HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

STATEMENT TO ACCOMPANY ADVERSE REACTION/EVENT DATA RELEASED BY THE HPRA

Introduction

This document provides background information on the HPRA adverse reaction/event reporting system and provides advice on interpretation of information collected through this system.

Spontaneous adverse reaction/event reports

The HPRA operates the national system for recording and reporting details of suspected adverse reactions/events occurring in Ireland which are notified in association with the use of medicines. This system was first established in 1968, with reports submitted to the HPRA directly by healthcare professionals and patients/consumers using the online or downloadable reporting options accessible from the HPRA website, in hard copy format via freepost or by telephone. They are also submitted to the HPRA indirectly from pharmaceutical companies through the European Medicines Agency's database, known as 'EudraVigilance'.

As part of its statutory role in the regulation of medicines, the HPRA is legally obliged to transmit certain details of reports received (excluding contact details) to the EudraVigilance database. Following transmission, partially anonymised details of these reports on the EudraVigilance database are accessible to other bodies also involved in safety monitoring of medicines, in accordance with legislative provisions. These bodies include the European Medicines Agency (EMA), the World Health Organization (WHO) and the pharmaceutical company(ies) that hold the authorisation(s) for the medicine concerned. Due to variations in information received by the various bodies and case management processes, minor differences may exist across the listings/outputs generated by the respective organisations.

Information collected through such reporting systems is an important aspect of monitoring safety of medicines, by increasing knowledge about known adverse reactions and also by acting as an early warning system for the identification of previously unrecognised adverse reactions. However, adverse reaction/event reports are rarely sufficient to prove that a particular effect has been caused by a specific medicine and need to be considered in the broader context of additional data, e.g. from clinical trials, epidemiological studies and global safety monitoring experience.

Adverse reaction/event listings:

- Include reactions/events notified in association with a suspected medicine/product. Each report relates to an individual patient.
- Lists all reactions/events included on the original report. It is important to note that listings are subject to change on the basis of updates to case information received over time.
- May contain information on more than one reaction/event; therefore the total number of reactions/events may exceed the number of reports received for the medicine/product concerned
- Use adverse reaction/event terms known as 'preferred terms'. This system is used to ensure consistency of terminology and to facilitate exchange of information with pharmaceutical companies and international bodies.
- In many cases provide only limited information on the reports received.

- Please note that listings are subject to change if/when updated case information becomes available, or information is received that allows identification of cases as duplicate reports (i.e. submission of the same case from more than one source over time). Identification of duplicate reports may lead to consolidation of reports under a new unique identification number.

Guidance on interpretation of adverse reaction/event listings

Interpretation of the data in an adverse reaction/event listing should take into account the following:

- Reports submitted to the HPRA come from a variety of sources including healthcare professionals and patients/consumers.
- Adverse reaction/event reporting rates are influenced by the seriousness of the reaction/event, their ease of recognition and the extent of use of a particular medicine. Report rates may also be stimulated by promotion and publicity about a medicine.
- Reports submitted to the HPRA in many instances arise from suspicions occurring during observation of an unexpected and/or unwanted event. The inclusion of a particular report/reaction/event on the listing does not necessarily mean that the medicine has caused the observed effect. Many factors have to be taken into account in assessing a causal relationship including a temporal association, the possible contribution of concomitant medication, and the underlying disease.
- Interpretation of reactions/events in cases where combination or multiple other therapies have been administered around the same time requires special care. This may be particularly relevant for vaccines, as several vaccines may be administered in combination.
- Certain reported reactions/events are conditions which often occur spontaneously. In these cases there may be a temporal relationship between the medicine and the reaction/event which is not necessarily causal. This applies particularly to vaccines
- The number of reports received should not be used as a basis for determining the incidence of a reaction/event as neither the total number of reactions/events occurring nor the number of patients using a medicine is known.
- Numerical comparisons should not be made between reactions/events associated with different medicines on the basis of the data included in listings alone. Comparisons may be misleading because of the limitations of the data.
- Reporting tends to be highest for newly authorised medicines during the first one or two years on the market and then falls off over time.

Use of data provided

If you wish to copy, circulate or publish this listing or extracts of the information contained within this listing, then please include a copy of the caveat document with it.

Any publication, in whole or part, of information obtained from the HPRA should include:

1. An acknowledgement of the source of the information.
2. An indication that the information contained in the listings comes from a variety of sources, often based on observation of an unexpected and/or unwanted event.
3. An indication that the inclusion of a report/reaction/event on the listing does not necessarily mean it has been caused by the medicine(s) in question.
4. An affirmation that the information does not represent the opinion of the HPRA.