Pharmacovigilance 2

In this chapter, the fundamentals of pharmacovigilance are outlined with a particular emphasis on the role of healthcare professionals in reporting adverse drug reactions (ADRs). It also explains why pharmacovigilance is speci cally important regarding biological medicinal products (biologicals).

2.1 Fundamentals of Pharmacovigilance

Before medicinal products are marketed, they undergo extensive risk assessment, including clinical trials. A er marketing authorisation, drugs are prescribed to larger populations in medical environments that are less controlled than clinical trials. Hence, medicines might produce ADRs during normal therapeutic use, despite risk assessment during marketing authorisation (Belton and the European Pharmacovigilance Research Group 1997).

It is estimated that ADRs account for ve percent of all hospital admissions and cause around 200,000 deaths per year in the European Union (EU) (European Commission 2008). Based on the estimation by the European Commission (Commission), the total cost of ADRs amounts to roughly €80 billion.

Hence, product safety is a substantive public concern and essential for public health. Patients might be harmed not only by a drug itself, but also due to the combined interaction of more than one prescribed drug. In order to prevent harm, the surveillance of medicinal products is vital and pharmacovigilance has become an important aspect of public health legislation (Johnson and Hutchinson 2015).

e World Health Organisation (WHO) de nes pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse e ects or any other medicine-related problem" (WHO 2004).

Pharmacovigilance pursues the following four general objectives (WHO 2004):

É The Editor(s) (if applicable) and The Author(s) 2017

M. Kaeding et al., *Pharmacovigilance in the European Union*,
DOI 10.1007/978-3-658-17276-3_2

it underestimates the frequency and thus the impact of the problem and makes the system more vulnerable to selective reporting which may introduce a serious bias (Alvarez-Requejo et al. 1998). Adequate availability of exposure information is necessary to timely link an emerging product safety issue to the correct product and batch (Klein et al. 2016). Even though the level of evidence of case reports is often poor, spontaneous reports contribute to the majority of safety withdrawals. And when there are no doubts about the causal relationship between an adverse event and a drug, spontaneous reports may be the sole source for regulatory action (Ebbers et al. 2011).

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