

Guideline on the label design for Injections

(Draft for Comments)

2018.3

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Guideline on the design of pharmaceutical packaging (example of case)

Part 1. Guideline on the label design for Injections

(Draft for Comments, 2018.03)

Foreword

This guide aims to provide guidance to the marketing authorization holder in the design of drug labels, so as to minimize clinical medication errors, ensure patients' medication safety and improve drug compliance by the application of the elements such as fonts, patterns, colors and layout.

This guide, as the first part of the "Guideline on the design of pharmaceutical packaging (example of case)", includes: Foreword, Scope, Normative References, Terms and Definitions, Basic Requirements for Labels, Design Principles of Labels for Injections and Appendix. (The guide to packaging design of other dosage forms will be developed subsequently, such as oral preparations, eye drops, inhalation preparations, topical preparations, etc.)

This guide was prepared in accordance with the Directives for Standardization (GB/T 1.1-2009), The Drug Administration Law of the People's Republic of China, Administrative Provisions on Package Inserts and Labels (No. 24 Order of China Food and Drug Administration, released in 2006), Working Regulations of Standardization Committee of China National Pharmaceutical Packaging Association, Procedures for Preparation and Revision of China National Pharmaceutical Packaging Association's Standards, and Guide to Design of Drug Packaging and Pharmacy Dispensing formulated by UK's National Patient Safety Agency, and based on the characteristics of injections.

This guide was proposed by the China National Pharmaceutical Packaging Association, which prepared the Guideline on the design of pharmaceutical packaging (example of case) through the study project of "Drug Packaging Design in China", together with the Partnership for Safe Medicines, Pharmacy Equipment, Technology Committee of China Association of Medical Equipment, Hospital pharmacy Committee of Chinese Pharmaceutical Association.

The drug marketing authorization holder may refer to and use this Guide under the premise of complying with the relevant national regulations.

Drafting Organization:

Main drafters of this guideline:

1. Scope

This guide is used to guide the graphic design and manufacture of internal and external labels for injections, including creating (or printing) labels directly on the surface of the injection package, and pasting the labels on the surface of the injection package after creating (or printing).

2. Terms and definitions

- 2.1 Label: it refers to the content printed or pasted on the drug package, which are classified into internal label and external label.
- 2.2 Internal label: it refers to the labels on the package in direct contact with the drug.
- 2.3 External label: it refers to the labels of other packages other than internal label. They are usually classified into the minimum marketing packaging label, and the transportation and storage packaging labels. The external label in this guide refers to the minimum marketing packaging label.
- 2.4 Black framed warning: it refers to the warning text in the instruction of prescription drugs. It is intended to explain the serious side effects or other potential safety problems that may be caused by the use of this drug, and, as the highest-level warning, it is generally placed at the forefront of the instruction. It is also called "Drug Black-Label Warning" or "Framed Warning of Drug".

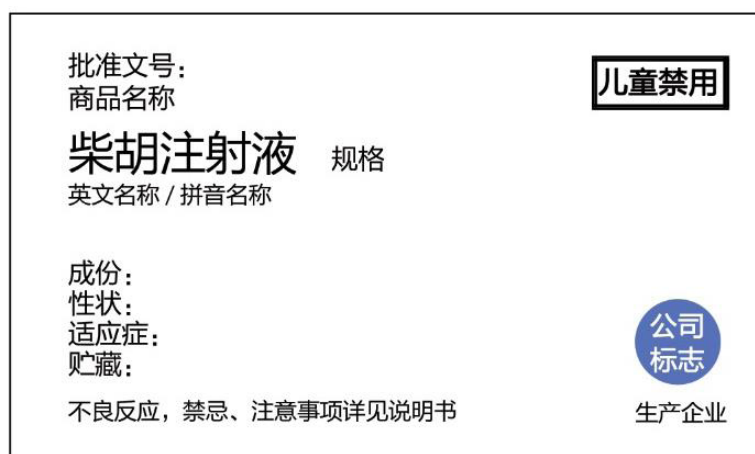


Figure 2.1: Black framed warning of Bupleurum injection

- 2.5 Traceability code: A set of numbers, special graphics, radio frequency identification (RFID) or augmented reality (AR) and other agreed coding rules, it is identified by specified equipment and then to read the recorded data, thus obtaining information such as manufacturing enterprises and drug strengths, and can also be used for anti-counterfeiting, and tracing plane and three-dimensional details such as drug sources and production (circulation) processes.

