Declaration of conformity of translations for Mutual Recognition Procedure (MRP) and the Decentralised Procedure (DCP)

The undersigned [name of the medicinal information responsible, company name] certifies that the translations into Dutch and French of the Summary of Product Characteristics (SPC) for [denomination of the medicinal product], and the translations into Dutch, French and German, of the package leaflet and the labels as provided for in Articles 11 and 1, 26° and 25° of Directive 2001/83/EC and in Articles 6 §1quinquies and 6septies of the Law of 25/03/64 on medicinal products, are an accurate rendering of the original content of the English documents approved pursuant to Article 28 of the same Directive for [MRP or DCP procedurenumber], in accordance with the provisions of the Notice to Applicants, Volume 2A, Chapter 2. This is the responsibility of the undersigned.

When random sampling, performed before the Marketing Authorization(s) have been granted, shows that the translations mentioned above are not an accurate rendering of the original content, the undersigned is called to account by the Federal Agency for Medicines and Health Products (FAMHP) and, have the translations returned for correction. The undersigned is responsible for the delays caused by these corrections. The clock is stopped for the period needed by the undersigned to perform the corrections.

If the Marketing Authorization(s) has(ve) already been granted, a rectification will have to be submitted without delay following the agreement between the FAMHP and the undersigned that the translations were not accurate renderings of the original content, in order to be in conformity with the decentralised or mutually recognized documents.
The phrase “accurate rendering of the original content” is to be construed in light of the protection of public health and is subject to the proportionality principle.

The medicinal information responsible of [company name]:

(signature, name and first name in caps)
Date: