Check list of the documentation that needs to be submitted for registering paramedical products, animal health care products and medical devices:

I. Administrative data:

1. Applicant's contact data
- name, address, telephone, e-mail, fax

2. In case of local representative (firm or person):
- Name of the contact person, address, telephone, e-mail, fax
- Authorisation the contact person to act on the applicant's behalf (power of attorney)
- Authorisation (from the manufacturer/the owner of the documentation to the local representative)that the product can be distributed in Hungary

3. Declaration that the firm is not acquainted with facts or data which would negatively influence the registration of the product

4. Declaration that the active substances and the manufacturing procedure are safe with a view to TSE (Certificate of suitability for TSE)

5. Data about distributing the product in other countries (country, product name, date of authorisation, registration number (if relevant)

6. The proposed text for product leaflet and label(s) **in Hungarian language**, according to the Annex 13 of 128/2009 (X.6.) Decree of Ministry of Agriculture**(**It also has to be sent by e-mail (in word format) to the following address: hajosa@nebih.gov.hu**)**

7. Proof of payment
Fee of the administrative procedure has been determined on the basis of the Decree No. 63/2012. (VII. 2.) as amended by Decree 87/2013. (X. 1.) of the Minister of Rural Development on the amount of service fees payable in the proceedings initiated before the National Food Chain Safety Office and the agricultural administrative departments of the county government offices as well as the rules of the payment of the administration service fee. (Annex 1, Section 6.6.1.1.)
The bank details are the following:
Magyar Államkincstár IBAN: HU97 10032000 00289782 00000000
Swift code: HUSTHUHB
Please state the name of the product andthe firm when transferring the fee.

II. Quality documentation

II/A Composition (in English or Hungarian)
1.Composition (qualitative and quantitative) of the product, with INCI names and numbers
2.Short description of nature and composition of packaging, pack sizes

II/B Certificate of analysis of the starting materials and the description of the quality control methods used for monitoring the finished product

II/C Quality requirements of the finished product
One sample of the finished product with the certificate of analysis

II/D Stability
1.The result of the stability investigations of the finished product (It can be only a declaration, that the firm garantees the quality of the product for x years)
2. The proposed storage conditions
3. The proposed self-life of the product

III.-IV. Safety and efficacy documentation
The safety and the efficacy of the product have to be verified by own investigation or by literature data.

Procedure fees:

- Paramedical products (new authorisation, renewal or variation): 20 000 HUF
- Animal health care products (new authorisation, renewal or variation): 10 000 HUF
- Medical devices (new authorisation, renewal or variation): 5000 HUF