3. Basic requirements for labels

- 3.1 The content of the drug label shall be based on the package insert, and shall not be printed with the content that implies efficiency, misleads use, or inappropriately promotes the product.

- 3.2 The design and manufacture of label shall make sure that the phenomena like the fall-off of printed words or weak paste are avoided. Appropriate label carriers (paper, plastic film) and connection method (such as pasting and printing) shall be selected according to the characteristics of drug packages. The label shall not be modified or supplemented by methods such as pasting, cutting and altering, etc.
- 3.3 The internal label of a drug generally include the generic name, indication or main function, strength, posology and method of administration, date of production, batch number, period of validity (expiration date), manufacturing enterprise, number of approval, specified identification (if any), trade name, English name, and traceability code. If the package size is too small to fully indicate the above contents, at least the following shall be indicated: generic name, strength, batch number, period of validity (expiration date), method of administration, and important information to be prompted.
- 3.4 The external label of a drug (minimum marketing package label) shall indicate generic name, composition, characteristics, indications or main function, strength, posology and method of administration, adverse reactions, contraindications, precautions, storage conditions, date of production, batch number, period of validity (expiration date), number of approval, manufacturing enterprise and so on. If the indications or main function, posology and method of administration, adverse reactions, contraindications, and precautions cannot all be indicated, the main contents shall be indicated, with the sentence "See the Package Insert" stated. Special attention shall be paid to the following items under Precautions: "black framed warning", "caution for athletes", "keep out of the reach of children", "children must use it under the guidance of adults" and other items, as well as the special administration methods for injections, such as, intrathecal injection, etc.
- Relationship between internal label and external label: the text content is not contradictory, and the selection of color and font shall be relevant, so that there will be no interference with each other during reading.
- 3.5 As to the labels used for transportation and storage packaging, the generic name, strength, storage, date of production, batch number, period of validity (expiration date), number of approval, and manufacturing enterprise of the drug shall be indicated at least, and other necessary contents such as quantity of packing, cautions during transportation or other markings may also be indicated as required.
- 3.6 If the strength and packing specifications of the same product manufactured by the same manufacturing enterprise are identical, the contents, formats and colors of the labels must be the same; if different, the labels shall be distinctive, or the specifications shall be clearly indicated.
- 3.7 The name of drug indicated in the label must be consistent with the corresponding content of the drug approval documents.
- 3.8 The generic name of the drug shall be remarkable and prominent, and meet the following requirements:
- 3.8.1 The font, font size and word space must be consistent. Do not use fonts that are not easy to recognize like cursive script and seal script. Do not modify the fonts in italics, hollows, shadows, etc.
- 3.8.2 The font shall choose a color that forms a strong contrast with the background so

that it is easy to recognize.

3.8.3 Do not write in different lines, unless it is impossible to write in the same line due to the limitation of packing size.

3.9 The trade name and generic name must not be written in the same line, and the font and color of trade name shall not be more prominent and remarkable than those of the generic name.

3.10 In case of registered trademark contained in the label, it shall be printed at the corner of the drug label.

3.11 Specified markings (see the attached figures) must be printed on the package inserts and labels of drugs with special markings stipulated by the State, such as narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs, drugs for external use, drugs passed "Drug Consistency Evaluation" and so on. The markings of narcotic drugs, psychotropic drugs, toxic drugs for medical use, radioactive drugs and drugs for external use shall be placed at upper right corner of the label.



Figure 3.1 narcotic drug



Figure 3.2 psychotropic drug



Figure 3.3 toxic drug



Figure 3.4 radioactive drug



Figure 3.5 drug passed "drug consistency evaluation"

