الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The Guideline for Naming and Graphic Design of Packaging for Herbal and Health Products

Version 1.0

Date of issue	07 November 2021
Date of implementation	07 May 2022

The Guideline for Naming and Graphic Design of Packaging for Herbal and Health Products

Version 1.0

Saudi Food & Drug Authority

Drug Sector

For Inquiries *Sdr.drug@sfda.gov.sa*

For Comments *Drug.Comments@sfda.gov.sa*

Please visit SFDA's website at
https://www.sfda.gov.sa/en/regulations?tags=2

for the latest update

Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document Control

Version	Author	Date	Comments
Draft	Executive Directorate of Regulatory Affairs	15 August 2021	Draft
1.0	Executive Directorate of Regulatory Affairs	07 November 2021	Final

Table of Content

ACRONYMS & GLOSSARY

SFDA	Saudi Food and Drug Authority
AHN	Approved Herbal Name
AHS	Approved Herbal Substance name
AIN	Approved Ingredient Name
AFN	Approved Food Name
PIL	Patient Information Leaflet
GCC	Gulf Cooperation Council
BP	British Pharmacopoeia
EP	European Pharmacopoeia
USP	United State Pharmacopeia

I. Introduction

1.1 Objective

The Drug Sector in Saudi Food & Drug Authority (SFDA) has developed this document to provide guideline for companies on the factors that need to be considered when choosing herbal or health products name and provide packaging design recommendations.

1.2 Background

The name of the herbal and health products" may be either a proposed name not liable to confusion with the common name; also it might be a common or scientific name accompanied by a trade mark or the name of the marketing authorization holder". This guideline is directed to applicant who are submitting a proposed name for herbal and health products, or submitting applications for name variation. In addition, it will help the applicant during the process of herbal and health products naming and give some recommendation on packaging design.

The packaging graphic design in this guideline are ideal designs and intended for solid oral dosage forms, which are the most common type of primary packaging, while the secondary packaging used on the container label. The design considerations and principles outlined also can be applied to other products dosage forms.

II. Scope

This guideline is applicable to SFDA registered or under-registration herbal and health products, which intended for human use in Saudi Arabia.

III. Related Guidelines

This document should be read in conjunction with the following drug sector documents:

- Data Requirements for Herbal & Health Products Submission
- Guideline for Presenting PIL and Labeling Information of Herbal and Health Products
- The GCC Guidelines for Variation Requirement.

IV. Assessing the Suitability of Herbal and Health Products proposed Names.

For herbal ingredients, there are different categories of approved names:

- **Approved Herbal Name (AHN)** refers to a species name expressed as its Latin binomial, for example, *'Hypericum perforatum'* and includes fungi, algae and yeasts. AHNs used in conjunction with information on the plant part and preparation to create a complete name such as *'Vaccinium macrocarpon fruit powder'*. This approach is used for both active ingredients and excipients.
- **Approved Herbal Substance name (AHS)** refers to a single herbal substance that is defined by a pharmacopoeial monograph, for example, 'St John's Wort herb dry'.
- **Approved Ingredient Name (AIN)** refers to an ingredient derived from a plant that is highly refined but is not chemically pure. AINs will be described by a default standard (an individual or specific monograph in the BP, EP or USP).
- **Approved Food Name (AFN)** refers to a food name, for example, 'blueberry'. Such names can only be used to identify excipients.

The applicant should examine and include information in his/her application using the following criteria:

- The trade name should not be derived from or related to the treatment or protection of a medical condition (whether in Arabic or English), Except for trade names compatible with the claim accepted by the SFDA.
- The trade name should not include misleading claims such as overstatement of product efficacy for marketing purposes, except for the terms stated below or alike:
    - **Fast acting, Express** (including derivatives such as Xpress) and any other terms indicating a ‘quick’ or ‘fast’ onset of action should only be used where this claim is supported by data and is relevant to the indication(s) for which the product is being marketed (e.g., onset of action in < 30 minutes from oral administration);

