National Office of Animal Health

Risk assessment and veterinary medicines

Briefing Document No.27

Introduction

Along with every other business, those who hold a stock of animal medicines for sale or supply will need to carry out a COSHH risk assessment. But what does this mean in relation to animal medicines? Is a 'safety data sheet' needed for each animal medicine? And where can businesses get the information on medicines to undertake a risk assessment.

Advice from the RCVS Practice Standards Scheme – risk assessments and the veterinary medicines perspective

The RCVS publishes its Practice Standards Scheme at http://www.rcvs.org.uk/PracticeStandards. Section 9.6, which relates to risk assessments, states the following;

"The practice must have undertaken a thorough assessment of the risks arising from the use of veterinary medicines substances hazardous to health within the practice (L)''

The text goes on to explain how and why the risks posed by veterinary medicines should be assessed;

"The risk to Health & Safety from veterinary medicines and other substances has to be assessed under the Control Of Substances Hazardous to Health Regulations 2002 (COSHH).

There is wide variation in risk – many are low to medium risk but there are some substances in veterinary practice which pose a very serious risk to health.

Implementing measures to control the exposure to low or medium risk substances can be adequately achieved when they are assessed by their therapeutic group/type/route of administration etc. The practice can set out standard measures to control exposures, for example:

- *Injectable anaesthetics;*
- *Pour-on anthelmintics;*
- *Steroidal compounds;*
- *Antibiotics.*

Within these groups, practices must identify any specific medicines or substances that could have longer-term health risks, such as allergies e.g. Penicillin, or sensitivities e.g. latex

Specific and detailed assessments and the resulting measures to control exposure must be made for high-risk substances such as:

- *Any hormones;*
- *Oil-based vaccines;*
- *Cytotoxic drugs;*
- *Gluteraldehyde disinfectants;*
- *Micotil (tilmicosin);*
- *Large animal Immobilon (etorphine);*
- *Zoonoses''*

While this advice is aimed at veterinary practices, other businesses, such as animal health distributors and pet shops will also need to go through the risk assessment process.

In order to facilitate the risk assessment process, suppliers will need to have access to information about the veterinary medicinal products which they hold.

Do I need a Safety Data Sheet?

The answer is, it depends, but the important thing to note is that a Safety Data Sheet is not required for every medicine.

In the eyes of the law, there is no such thing as a ''COSHH data sheet.'' The correct term is "**Safety Data Sheet''** or "REACH safety data sheet.''

REACH is a new European Regulation that covers the Registration, Evaluation, Authorisation and restriction of CHemicals. It entered into force in 2007. REACH has replaced a number of pieces of older chemicals' legislation, including the Safety Data Sheet Directive.

Therefore, in the United Kingdom, the requirements for safety data sheets have moved from The Chemical (Hazard Information and Packaging for Supply) Regulations (CHIP Regulations) to REACH.

Veterinary (and human) medicines are exempt from some parts of REACH. In particular, medicinal products for veterinary use within the scope of Regulation (EC) No. 726/2004, Directive 2001/82/EC that are supplied in the finished state, intended for the final user are exempt from the requirement to supply a Safety Data Sheet.

Therefore, as long as the veterinary medicine is supplied in its final formulation and packaging for the final consumer, a Safety Data Sheet (SDS) is not required.

So, Safety Data Sheets are not legally required for veterinary medicines and many medicine companies do not produce them.

So how can a risk assessment be done?

Safety Data Sheets should not be confused with the Product Data Sheets and Summary of Product Characteristics (SPCs). Veterinary practices and other suppliers of animal medicines should ensure that they have access to the current version of either the SPC or the Data Sheet for each authorised medicine used or stored in the practice.

These provide all the necessary information to carry out the required risk assessment.

They are available in the current NOAH Compendium of Data Sheets and can also be found online at http://www.noahcompendium.co.uk/ Alternatively, SPCs for all veterinary medicines can be found at: www.vmd.gov.uk/ProductInformationDatabase/Default.aspx.

SPCs for human medicines used by veterinary surgeons under the cascade (where there is no licensed veterinary medicine available) can be found at: www.emc.medicines.org.uk.

It should be noted that the lists mentioned are not exhaustive and practices and other businesses stocking animal medicines should consider their own individual medicine/substance usage.

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Further reading

The REACH legislation can be accessed via the following link;
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF

For details from the Health and Safety Executive (HSE) on REACH exemptions, please refer to the HSE website via the following link;
http://www.hse.gov.uk/reach/resources/exemptions.pdf

What is NOAH?

The National Office of Animal Health (NOAH) represents the UK animal medicine industry: its aim is to promote the benefits of safe, effective, quality medicines for the health and welfare of all animals.

NOAH's members account for well over 90% of the UK licensed animal medicine market for pets, working and farm animals.

A full range of NOAH's briefing documents, press releases and other published documents can be found at www.noah.co.uk, which also provides links to other official and industry sites.