
# Identification and evaluation of computer models for predicting environmental concentrations of pharmaceuticals and veterinary products in the Nordic environment.



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Abstract: According to European Union Council directive 2001/83, an application for the marketing authorization of a medicinal product shall be accompanied by an environmental risk assessment, including an exposure assessment. Computerized exposure models constitute an important tool in predicting environmental exposure to substances yet to be introduced on the market. This paper reports the process of identifying appropriate exposure models for estimating PECs (Predicted Environmental Concentrations) for pharmaceuticals and veterinary products, focusing on emissions to Swedish aquatic and terrestrial environments via water and sludge from sewage treatment plants. From a large number of information sources, a set of 181 potentially relevant exposure models was identified. A process of scrutinizing and testing these models resulted in a final selection of two models, namely SimpleTreat 3.1 that is used to estimate distribution and elimination of chemicals in sewage treatment plants (resulting in a PEC), and VetPec, suited for veterinary products, that estimates PEC in soil (including pore water), groundwater, and surface water. It is concluded that there is still potential for further development of exposure model(s) specifically designed for pharmaceutical emissions to the Nordic environment and climate. Furthermore, increased regulatory data requirements would facilitate the use of existing models, and improve the quality of the output data from these models.

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