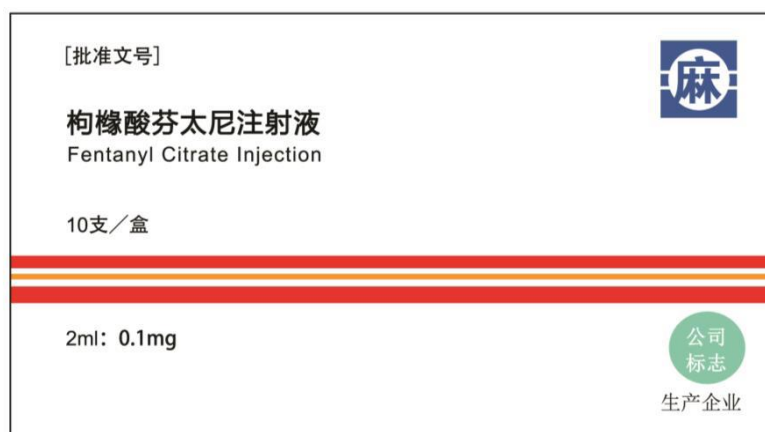


Figure 3.6 correct illustration

3.12 The labels identifiable by blind people are advocated.

- 3.13 It is advocated to establish an agreement on drug type and background color according to the needs in clinical use, such as main functions and administration methods.
- 3.14 When the label already contains traceability codes, such as two-dimensional code, bar code, RFID, AR and other information carriers, the specified information content shall also be printed (pasted) on the label.
- 3.15 Use of color
- 3.15.1 The marketing authorization holder may distinguish products or strengths by color to facilitate clinical use and reduce medication errors. However, relying only on color identification may also lead to wrong choices due to differences in light and environment, and differences of people in color identification; therefore, label designers should have a comprehensive consideration of the aforementioned.
- 3.15.2 When labels of different drugs use the same color on a large scale (except for direct printing internal labels), the difficulty of drug identification will increase. Especially when drugs with similar names are placed in similar positions or different drugs with similar packing colors are used by the same patient, the patients get confused easily and the risk to select wrong drugs will increase.
- 3.15.3 The establishment of color coding system can help people identify drugs by color.
- 3.15.4 The choice of color is not related to a particular feature of the drug, especially there is no fixed pattern in color blending.
- 3.16 The change of label design shall be submitted to the drug administration for record-filing.

4. Design principles of label for injections

Injections are sterile products prepared using APIs and suitable excipients, which are intended for administration by injection into the body. Injections are classified as solution for injection, sterilized powders for injection and concentrated solutions for injection, etc. In clinical application, they are injected directly into the tissues, blood vessels or organs of human beings in liquid state. Therefore, the absorption is fast and the effect is rapid, especially for intravenous injection, which can directly enter the blood circulation, and is more suitable for rescuing patients with critical diseases. The dispensing and injection of drugs is a high-risk treatment process for patients and health professionals. Optimized label design can reduce the risk of errors and damages. In the process of developing and designing drug labels and packaging, consideration shall be given to end users and the environment to use these drugs. Drug manufacturing enterprises shall assess and minimize the risk of medication errors due to problems in the design of internal and external labels, and then submit the design protocol for review and approval by relevant national departments.

In addition to conforming to the "Basic Requirements for Labels", injection labels shall also focus on its own particularity. Besides trade name (if any), generic name (if there is an English name or Pinyin name), strength, usage, and fixed location of the special marking (if any), other information on the label, such as composition, characteristics, storage, manufacturing enterprise, period of validity, number of approval, can be adjusted, as shown in the figure below:



General figure Correct illustration

4.1 General principles

4.1.1 Main information panel

Key information shall be highlighted when designing the front panel and other information may be displayed on the back panel, as shown in Figures 4.1.1 (a) and 4.1.1 (b) below.



Figure 4.1.1 (a) Wrong illustration



Figure 4.1.1 (b) Correct illustration

4.1.2 Similar drug names

Special attention shall be paid to different drugs with similar appearance and pronunciation in designing the generic names and trade names used in labels. In

particular, there shall be obvious differences between the labels of the drugs with similar appearance and pronunciation that are manufactured by the same enterprise, and these differences may be achieved by printing ribbons or other methods, as shown in Figures 4.1.2 (a) and 4.1.2 (b) below.



Figure 4.1.2 (a) Wrong illustration

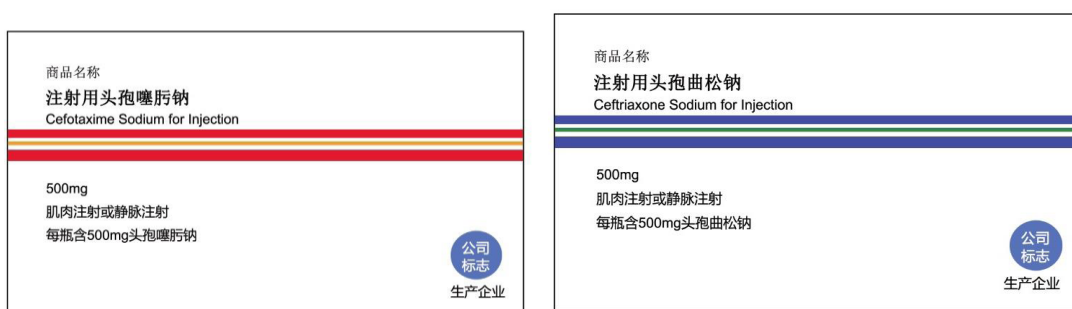


Figure 4.1.2 (b) Correct illustration

4.1.3 Strength

4.1.3.1 There is no need to display the precision of concentration on the minimum marketing packaging label, and to add "0" after the number of strength, as shown in Figures 4.1.3.1 (a) and 4.1.3.1 (b) below.



