GOVERNO DE PORTUGAL
MINISTÉRIO DA SAÚDE

infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde I.P.

Guideline on good pharmacovigilance practices (GVP)

Module XVI Addendum I – Educational materials

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Module XVI Addendum I – Educational materials

SCOPE

- Annex to the GVP XVI
- Based on GVP V and GVP XVI
- Concise and practical guidance
  - Provide clarity for MAHs submission
  - Provide useful “check-list” criteria for assessor
  - Increase harmonisation between Member States but giving the possibility of having additional national criteria

★ Information on submission, format, content and national implementation

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Submission

Draft

- cover letter:
  - MAH contact
  - origin of the request with supportive documents (e.g. EC decision including conditions of the MA, approved RMP…)
  - detailed implementation plan (target populations, dissemination method, intended dissemination time)

- documents in a common open text-processing electronic format

- language required by the Member State

- the intended lay-out

- updates of educational material – highlighted changes

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Format

Draft

- invented name of the medicinal product followed by the active substance(s) and/or therapeutic class in brackets

- invented name - only where strictly necessary

- the title line "Important Risk Minimisation Information for <Healthcare Professionals, Patients>" to clarify the purpose of the educational material

- type of educational material, e.g. administration guide

- bullet points - clarity

- version control

- logos of the MAH/product

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Content

Draft

- reference documents

- key elements as agreed at European level

- SmPC and/or PL may be attached

- images and graphic presentations of the information should only be used when text alone is insufficient to adequately convey the key element(s) when sole text is insufficient and should not be promotional

- purpose to be respected - no additional information such as efficacy data, comparisons of safety with other medicinal products…

- encourage the reporting of any suspected ADR and the modalities to report in the NCA

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National implementation

Draft

- timelines for the assessment may vary

- if the request for implementation of educational materials follows a referral or a single PSUR assessment procedure, the assessment of the draft educational material will be agreed as part on the procedure outcome

- MAHs to provide the final version in pdf format by e-mail

- NCAs may publish agreed educational materials on their websites

- MAHs to publish on specific websites

- criteria for approval of the specific websites

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Comments and main points for discussion

- Large input from MS
- Further discussion:
  - More dynamic approach to EM
  - CHMP opinion /CMDh position vs EC Decision
  - Harmonisation between EM for products with the same active substance
  - Updates assessment
  - TT for assessment
  - MAH website

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TT and action points

- Public consultation – March / April 2015
- Final adoption – Q3 2015

- Your input on questions for public consultation

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