

REQUIRED DOCUMENTATION FOR PRODUCT CLASSIFICATION

Pursuant to authority of Medicines and Medical Devices Agency of Serbia determined by the Article 6, paragraph 8 of the Law on Medicines and Medical Devices ("Official Gazette RS" No. 84/04 and 85/05, other law), the Agency issues expert opinions on product classification.

With reference to the above stated, Applicant for acquiring expert opinion submits the following documentation to the Agency:

- Free Sale Certificate (proof of competent authority concerning the status of the product in question in the country of origin)
- Data on manufacturer (Certificate of standards implementation e.g. HACCP, GMP etc.)
- Declared composition of the product (list of active substances and other excipients – quantitatively presented)
- Manufacturing technology
- Product specification
- Certificate of Analysis
- TSE certificate (identified absence of substances causing transmissible spongiform encephalopathies in raw materials)
- Declaration of absence of genetically modified organisms (GMO) in food (dietary) supplements
- Instructions for use in the Serbian language
- On the product packaging it should be declared:
 - < Detailed instructions for use in the Serbian language;
 - < Name and address of the product importer
 - < Product batch number
 - < It should be emphasized that it is a food supplement, if it is dietary supplement
- Possible warnings should be clearly stated on the product packaging
- Advertising material, brochures in the Serbian language
- One original product – sample

Documentation should be submitted for each product stated in the Application. Expert opinion on medicine classification is, above all, based on the definition of medicinal product stated in the Article 20 of the Law on Medicines, EU Guidelines regulating this field, recommendations of scientific organizations in Europe and worldwide, and previous experience in classification of products, that may, according to their action, quality and safety, be classified as medicines and medical devices, or dietary supplements and cosmetics.

Fee of CSD 5,000.00 for this Decision shall be dully charged pursuant to the Article 14, Paragraph 3 of the Decision on the amount and way of charging the fees for the services rendered by the Medicines and Medical Devices Agency of Serbia ("Official Gazette RS", No. 52/05). Account number of the Agency is 840-712667-07, model 99.