Figure 4.1.3.1 (a) Wrong illustration

Figure 4.1.3.1 (b) Correct illustration

4.1.3.2 Different strengths of the same product from the same manufacturer shall be distinguished clearly, as shown in Figures 4.1.3.2 (a) and 4.1.3.2 (b) below.



Figure 4.1.3.2 (a) Wrong illustration

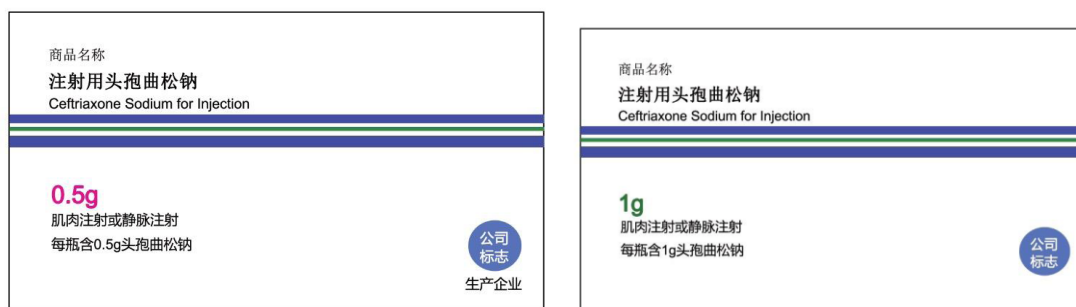


Figure 4.1.3.2 (b) Correct illustration

4.1.3.3 The strength of liquid shall be clearly distinguished, as shown in Figures 4.1.3.3 (a) and 4.1.3.3 (b) below.



Figure 4.1.3.3 (a) Wrong illustration



Figure 4.1.3.3 (b) Correct illustration

4.1.4 Route of administration

Affirmative information is used to indicate correct route of administration, and it is forbidden to use negative or incomprehensible terms, as shown in Figures 4.1.4 (a) and 4.1.4 (b) below.



Figure 4.1.4 (a) Wrong illustration



Figure 4.1.4 (b) Correct illustration

4.1.5 Medicines for dilution

Highlight the fact that the medicine requires dilution, and state a minimum dilution volume where appropriate, as shown in Figures 4.1.5 (a) and 4.1.5 (b) below.

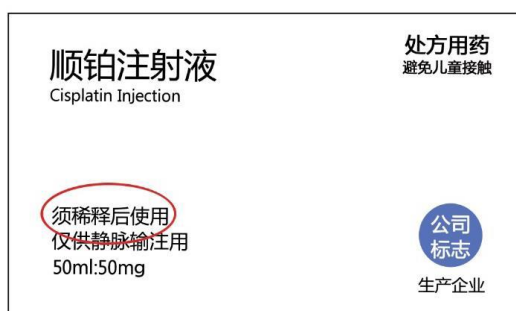


Figure 4.1.5 (a) Wrong illustration

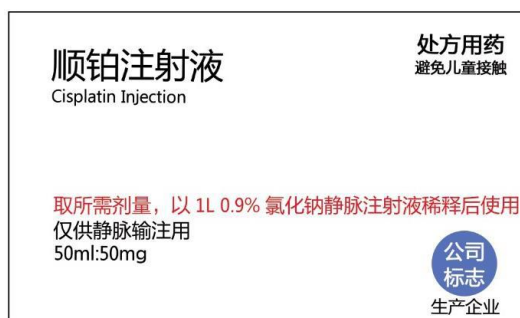


Figure 4.1.5 (b) Correct illustration

4.1.6 Storage conditions

The storage conditions shall be stated on the label, which shall be based on the stability study of the preparations. If necessary, special statement shall be provided, especially for preparations that cannot be frozen. Terminologies, such as "environmental conditions" or "room temperature" shall be avoided. The storage conditions on the label shall directly reflect the stability of the preparations. Special requirements for storage conditions shall be highlighted, particularly if the drug requires refrigeration, affirmative language shall be used to give hints to users, as shown in Figures 4.1.6 (a) and 4.1.6 (b) below.

