Interpreting the data

The data provided relate to reports where the product was used alone or in conjunction with other products, and may or may not be related to the observed events. Hence the figures as such should not be interpreted to mean that the product has been shown to cause these effects.
For each report, the likelihood that the events are linked to the use of a particular product can only be established after thorough analysis to ensure that the events are not linked to other causes such as an underlying disease or the use of other medicines.

The information in the reports is often incomplete and does not always enable to conclude that a particular product caused an effect in an individual case. Regulators rely on the totality of reports in the database and detailed statistical analysis of how often certain events occur with a particular product compared to others (the background rate in the database). Sometimes certain signals suggesting a possible association may trigger the need for more in-depth investigations through the use of specific additional post-authorisation safety trials.

The absolute number of reports for a particular product should not be compared to the number of reports of any other products since the numbers will depend on factors such as how widely a product is being used, how long a product has been marketed for and what products are used for in the field. It is therefore inappropriate to compare the safety of different products on the crude number of reports made available.

More about the medicine and the EU regulatory system

Nobivac L4 is used to vaccinate dogs to reduce the risk of developing an infection with certain Leptospira strains. Leptospirosis disease in dogs results in bleeding, hepatitis (infection of the liver) and jaundice (yellowing of the skin and eyes) or nephritis (kidney infection). The main infection source is from urine or urine-contaminated water or soil. The vaccine also reduces the excretion (shedding) of the virus into the urine by the infected dogs, thereby reducing the risk of transmission.

The European Commission granted a marketing authorisation valid throughout the European Union, for Nobivac L4 on 16 July 2012. For more information about treatment with Nobivac L4, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist. More information on Nobivac L4 can be found on EMA's website: ema.europa.eu/Find medicine/Veterinary medicines.

There is a legal obligation in the EU to continuously monitor and evaluate the use of a product when the product is marketed to ensure its safety and efficacy. This process is called pharmacovigilance and involves the company responsible for the product and regulatory authorities collecting reports on adverse events and suspected lack of efficacy. The reports are then routinely evaluated as part of the continuous assessment of the product to ensure that the benefits of the product continue to outweigh the risks and to improve the knowledge of the product. When necessary, such reports may lead to recommendations to improve information on the safety profile of the product or the instructions for using the product as well as adding new warnings and precautionary advice.