

**Approximate study time:** 45 minutes**Level:** Introductory/Intermediate**Audience:** Drug Safety, Regulatory, Compliance, Manager**Category:** Drug Safety**Region:** Europe**CPD Points:** 0.75**Module outline**

- Module overview
- Principles
- Procedure
- Assessment

An Urgent Safety Restriction (USR) is a regulatory action taken, in response to a safety signal, to make an interim change to the terms of the marketing authorisation for a medicinal product in Europe. This module describes the principles and procedures for USRs.

**Who will benefit from this module?**

All staff working in medical, drug safety, or pharmacovigilance departments of pharmaceutical or biotechnology companies with products authorised in Europe should have access to this module. It will also be of value to healthcare professionals and regulatory authority personnel.

**Learning objectives**

- Explain the purpose of Urgent Safety Restrictions in Europe
- Describe how an USR may be triggered
- Describe the general regulatory requirements for preparation and initiation of an USR
- Outline the 24-hour procedure for execution of an USR
- Specify the requirements for a variation application following an USR

**Module outline****Module overview**

An outline of the module's objectives, and notes on terminology.

Principles

In this session we define Urgent Safety Restriction and explain its purpose in the European Union and other countries of the European Economic Area. We describe how an USR may be triggered. Finally, we give some examples of safety signals that may, and some that may not, give rise to an USR.

Procedure

In this session we describe how to prepare for and initiate an Urgent Safety Restriction (USR) for a centrally authorised product and for a product authorised through the Mutual Recognition or Decentralised Procedure. We outline the 24-hour procedure for execution of an USR, and the follow-up actions required, in each case. Finally, we specify the requirements for a variation application following an USR.

Assessment

Multiple-choice mastery assessment.

