



NATIONAL and MRP VARIATIONS



GUIDELINE – GENERAL INFORMATION

This guideline is to be used for variations of marketing authorisations of medicinal products for human use submitted to the National Institute of Pharmacy (NIP) under mutual recognition or national procedure.

1. Applicants are to submit

– one application form

for each strength of the medicinal product

and

– one cover letter

for each variation.

2. Within the cover letter please always include the following information:

– e-mail

– Fax number

– Telephone number

of the

Hungarian representative office (if applicable)

and the

regional/global headquarters (if applicable)

3. Please note that the documentation can be submitted in an electronic form

but

– the cover letter

– the application form

– the proof of payment

– the certificates

– and the SmPC, PIL or Labelling (with corrections indicated)

are to be submitted on paper as well.

4. Please note that in case of any change in the SmPC, PIL or Labelling the electronic version is needed with corrections indicated.

5. Please use the following email addresses to contact us:

mrp-dcp-var-cms@ogyi.hu – MRP, variation, CMS status

mrp-dcp-var-rms@ogyi.hu – MRP, variation, RMS status

nat-var@ogyi.hu – National variation

6. You can find detailed information about the number of copies you need to submit for a variation application in this attachment.

Variation - MRP,National - IV - EN - 060803.pdf