- **Once-a-day** should only be used where a unit dose is taken or administered once in a day. Half-a-tablet twice a day, with the justification that the total dose per day is equivalent to one tablet is not acceptable. Once-a day may be used where one or more tablets are taken or administered once a day;
- **Plus, Extra** (including derivatives such as Xtra) should only be used where the product contains an additional active ingredient which confers a synergistic or additional therapeutic action or benefit;
- **Advance** should only be used when it can be demonstrated that enhancement has been achieved with the new product compared with the existing product. This may be an enhancement in a therapeutic action or enhancement resulting from a formulation change. The addition of increased amounts of the active ingredient and/or excipient(s) without evidence of enhanced therapeutic benefit is not acceptable justification; similarly, minor changes in formulation that do not provide recognizable benefits over the existing product do not constitute enhancement;
- **Maximum strength** should only be used where there are different strengths of products containing the same ingredient and the strength is the maximum available;
- **Flavours** have to be identified such as, (e.g. the term 'strawberry' in a name is acceptable if there is fruit or natural extract contained in the product; if it is produced as an artificial flavouring. Also, it will have to be listed as 'strawberry flavour' in the product name).
- **Triple action:** It should only be use if the product clearly has three different actions. Some products might contain a single substance with three different actions or three ingredients with different modes of action. If the claim has a qualified action, (e.g., 'Triple action pain relief'), the three different actions must be relevant to the pain relief;

- No terms should be added to the trade name unless it reflects the product nature, for example: essential, complete, extract, standardized.
- No phrases should be added to the trade name unless it is scientifically proved, for example: sugar free, salt free, organic, healthy and non-harmful.

- The trade name shall not confused with the generic or trade name of other pharmaceutical, herbal or health products registered or listed in the SFDA or on other international regulatory authorities.
- If the product includes more than one active ingredients, the trade name should include all active ingredients and not just one of them or the company can suggest a different trade name.
- If the product contains single active ingredient the active ingredient name may be used as a trade name, subject to an addition either company full name or abbreviation.
- Obtaining a trademark for the proposed name is not considered as a justification for accepting the proposed name

V. The Graphic Design of product Packaging

1. General criteria

- The outer package, product label and PIL shall not include any images or figures that are:
    - Violating Islamic laws, traditions and customs of society.
    - Disgracing general modesty.
    - Showing an advertising or promotional nature i.e., images or figures not related to the approved properties of the herbal or health product
    - Referring to a herb, plant or active ingredient that does not actually exist in the herbal or health product.
    - Referring to the protection from a specific medical condition.
    - Affecting the clarity of information printed on the outer package.
- The outer package, product label and PIL shall not include any logos or phrases that are:
    - Violating Islamic laws, traditions, or customs of society.
    - Disgracing general modesty. – Referring to the protection from a specific medical condition.
    - Containing information misleading the customer by overstatement the efficacy of herbal product, for example: effective, guaranteed, magical, etc.
    - Incomprehensible or cannot be verified by public, for example: clinically proven.
    - Referring to a herb, plant or active ingredient that does not actually exist in the herbal or health product.
    - Referring to the therapeutic effect of the herbal or health product.
    - Referring to registration and marketing in other countries, for example: " FDA approval & No.1 in market X "
- Primary or secondary package shall not lead to confusion with another herbal or health or pharmaceutical product (in color or design).

2. Design Recommendations for Primary Packaging (Blister Packs)

2.1 Product name and strength

The name and strength of the product should appear over each blister pocket. Batch number and expiry date should be applied on each blister pocket as well. If it is not possible, the batch number and expiry date should be added at the end of each blister strip, preferably at both ends.

√

X

In certain cases (such as: small blister) it may not be possible to design the packaging to accommodate all critical information on each blister cell. In such circumstances, important information can appear multiple times across the back of the blister or the important information should be displayed in such a manner that it is not destroyed or eliminated when dosage units are removed.

