

Annex 7
to the Procedure for Review of Registration
Materials Pertinent to Medicinal Products
Submitted for the State Registration (Re-
Registration) and Materials about
Introduction of Changes to Registration
Materials during the Validity Period of
Registration Certificate for Medicinal
Products Registered by Competent
Authorities of the United States of America,
the Swiss Confederation, Japan, Australia,
Canada and Medicinal Products Registered
by Competent Authority of the European
Union Through Centralized Procedure
(Item 1 of Part III)

LETTER OF CONFIRMATION

Applicant (applicant's representative) _____,
(name)

represented by _____,
(full name)

confirms that:

changes to registration materials according to

(legal act of appropriate country, article)

are not subject to approval by competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada or competent authority of the European Union – for medicinal product registered through centralized procedure/materials about introduction of change to registration materials submitted to the Center are materials on which basis the changes were introduced in registration dossier by regulatory authority

(name of regulatory authority)

of _____,
(country)

he is **responsible** for efficacy, safety and quality of registered medicinal product

(name of medicinal product, pharmaceutical form and dose)

and **for reliability of information** contained in submitted to the Center materials, that all data have been received by the applicant in established due order and the rights of third party are not violated, protected by the patent, certificate of mark to goods and services and all envisaged fees shall be paid according to requirements of legislation.

On behalf of the applicant	_____ (signature) _____ (full name)
Seal (if available)	_____ (position)