

## 70. Exposure Data for Pharmacovigilance - Methods and Parameters

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Data on exposure to medicinal products in the overall population are essential for risk assessment in pharmacovigilance. They are needed to determine the public health impact of safety concerns and as denominator, putting the number of spontaneously reported cases of adverse reactions in quantitative relation to such exposure.

In the European Union, there is even a legal basis for the regulators to request such data from marketing authorisation holders, and they are part of the internationally agreed formats for Periodic Safety Update Reports and Pharmacovigilance Plans. Routine access to exposure data by those responsible for public health should be promoted by legal and technical provisions, safeguarding data privacy.

When estimating exposure in the overall population during a defined time period, different points have to be considered, depending on the type and source of data, i.e. prescription and sales data collected at the various levels of the distribution chain. Points to consider include import/export/parallel distribution and shelf lives/stock building. Prescription data from databases established for pharmacy reimbursement and pharmacy sales data on over-the-counter products are usually the most complete and time-accurate data.

Exposure data, either from the overall population or also from study populations, can be expressed in different ways. In this respect, the following will be discussed in the presentation:

- the advantages and disadvantages of different measurement units such as number of units, number of daily doses and number of patients;
- the differences between various adverse frequency parameters based on these measurement units;
- the appropriate use of these parameters in relation to the hazard functions of adverse reactions.

While all parameters may be used to detect potential risks, they can be used appropriately for risk quantification and comparison only if a risk is equal over treatment time or over defined time periods after treatment.