2.2 Blister strips foil

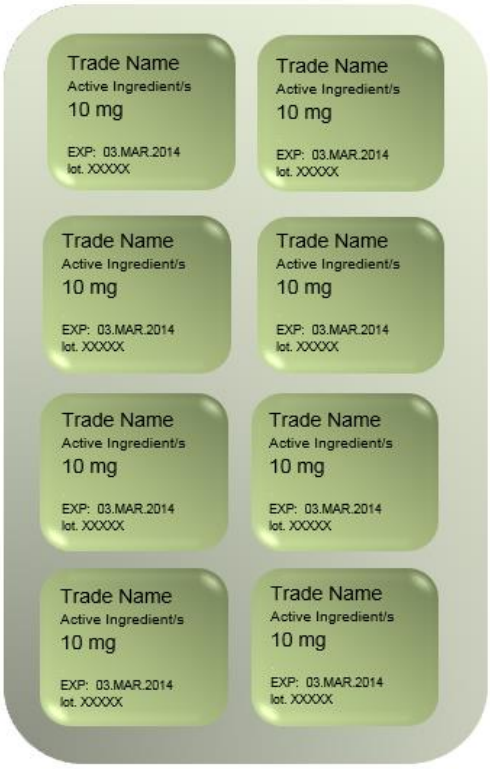
Use non-reflective, matte material. Reflective foil can cause glare by light reflecting on the foil which reduces the legibility of any information.

√

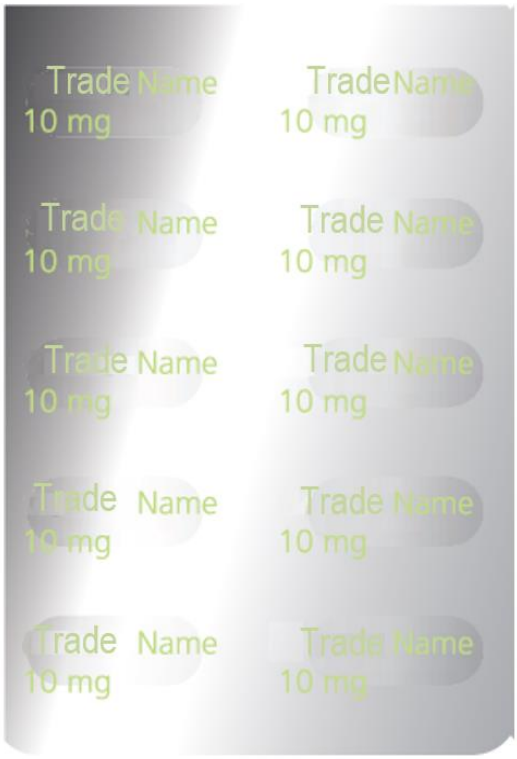
X

2.3 Type and background color

The color type should contrast strongly with the color of background. Legibility can be reduced by the combined effect of the foil material, a small font size and a background color that does not sufficiently contrast with the font color.



√



X

2.4 Type size and font color

Use bold or semi-bold type and avoid lightweight type. Maximize the font size to a size that is appropriate for the size of the container. Small type size and a lightweight font on a foil background impairs legibility.

√

X

2.5 Match the styles of primary and secondary packaging

A product's primary and secondary packaging should have an identical or linked visual style.

3. Design Recommendations for Secondary Packaging

Secondary packaging represent the outer package of a product. It serves to hold the primary packaging and is not in contact with the product. The combined impact of all design elements, such as color and typography, should be evaluated.

3.1 Typing important information in the same field of vision on at least three non-opposing faces (one side for Arabic & one side for English)

A standard packaging container has six faces on which information can be displayed. Critical information should be in the same field of vision on at least 3 of the non-opposing faces of the secondary packaging. This means putting the information on the top or bottom face, one of the sides, and one on the ends. If it is feasible, display a product description (the brand name, generic name and dosage strength of the product) on more than three non-opposing faces.

All required information should appear on the outer package. This includes, but is not limited to, the following: Trade name, active and inactive ingredients, dosage form, therapeutic indication, dose information, side effects, caution, storage condition, manufacturing, and marketing authorization holder information. In case of limited space, the submission of a patient information leaflet (PIL) is required.

3.2 Orient text in the same direction

The text on every face, excluding the ends, should be oriented in the same direction in a way to simplify the reading of the product's information when it is placed at any side on the shelf.

