transactional Reporting Service, and Academic Permission Service (APS) provided that the fee of \$3 per page is paid directly to CCC 222 Rosewood Drive, Danvers, MA 01923 USA. Data transfer of the Associations Copyright © data, Journals, Handbooks or publications between geographic zones (as defined in paragraph 13) is strictly prohibited without the prior written consent of the Secretary.
- 7. Members may subscribe to the Association's IAGIM Online journals, such as *International Journal of Generic Drugs* or *Drug Development Series* as per published conditions. Members shall be entitled to access to the Association's Drug Development Archives ('IAGIM CENTER') on the World Wide Web; Special published discounts and Drug Development Promotions of the Association's Publications occur from time to time.

- 8. Ru<mark>les</mark> on Resea<mark>rch & Devel</mark>opment, Know-how Data, Ventures and JV Projects:
- 9. The Client, Pharmaceutical Manufacturers, Pharmaceutical Consultants, Legal Offices, Universities, Technicons, Contract Laboratories CRO's and other Approved Third Parties as an IAGIM Member shall abide in full by the Association's Rules, as published, on the date of acceptance by the Association as a fully paid-up Member. The Secretary shall publish and distribute (via print & web) the association rules and regulations, as amended annually.
- 10. Drug development, research, development data, SOPs, TTD, analytical assays, know-how dossiers, R-T-Go™ and other development, manufacturing, registration or technical data shall be licensed to the member and shall not be sold to the purchaser. License Agreements for End-Users (EULA) shall apply to *any* know-how transaction (excluding journals and the 24 handbook series). Payments shall be made payable to LOCUM INTERNATIONAL by either a bank check drawn on a First Class US or UK bank; credit card; electronic bank transfer, transferable to the Association's Nominated Bank. Transactions via the Association's PAY-AS-YOU-USE System or any of the above payment systems shall exclude any double benefit. Data or information located in any extended development plan shall be for the sole use of the member and shall not be transferable.

## 11. Rules on Purchases, Applicants or Manufacturers:

- 12. Any CMC Know-how agreement is solely limited to the marketing and sales area pertaining to the geographic zone. **Exclusivity Agreements** are based on the 'three times rule' per zone.
- 13. Geographic zones are; Zone 1. US & Canada; Zone 2. EU States; Zone 3. Pacific Rim + Australia, New Zealand; Zone 4. China, Hong Kong & India; Zone 5. Middle East; Zone 6. South America + Mexico; Zone 7. African Continent; Zone 8. Japan & Singapore; Zone 9. Russia and Independent states; Zone 10. Eastern European States. The Association's data is copyright and not for resale, transfer or re-engineering (transformation) by the purchaser.
- 14. Purchase price shall be confirmed by email by IAGIM after the order date, prior to shipment or e-transfer by the Association to the member. Annual membership payments linked to the R-T-Go<sup>TM</sup> Series shall be debited to the member's credit card on the appropriate due date, or when appropriate *two* months prior to the expiration of the members credit card. LIG's absolute right to debit a member's credit cards shall act as a payment guarantee for any compulsory membership under various license agreements. All credit card *charge-back rights* are waived by members who elect to use a credit card for a purchase or payment dues.
- 15. Membership and all issued EULAs shall be revoked (within 30 days) subject to compulsory annual subscriptions remaining unpaid after 30 days have expired from the due payment date.
- 16. Any product development or subsequent registration arising from the supplied know-how data shall be exclusively binding to the member. Know-how data shall be deemed as supportive data, and where appropriate additional qualification and/or pivotal demonstration lots shall be manufactured at the commercial site with appropriate quality testing.
- 17. Master Formula, & Manufacturing Instructions, Full Specifications, Audit reports.Methods, Validations, Operating Procedures, SOPs, TTD, C of A, Stability Profiles, Data Reports and other R-T-Go know-how or any documentation (or special data) shall be made available to the certified member (as per membership certificate) for the sole purpose or use in the member's use or proposed drug development program and shall not be for transfer, review or resale to any *third* party.
- 18. Association Members shall inform the secretary of any data transfer to any company, affiliated or associated company or organization during the duration of the membership period.
- 19. Know-how CMC dossiers of drug products shall be held <u>confidential</u> by members (not for transfer or resale) and used solely for the members *internal* product development purposes and shall not be given, shared, sold, leased or made available in any manner to any outside party without the express written permission and authorization of the General Secretary.

Dori Belle BA, D/Pharm.

Supersedes JAN 2002.

Association Secretary - I.A.G.I.M. - January 2003.