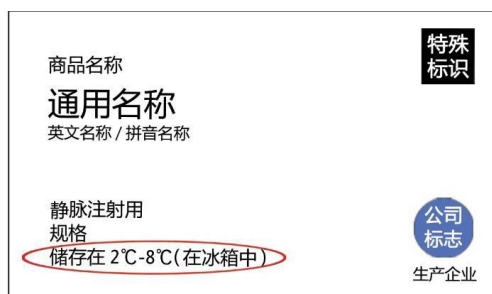


Figure 4.1.6 (a) Wrong illustration

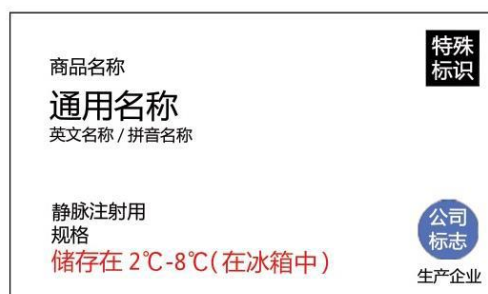


Figure 4.1.6 (b) Correct illustration

4.1.7 Injectable medicines intended for use by patients (e.g. insulin)

For multi-dose and multi-use injectable medicines, such as insulin, in addition to indicating the packing specification, the labels shall also include the content of drug, which is expressed as follows: dosage/unit volume, unit/ml, or mg/ml. In case of any Braille, it needs to be present on the packs. Ensure that the use of Braille does not detract from the other design features, as shown in Figures 4.1.7 (a) and 4.1.7 (b) below.

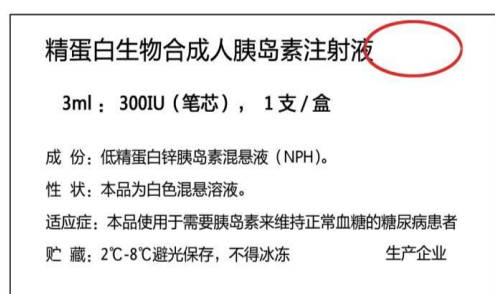


Figure 4.1.7 (a) Wrong illustration

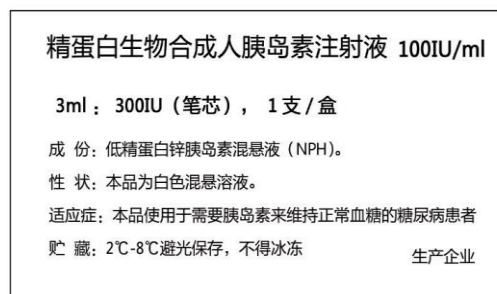


Figure 4.1.7 (b) Correct illustration

4.1.8 Injectable medicines for multiple persons: add (* persons per unit) under Strength, as shown in Figures 4.1.8 (a) and 4.1.8 (b) below.



Figure 4.1.8 (a) Wrong illustration

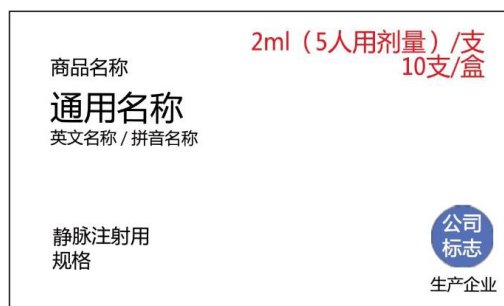


Figure 4.1.8 (b) Correct illustration

4.1.9 Period of validity (expiration date)

The figures shall be printed in a clear and easily recognizable position on the internal and/or external label, and the ink printing method shall be used as far as possible. If the drug is often used in sterile environment, the digital embossing method can also be selected, but the legibility of the figures must be ensured, as shown in Figures 4.1.9 (a) and 4.1.9 (b) below.



Figure 4.1.9 (a) Wrong illustration



Figure 4.1.9 (b) Correct illustration

4.1.10 Precautions

In case of more than 2 precautions, they shall be written in sections to make it easier for users to read, as shown in Figures 4.1.10 (a) and 4.1.10 (b) below.

