Appendix 5: Glossar

Definitions and abbreviations

1. **API** shall mean active pharmaceutical ingredient.

2. **Authority** means any national or supra-national authority, agency or legislative body, which has jurisdiction over any matters concerning the manufacture, storage, sale or inspection of the Products, including without limitation the European Commission and the European Medicines Agency.

3. **Batch** means a quantity of material or Product produced during a defined cycle of manufacture which is expected to be homogeneous within specified limits. In order to complete some stages of manufacture, it may be necessary to divide a batch into sub-batches which are processed separately and later combined into the final batch.

4. **Bulk Product** means any pharmaceutical product composition containing a specific dosage of the API, which complies with the specifications, and, which, is completed to the stage either of product ready for assembly into final containers or individual containers ready for assembly to final packs for distribution as finished product.

5. **Certificate of Analysis or CoA** means a batch-specific document issued and approved by a authorized (qualified) person confirming the performance of the quality control tests of the Product for compliance with the defined specifications, the results of such tests and stating the Manufacturing and expiry date.

6. **Certificate of Conformance or CoC** means a certificate stating that the Product(s) were manufactured according to the Marketing Authorisation File and the cGMP and providing information about deviations, if any. Furthermore it is stated that the quality was tested according to the Marketing Authorisation File, giving reference to the number and edition of the relevant testing procedures, as well as that the results of the testing confirm that the Product(s) meet the specifications.

7. **EU** shall mean European Union.

8. **EU-GMP (Good Manufacturing Practices)** are rules defined by a competent authority on the basis of the guideline adopted in European regulations governing on medicinal product manufacturing establishments in order to guarantee that the products are manufactured and controlled according to the appropriate quality norms.

9. **Finished product** is a product which has undergone all manufacturing processes including packaging.

10. **Final Release for the Market** shall mean the decision by which the Qualified Person certifies that the product meets the requirements of the GMP Guidelines and its marketing authorization registration file and that the product can therefore be distributed.

11. **Know-how** shall mean technical and processing data, information and knowledge concerning the compound and/or the product, including but not limited to specifications, manufacturing instructions, quality control procedures and other like data in CGs possession, and which has been or shall be during the term of this Agreement disclosed by CG to CA.

12. **Manufacture, manufacturing** shall mean all steps and operations involved in the production of Products starting from compound, including pharmaceutical formulation, packaging, labeling, in-process and quality control, release activities and storage of the Products, compounds and materials, until delivery thereof to CG or a party designated by CG.

13. **Manufacturer's Authorization** means, with respect to any country, any regulatory authorization required to manufacture one or more products or classes of product as granted by the relevant Governmental Authority. It could be also in form of a GMP-certificate.

14. **Marketing Authorization (MA)** means, with respect to any country of the territory, the regulatory authorization required to market and sells the Product in such country as granted by the relevant Governmental Authority.

15. **Marketing Authorization File** shall mean the dossier including all scientific, technical and pharmaceutical studies, registration details and all other information concerning the quality, efficiency and safety of a product in the initial version submitted in support of the application for a MA of the said product as updated.

16. **Materials** shall mean all inactive materials, ingredients, excipients etc., and all packaging and labeling components and materials, purchased from CG directly, or acquired by CA with respect of CG's requirements and specifications as the case may be, for use in the manufacture of the Products.

17. **n/a** shall mean not applicable.

18. **National Drug Law** means all applicable laws, rules and regulations including, without limitation, any rules, regulations, guidelines or other requirements that may be in effect from time to time in any relevant legal jurisdiction in the territory.

19. **Packaging Material**
Primary packaging material shall mean every packaging material with direct product contact, e.g. blister foils, PE-bags for bulk material.
Secondary packaging material shall mean packaging material surrounding the primary packed product, e.g. folding boxes, PE-containers, labels for PE-containers.

20. **PQR** shall mean Product Quality Review.

21. **Product** shall mean the Product containing compound as active ingredient alone or in combination with other active substances, manufactured as required by CG pursuant to this Agreement, under trademark and under CG label, as specified in Appendix I.
Product may also be an active pharmaceutical ingredient manufactured in loan e.g. by means of chemical synthesis.

22. **QC** shall mean quality control.

23. **QMS** shall mean Quality Management System.

24. **QP** shall mean Qualified Person.

25. **Reference samples** is a sample of a batch of starting material or finished product which is stored for the purpose of being analyzed should the need arise during the shelf life of the batch concerned.

26. **Retained sample** is a sample of a fully packaged unit from a batch of finished product. It is stored for identification purposes. For example, presentation, packaging, labeling, patient information leaflet, batch number, expiry date should the need arise during the shelf life of the batch concerned.

27. **Reprocessing** means the modification of all or part of a batch of product of an unacceptable quality so that its quality may be rendered acceptable by one or more additional operations. It is limited to the cases mentioned in chapter 5.62 EU-GMP.

28. **Specification(s)** means the written descriptions of the sum of all quality attributes with a definition of the tolerances and acceptance criteria for Product, Starting Material, and Packaging Material