CGA

Compressed Gas Association

The Standard For Safety Since 1913

CGA M-21—2022

GUIDELINE FOR DETERMINING PHARMACOVIGILANCE REPORTING REQUIREMENTS IN NORTH AMERICA

SECOND EDITION

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NOTE—Technical changes from the previous edition are underlined.

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1 Introduction

In many countries, mandatory regulatory worldwide systems for companies manufacturing or distributing medical gases or medical devices, e.g., European Union (EU), United States, and Canada, require an effective pharmacovigilance system within the company.

For globally based medical gas organizations, these systems typically involve coordination within an applicable company to have a centrally located pharmacovigilance department that manages the global reporting requirements. Pharmacovigilance departments coordinate the flow of information from the field to each region and support the decision making and reporting efforts of the regions to their local regulatory agencies and globally, if appropriate.

A detailed explanation of the reporting requirements in North America (U.S. & Canada) will show the regional responsibilities for global organizations as well as specific reporting requirements for independent companies operating within one country that are not part of a global organization.

In Canada, medical gases considered drugs require a marketing authorization that is similar to the European model. GUI-0102, *Good Pharmacovigilance Practices (GVP) Guidelines*, specifies the elements of good pharmacovigilance practices for the manufacturers and importers of medical gases, as drugs, marketed in Canada for human use [1].

In the United States, most medical gases are approved drugs under a "certification" process identified in Section 576 of the Federal *Food, Drug, and Cosmetic Act* [2]. These designated medical gases were never evaluated through a traditional New Drug Application (NDA) process and therefore do not technically fit the reporting criteria of 21 CFR Part 314 "Applications for FDA Approval to Market a New Drug" [3].

The medical gas industry understands the intent of both the U.S. Food and Drug Administration (FDA) and Health Canada to maintain an awareness of potential adverse events that might indicate a need for special focus and attention. To satisfy this intent, CGA has developed this guideline for the industry to provide guidance on how to satisfy the U.S. and Canada reporting requirements.

2 Scope

This publication provides guidance for pharmacovigilance reporting to FDA and Health Canada. This guidance is intended to aid United States and Canadian companies that market common medical gases (i.e., oxygen, nitrogen, medical air, carbon dioxide, nitrous oxide, helium, and carbon monoxide and medically appropriate mixtures thereof) in setting up a pharmacovigilance reporting system that satisfies local and regional regulatory requirements, bearing in mind any global requirements when applicable.

This publication does not address reporting requirements for gases or medical gas equipment classified as medical devices (materiovigilance).

CGA continues to work with the FDA and Health Canada on pharmacovigilance requirements for common medical gases.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.