

Environmentally classified pharmaceuticals

Reducing residues of pharmaceutical products in ground, water and air is one of Stockholm County Council's five most important environmental issues. One key aspect to this work is the assessment and classification of pharmaceuticals according to their impact on the environment. Pharmaceutical substances are assessed with respect to their environmental risk. The environmental classification is also based on a hazard assessment of the active substance in the medication based on the three characteristics of biodegradability (Persistence), accumulation in adipose tissue in aquatic organisms (Bioaccumulation) and toxicity for aquatic organisms (Toxicity).

The classification system is the result of a collaboration between LIF (the Swedish Association of the Pharmaceutical Industry), Apoteket AB (the National Corporation of Swedish Pharmacies), Läkemedelsverket (the Swedish Medical Products Agency), SKL (the Swedish Association of Local Authorities and Regions), and Stockholm County Council. It was developed in consultation with ecotoxicological experts.

Environmental risk

The environmental risk refers to risk for the aquatic environment, and can be

- Insignificant
- Low
- Moderate
- High

The Swedish Association of the Pharmaceutical Industry began to conduct environmental risk assessments of pharmaceuticals in 2005; these assessments are to include all medications by 2010.

Environmental hazard

The classification system assesses the hazard of a substance according to its

- *Persistence* – ability to resist degradation in the aquatic environment.
- *Bioaccumulation* – accumulation in adipose tissue of aquatic organisms.
- *Toxicity* – the potential to poison aquatic organisms.

When Stockholm County Council presents the classification in the brochure "Environmentally Classified Pharmaceuticals", each of these characteristics is assigned a numerical value (0–3). The total of these values constitutes the PBT index for the substance. The PBT Index can assume values in the interval (0–9). The hazard model was formulated by Stockholm County Council and Apoteket AB in 2003.

Practical use of the classification system

- Results from the environmental classification system are taken into account when Stockholm County Council recommends pharmaceuticals in the Wise List.
- When the Wise List cannot be used for medical reasons, prescribing doctors can use the classification system when selecting among medical equivalents.

- When comparing the environmental impact of two substances, consideration must be given to both the risk and the PBT value since bioaccumulation and persistence are not included in the risk assessment.
- Information programs and courses targeting prescribing doctors.
- Influence the pharmaceutical industry.

The Wise List is a list of pharmaceuticals for common diseases recommended by Stockholm County Council. The pharmaceuticals have been chosen by medical experts because they are effective, safe and priceworthy.

Results of the classification so far – 2006

Risk assessment: 24 % of the classified pharmaceuticals have been risk assessed

- 88 % insignificant risk
- 8 % low risk
- 4 % moderate risk
- 0 % high risk

Hazard assessment: The substances classified so far account for 40 % of the sales volume in Stockholm County, calculated in defined daily doses (DDD). The classification will gradually be expanded and by the end of 2006 it is expected to cover 50 % of all DDDs prescribed within the county council's jurisdiction.

- 97 % were persistent
- 32 % had a potential for bioaccumulation
- 56 % were toxic or very toxic in the aquatic environment

Looking ahead...

Today's classification system considers a pharmaceutical's lethal effect. The aim is to develop the system to also take into consideration other effects, such as pharmacological effects of the residues, as well as carcinogenic, mutagenic and reproductive effects. Metabolites will be assessed and evaluated.

Summary

In the work to reduce residues of pharmaceutical products in ground, water and air, stakeholders in Swedish health care have devised a system of classification of pharmaceuticals in which risk, persistence, bioaccumulation and toxicity are measured. The classification system is used in the development of the Wise List and as an information tool to all health care staff.