



7 November 2012
EMA/709860/2012
Patient Health Protection

Guidance on format of the risk management plan (RMP) in the EU part II: Module SI - Epidemiology of the indication(s) and target population

Active substance	
Product(s) concerned (brand name(s)):	
MAH/Applicant name	

Data lock point for this module

<Enter a date>

Version number of RMP when this module was last updated

<Enter a version no>

This guidance should be used in conjunction with the information in Good Pharmacovigilance Practices:
Risk Management Systems.



This should normally be completed for each indication. If a medicine has an indication for both prevention and treatment of the same disease (e.g. malaria) or for one disease but used in combination with different other therapies (oncology), it may be appropriate to include the "linked" indications together.

If the indication targets a subpopulation of those with the disease, provide the information for the target population as well as the disease as a whole e.g. patients with metastatic breast cancer who have failed one or more prior treatment.

If a disease can target both sexes, despite being predominately in one, information should be provided for both – e.g. breast cancer – unless it is a medicine contraindicated in one sex.

Indication

Brand names of concerned products (with this indication)

SI.1 Epidemiology of the disease

This may discuss inter-regional (e.g. EU, US, Asia, Africa etc.) variations but have a prime focus on the EU. If the epidemiology varies across countries within the EU, this should be discussed.

- Incidence and prevalence
- Demographics of the target population – age, sex, race/ethnic origin.
- Risk factors for the disease
- Main treatment options
- Mortality and morbidity (natural history)

SI.2 Concomitant medication(s) in the target population

Discuss other medications frequently used with the medicinal product either to treat the disease or complications of it (e.g. anti-hypertensives will frequently be used alongside hypoglycaemic medication in the treatment of diabetes; some oncology products are always used in combination etc.).

SI.3 Important co-morbidities found in the target population

Provide incidence, prevalence and mortality. If the incidence of a co-morbid disease commonly found in the target population is increased compared with the incidence in the general population of the same age/sex as a result of the disease itself, this should be specifically discussed (e.g. for a medicinal product to treat rheumatoid arthritis, the incidence of coronary heart disease is increased in people with rheumatoid arthritis compared with that seen in patients without RA of the same age and sex)