
13 Pharmacovigilance of Biosimilars

*Shehla Hashim, Souleh Semalulu,
Felix Omara, and Duc Vu*
Health Canada

CONTENTS

| | |
|---|-----|
| 13.1 Introduction | 361 |
| 13.1.1 Role of Pharmacovigilance in Drug Safety | 361 |
| 13.1.2 Biopharmaceuticals and Biosimilars | 363 |
| 13.2 Scientific Guidelines for the Regulation of Biosimilars | 364 |
| 13.3 Challenges in Pharmacovigilance of Biosimilars..... | 365 |
| 13.3.1 Uncertainties with Safety Profile of the Product at Authorization... | 365 |
| 13.3.2 Issues with Interchangeability/Substitutability/Switching..... | 367 |
| 13.3.3 Challenges with Naming and Tracking of Biosimilars | 368 |
| 13.4 Conclusions..... | 370 |
| References..... | 371 |

13.1 INTRODUCTION

Medicinal products are initially approved based largely on the safety and efficacy data from randomized clinical trials. Such trials are often conducted in selected target populations, where the sample sizes are small and the treatment duration is short; therefore, rare events and adverse events with long lag periods are not fully characterized, and safety in the wider general population is unknown. Thus, there are uncertainties with regards to the entire safety profile of the drug at the time of authorization. Once authorized, the safety of drugs is dependent on several factors such as how they are used in the “real world” under the authorized indications, the nature of the drug, characteristics of individual patients, and the quality of the product. This necessitates systematic and continuous monitoring of drug safety throughout its life cycle, in order to detect any new adverse events and to minimize both known and previously unknown safety concerns that may arise in the postmarket setting in order to maintain a positive benefit–risk profile of the drug.

13.1.1 ROLE OF PHARMACOVIGILANCE IN DRUG SAFETY

Pharmacovigilance as a discipline originated following the medical disaster with thalidomide in 1961. Thalidomide was used by pregnant women, and it resulted in congenital abnormalities in the infants born to these mothers. Following these