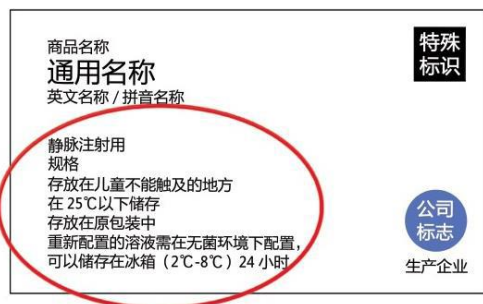


Figure 4.1.10 (a) Wrong illustration

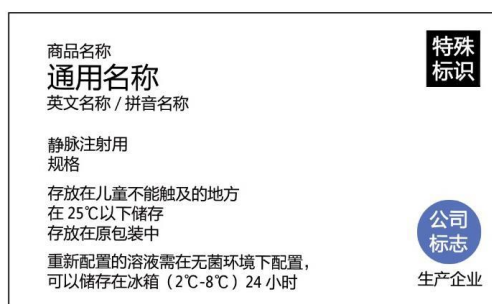


Figure 4.1.10 (b) Correct illustration

4.1.11 All kinds of bar codes (traceability code and other information) used by manufacturers may be placed in a secondary position, so as to leave space for clinical barcode, as shown in Figure 4.1.11 (a) and 4.1.11 (b) below.

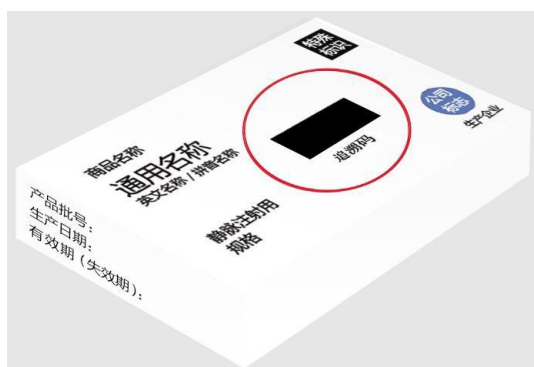


Figure 4.1.11 (a) Wrong illustration



Figure 4.1.11 (b) Correct illustration

4.1.12 The important information of the drug shall be indicated at least on the three non-opposite outside surfaces of the minimum marketing package, such as generic name, strength, posology and method of administration, etc. The label shall leave a certain blank area so that the clinical pharmacists can paste the additional label if necessary, as shown in Figure 4.1.12 below.



Figure 4.1.12 Correct illustration

4.1.13 Words, images or trademarks shall be placed separately, and placed in the blank space, as shown in Figures 4.1.13 (a) and 4.1.13 (b) below.



Figure 4.1.13 (a) Wrong illustration



Figure 4.1.13 (b) Correct illustration

4.2 Design principles of ampoule label

4.2.1 Text content

It shall at least include generic name, strength, administration method, batch number or period of validity.

4.2.2 Text direction

As the ampoule is small, the internal label shall choose a direction in which the words can be read completely without rotating (or moving) the label. If the ampoule is too small to print horizontally, it shall be printed longitudinally, as shown in Figures 4.2.2(a) and 4.2.2 (b) below.



Figure 4.2.2 (a) Wrong illustration



Figure 4.2.2 (b) Correct illustration

4.2.3 Forms of label

Glass ampoules are usually printed directly (internal labels of other glass packaged injections are also applicable). It shall pay attention to the risk of words loss during clinical preparation and disinfection. Use paper label where possible. If directly printed labels or transparent plastic labels must be used, significant information shall be highlighted by the font color, thus trying to avoid seeing the reverse overlapped information, as shown in Figures 4.2.3 (a) and 4.2.3 (b) below.

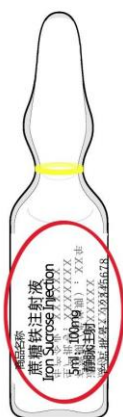


Figure 4.2.3 (a) Wrong illustration



Figure 4.2.3 (b) Correct illustration

4.2.4 Plastic ampoule

In using self-adhesive labels, it shall be ensured that the labels will not detach, and pay attention to the migration of label adhesives to the drug liquid, as shown in Figures 4.2.4 (a) and 4.2.4 (b) below.

