

# PHARMACEUTICAL & FEED ADDITIVE MARKETING AUTHORISATIONS

## USER RISK ASSESSMENT

The Annex to Council Directive 81/852/EEC (as amended), Part 3, Chapter II, paragraph h) specifies that the safety dossier must include

*"a thorough discussion of any risks for persons preparing the medicinal product or administering it to animals, followed by proposals for appropriate measures to reduce such risks."*

Information on user safety should therefore be submitted with renewal applications and should include the following information.

### User safety

An assessment of the risk presented by the product for those using or administering should be presented, incorporating the following aspects:

- an appraisal of the inherent toxicity of the product
- an appraisal of the exposure of the user
- conclusions including proposed risk management steps

For each of these aspects the type of information which may be included, as appropriate, is indicated in the lists below, but it should be noted that these are not intended to be exhaustive.

1. An appraisal of the inherent toxicity or other harmful effects such as flammability of the active ingredient, other components or formulation, and additionally, as appropriate, summaries of studies on:

- skin irritation
- eye irritation
- skin sensitisation
- percutaneous toxicity including in vitro absorption studies
- inhalation toxicity
- known adverse reactions to similar products

It should also include summaries of the numerous types of special studies as appropriate, such as the following:

Immunotoxicity	endocrine function tests
neurotoxicity	liver and renal function tests
skin and eye irritation	effects on enzymes
sensitisation	relay toxicity
Inhalation toxicity	mechanism studies

2. An appraisal of the exposure of the user, or others who may come into contact with the product, (e.g. animal handlers, children, etc.) in relation to the usage of the product:

- route and degree of exposure e.g. inhalation of vapours and dusts (including information on particle size analysis and dust generation during typical usage); skin contact (including splashing and handling animals after application); ingestion (including accidental/deliberate misuse); and accidental self injection
- frequency of use and volume used on each occasion
- identification of the end user e.g. vet, farmer, small animal owner
- worst case calculations may be helpful in assessing the potential risk

3. Conclusions including risk management proposals regarding, as appropriate:

- contraindications and safety warning phrases
- handling technique
- other methods of controlling user exposure, e.g. engineering methods such as dust, vapour or gas extraction, packaging, such as appropriate pack sizes and special closures
- protective clothing
- action to be taken in the event of accidental exposure, e.g. self -injection, ingestion etc.
- advice to doctors
- Occupational Exposure Limits (OELs) - if these have been set
- sufficient information to enable the user to do a COSHH assessment if applicable

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