1. INTRODUCTION

Reporting adverse drug reactions and special situations is an integral element in the safety monitoring and Pharmacovigilance (FV) of medications. In compliance with its legal obligations, DIATER collects and manages all suspected adverse drug reactions (ADR) that are reported by consumers and healthcare professionals on a voluntary basis.

This guide supports health professionals, consumers, etc. to complete the DIATER ADR Reporting Form in the event of ADR related to DIATER products, according to the information necessary for their management according to the current European PV regulations and DIATER's internal procedures.

The Minimum Information Required for an ADR case (*) is: a single identifiable patient, and at least one suspected DIATER medication, an identifiable reporter, a suspected DIATER product and a suspected ADR which was related to the DIATER product.

2. WHAT IS A SUSPECTED ADVERSE DRUG REACTION?

2.1. Suspected Adverse Drug Reaction (ADR)

Any harmful and unintended response to a medication. This includes ADRs arising from the use within the provisions of the authorised conditions, as well as from the use outside the authorised conditions, overdose, dependence, misuse, abuse, medication errors, occupational exposure and exposure during pregnancy or lactation.

2.2. Suspected Serious Adverse Drug Reaction (ADR)

Any ADR that meets any of the severity criteria indicated in the DIATER ADR Reporting Form, with the following clarifications:

- medical relevance: the ADR that does not meet the rest of the specified criteria, but puts the patient at risk or requires an intervention to prevent any of the specified outcomes,
- lack of effect: only in patients who respond to treatment after the recommended immunotherapy period according to the WHO Opinion Article Allergen immunotherapy: Therapeutic vaccines for allergic diseases

3. WHAT TO REPORT?

- **Any ADR**, even if the reaction is well known
- **Suspected interactions** with other medications and medicinal plants
- **ADRs that are not serious**, but that are considered **clinically significant** by the healthcare professional (e.g., increased frequency or unusual occurrence of a known adverse reaction)

If in doubt, please report. It is not necessary to be sure that the ADR is related to the suspected medication.

IMPORTANT: Click on the **Send to DIATER** icon to automatically send the Form to its PV Department via email. You may keep a copy of the Form for your information.