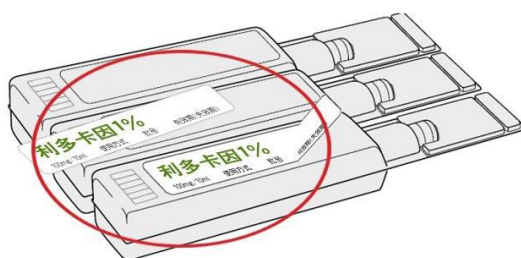


Figure 4.2.4 (a) Wrong illustration

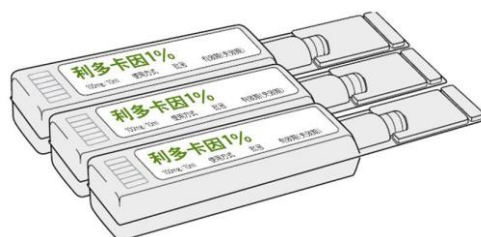


Figure 4.2.4 (b) Correct illustration

4.3 Design principles of injection bottle label

4.3.1 Important information on the bottle

The internal label on the glass bottle shall highlight major information. The font size of key information shall not be less than 12 (small 4). The Song body, regular script and bold type can be used. English and pinyin can be written in upper and lower case, and bold. Do not use dense text, and leave appropriate space between words, letters and lines, thus avoiding squeezing the text together, as shown in Figures 4.3.1 (a) and 4.3.1(b) below.

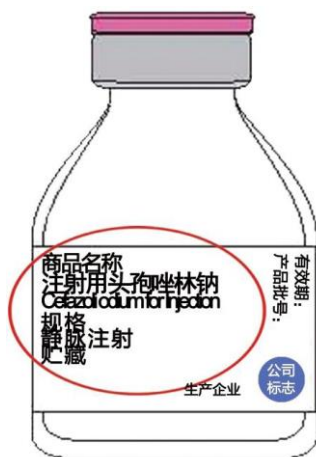


Figure 4.3.1 (a) Wrong illustration



Figure 4.3.1 (b) Correct illustration

4.3.2 Text direction

Same as the recommendations mentioned in 4.2.1. If the width of the bottle is less than the height of the label, the text direction shall be longitudinal, as shown in Figures 4.3.2 (a) and 4.3.2 (b) below.



Figure 4.3.2 (a) Wrong illustration

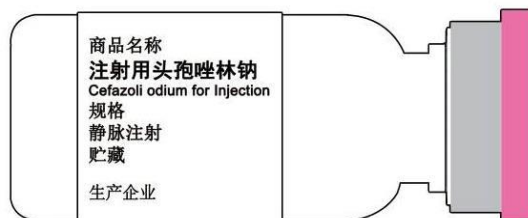


Figure 4.3.2 (b) Correct illustration

4.3.3 Tone matching

The design of the internal label shall match the design of the external label. When coloring the bottle cap, a uniform color shall be used on both internal and external labels, as shown in Figures 4.3.3 (a) and 4.3.3 (b) below.



Figure 4.3.3 (a) Wrong illustration

Figure 4.3.3 (b) Correct illustration

4.3.4 Multi-dose vial

Highlight the storage time or requirements after opening the drug, and reserve a place for recording the opening date, as shown in Figures 4.3.4 (a) and 4.3.4 (b) below.



Figure 4.3.4 (a) Wrong illustration



Figure 4.3.4 (b) Correct illustration

4.4 Design principles of prefilled syringe label

Text content: it shall at least include the generic name, strength, administration method, batch number or period of validity.

Text direction: It is recommended that the direction of the label text is along the longitudinal direction of the syringe, so as to ensure that a blank area can be left to observe the contents. Important information is highlighted through font color, and the color in which the text can show is avoided. Volume scale markings shall be visible, and not be covered by labels.

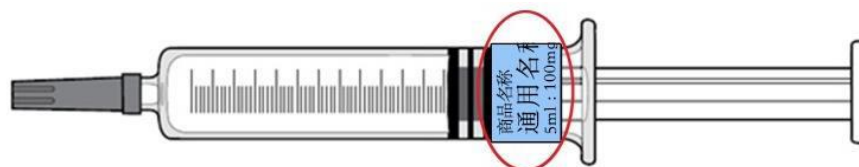


Figure 4.4 (a) Wrong illustration

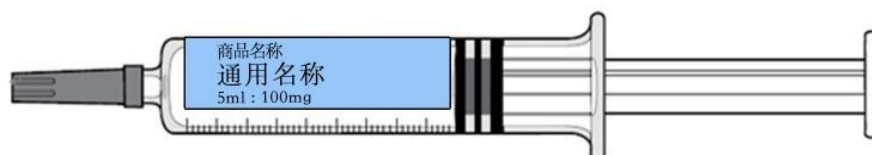


Figure 4.4 (b) Correct illustration

4.5 Design principles of infusion bag label

4.5.1 Principle of text

As to the information printed directly on the infusion bag, dark fonts are recommended. As to similar packaging of different drugs, it is recommended to use different colors to

distinguish them. Important information that needs to be emphasized can be highlighted by different colors. The text direction shall be subject to the direction in use, as shown in Figures 4.5.1 (a) and 4.5.1 (b) below.



