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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0869.2-2016

Replacing YY/T 0869-2013

Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation codes

医疗器械 不良事件分级编码结构 第2部分：评价编码

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Foreword

1 Scope

YY/T 0869.2 is Part 2 of the Chinese hierarchical coding structure for medical device adverse events, covering the evaluation codes: the vocabulary used to record what an investigation concluded about an event, as distinct from what the event was. Post-market surveillance only becomes useful when reports can be aggregated, and aggregation needs codes rather than prose, which is why the assessment of cause and outcome is standardised alongside the event itself. Part 1 covers the event type codes. It corresponds to the international adverse event terminology work that regulators use to exchange signals across markets. For a manufacturer running vigilance for the Chinese market, this is the coding scheme the evaluations in its reports have to use.

This part of YY/T 0869 specifies the classification of the relevant medical device adverse events in the analysis or evaluation results. Requirements. These codes are expected to be used primarily by medical device manufacturers and regulators. Encoding is not only used to cause death or serious injury And can also be used to analyze or evaluate the results of events other than death or serious injury. This section is not intended to determine whether an incident needs to be reported.

3 Adverse Event Evaluation Code Requirements

Adverse event evaluation codes describe the characteristics of adverse event analysis or investigation of the latest conclusions. The code shall be a five-digit number selected from Table 1 code.

Note 1. Multiple coding is necessary to fully evaluate the adverse events.

Note 2. Adverse event evaluation codes are useful for manufacturers and regulators to track reported adverse events. When combined with bad event type encoding, The characteristics

of the adverse events can be conveyed concisely.

10 Reference 11

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 2 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 0869.1-2016 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;

--- delete the "bad event type code" and "bad event cause coding" two parts;

--- increased the "adverse event evaluation code requirements" and "adverse event evaluation code" two parts;

--- Appendix A is modified to "Coding System Structure"; - "Appendix B encoding example" was deleted;

--- modified the "reference". This part uses the translation method equivalent to ISO /T S19218-2..2012 "Medical device adverse event classification coding structure Part

2 Points. evaluation code "(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 partial replacement of the standard version of the previous release.

--- YY/T 0869-2013.

The design of the adverse events as specified in this part of YY/T 0869 is mainly due to the manufacturer of the related equipment. Through this Part of the provided structure, adverse event evaluations can be used to collect postmarketing stages of medical device supervision information. Use a common code that is easy to use International exchange of information. This part of YY/T 0869 can be used by health care providers and other users of the device. However, some evaluation code description The characteristics of the analysis or survey results carried out by the manufacturer or the regulatory authority. Manufacturers or regulators may use adverse events in the following areas Evaluation code. - Identify or

investigate adverse events with globally recognized evaluation codes, and - Apply these codes as part of the medical device monitoring or reporting system. Appendix A shows how to combine bad event coding with other data elements to facilitate global data exchange between regulators. Classification of Medical Device Adverse Event Part 2. Evaluation code