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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 0869.1-2016

Replacing YY/T 0869-2013

Medical devices - Hierarchical coding structure for adverse events - Part 1: Event type codes

医疗器械 不良事件分级编码结构 第1部分：事件类型编码

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Foreword

2 terms and definitions

1 Scope

YY/T 0869.1 is Part 1 of the Chinese hierarchical coding structure for medical device adverse events, covering the event type codes: the structured vocabulary that says what happened, from the device malfunction observed to the clinical consequence for the patient. A hierarchy matters because reports arrive at different levels of detail, and a scheme that forces a reporter to be more specific than they can be produces worse data than one that lets them stop at the right level. It is the companion to Part 2 on evaluation codes. For a manufacturer operating post-market vigilance in China, or building a complaint handling system that has to serve several markets at once, this is the coding structure Chinese reports are written in.

This part of YY/T 0869 specifies the requirements for describing the hierarchical coding structure of adverse events related to medical devices. This code prepares Period is used by medical device users, manufacturers, regulators, medical institutions and other organizations. Coding may be used to fight with death or serious Injury-related events, or to faults that may cause death or serious injury. This section is not intended to determine whether an incident needs to be reported.

3 Adverse event type encoding requirements

The adverse event type encoding describes the use/failure/failure characteristics of the medical device observed at the time of the event. The code should be selected from Table 4 of the four-digit code.

Note 1. A single code that is closest to the depicted adverse event can be used. However, sometimes in order to fully represent an adverse event may need to use multiple coding.

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Note 2. Adverse event type coding is useful for describing the dangers of an adverse event. It may also be useful in the User Reporting System. When combined with adverse event evaluation codes (from YY/T 0869.2), the characteristics of adverse events can be better expressed.

Note 3. Selection of adverse event type codes to describe adverse events at the time of the incident, reflecting the latest assessment of adverse events and taking into account the occurrence of the incident and The report submits any additional information obtained during this time.

11 Reference 12

YY/T 0869 "Medical device adverse event classification coding structure", by the following components. Part 1. Event type encoding; Part 2. Evaluation code. This part is part 1 of YY/T 0869. This part is drafted in accordance with the rules given in GB/T 1.1-2009. This part together with YY/T 0869.2-2016 instead of YY/T 0869-2013 "medical device adverse event type and cause of the series Code structure ", this part and YY/T 0869-2013 compared to the main changes are as follows:

--- modified the "preface";

--- modified "Introduction"; - the terms "permanent damage" and "permanent damage" are removed; - the term "intended use" has been added;

--- modified the "bad event type code" content;

--- delete the "bad event cause code" content;

--- modified "Table 1 bad event type encoding" content;

--- "Appendix A" is modified to "Coding system structure";

--- "Appendix B" is modified to "Event Type Code Selection Example";

--- modified the "reference". This part uses the translation method equivalent to ISO /T S19218-1..2011 "Medical device adverse event classification coding structure Part

1 Points. event type encoding "(English version). Please note that some of the contents of this document may involve patents. The issuer of this document does not assume responsibility for the identification of these patents. This section is proposed by the State Food and Drug Administration. This part of the National Medical Device Quality Management and General Requirements Standardization Technical Committee (SAC/TC221) centralized. This part of the drafting unit. Beijing Guoya Huaguang Certification Co., Ltd. This part of the main drafters. Milan British, Zheng Yi Han, Chen Zhigang. This part of the previous version of the standard to replace the release of the situation.

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--- YY/T 0869-2013.

YY/T 0869 In this section, the adverse event coding system envisages a medical device adverse event report originating from one of two sources. Related equipment users or manufacturers. In this section, the user may be a medical service person, but may also be the general public. by YY/T 0869 provides the structure of this part, the type of adverse events can be used in the post-marketing stage to collect medical equipment supervision information. use The common code also makes it easy for the information to be exchanged internationally. This part of YY/T 0869 may be used by the user, manufacturer and regulatory authority in the following manner. - users can report to manufacturers or regulators, using a code to describe the general understanding of the adverse events;

--- Manufacturers and regulators are easy to identify generally accepted types of adverse events that can be obtained globally by regulators Recognition; - Users and manufacturers can also apply these codes as part of a medical device monitoring or reporting system. Classification of Medical Device Adverse Event Part 1. Event Type Encoding

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