Figure 4.5.1 (a) Wrong illustration

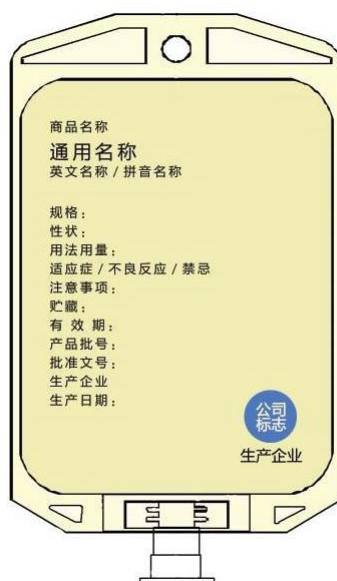


Figure 4.5.1 (b) Correct illustration

4.5.2 Printed text

The font chosen shall ensure that the space between the characters can still be recognized even if these characters are erased, as shown in Figures 4.5.2 (a) and 4.5.2 (b) below.



Figure 4.5.2 (a) Wrong illustration

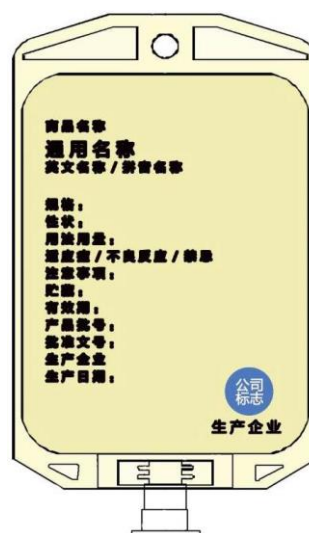


Figure 4.5.2 (b) Correct illustration

4.5.3 Other requirements

Try to use unsmooth materials to improve identification and avoid reflection.

Appendix 1

Assessment of the label design*

1. User test

Label design shall consider potential users to the greatest extent. If the user is a patient, the needs and identification capabilities of the elderly shall be considered, especially the special identification capabilities of the visually impaired. If the user is a healthcare professional, consideration shall be given to his/her demand in the process of distribution, preparation and administration.

Label design companies and users shall develop appropriate evaluation methods to evaluate whether the label caters to the demand of the users for drug packaging labels and their requirements for identification capability.

Objective: some core drug packaging tests are quite important to the safe use of drugs. The purpose of these tests is to assess how users get the information they need from the package, and how to understand it. These tests shall be able to highlight any bad results and detect the best combination of different design elements.

2. Method

At least 20 users are tested, including patients, as appropriate. The test varieties shall include some other injections, and other doses and formulations of the same drug. Ask the users to prepare medicines in the syringe or in the infusion bag according to the information provided by the manufacturer. The results would be different for different drugs. The test shall be completed by the manufacturer. Designers shall also be involved.

3. Participants

The first 10 people for user test shall choose the users who are most likely to encounter difficulties. These users shall include users with lower visual ability, or lower cognitive ability and dexterity. If they are confused about packaging, attention shall be paid to how they handle this difficulty. If the users do not understand the problem, do not give them an answer directly, but ask them how they understand it instead.

* See references 2 and 5 for details.

4. Procedure

One user is tested at a time, for at least half an hour each. They may be requested to use more than one drug packages, but there shall be no more than 15 questions in each part. Don't ask two questions about the same information.

Let users read the information on the packaging label according to their daily habits:

1. Observe and write down what they have done.
2. Ask the users to write down what they have done in their own language.
3. Ask questions that may expand information.
4. Ask questions about the identification of special design elements on the package.
5. Check whether some certain special information on the package may be obtained rapidly and easily.
6. Check whether the information on the package is easy to understand and informative.

7. Ask the users to select a piece of information and explain it in their own languages. It will reveal how well they understand this information. If physical processes are involved, such as mixing with other substances, the users shall be requested to actually operate and complete the steps required on the package.

Appendix 2

References

1. Guideline on the readability of the labeling and package leaflet of medicinal products for human use, European Commission
2. Guidance for Industry - Safety considerations for container labels and carton labeling design to minimize medication errors, USA
3. Act on securing quality, efficacy and safety of pharmaceuticals, medical Devices, etc., Japan
4. National standard for user-applied labeling of injectable medicines, fluids and lines, Australia
5. A guide to labelling and packaging of injectable medicines, National Patient Safety Agency, UK