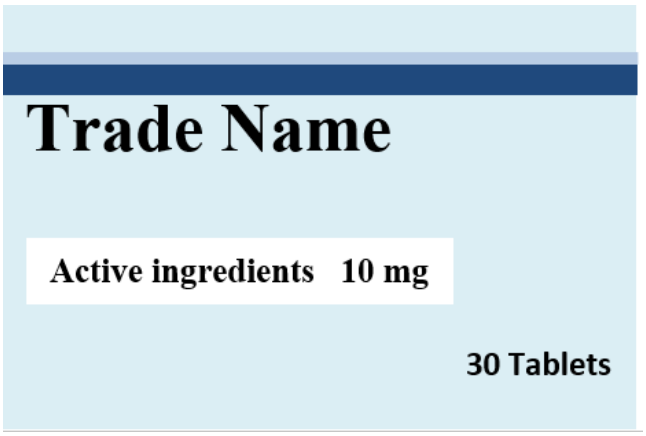
3.3 Use blank space to emphasize important information

Leave sufficient space around important information, so that it can be easily seen. If the secondary packaging is cluttered with text and images, it can be difficult to recognize important information and identify the correct packaging.

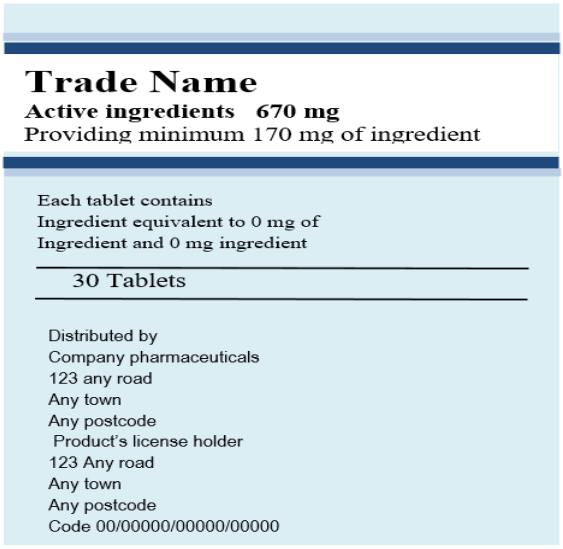
Important information like

1. Brand and active ingredients of the product.
2. Strength and dosage form.
3. Total volume or concentration of bottle, plus the “per mL” amount (e.g., 10 mg/2 mL and 5 mg/mL).
4. Warning statements in some cases.

The net quantity number should be shifted away from the strength number



√



X

3.4 Ensure the active ingredients names are clear

The active ingredients names should be at least 50% the size of the brand name.

√

X

3.5 Do not add trailing zeros to numbers

Do not add trailing zeros to numbers; always use whole numbers.

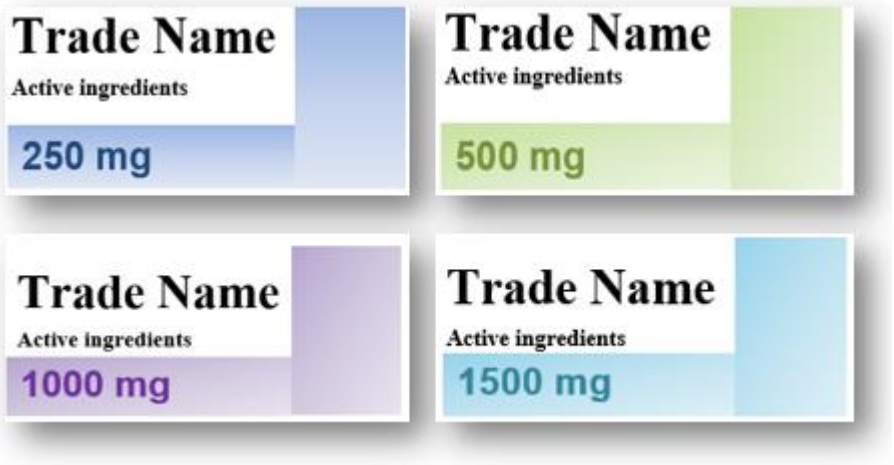
√

X

3.6 Use the same unit for all different strengths from the same Herbal and Health Products

In addition, different strengths of the same product should be expressed in the same way, such as 250 mg, 500 mg, 750 mg. (e.g., 500 mg, not 0.5 g)

√



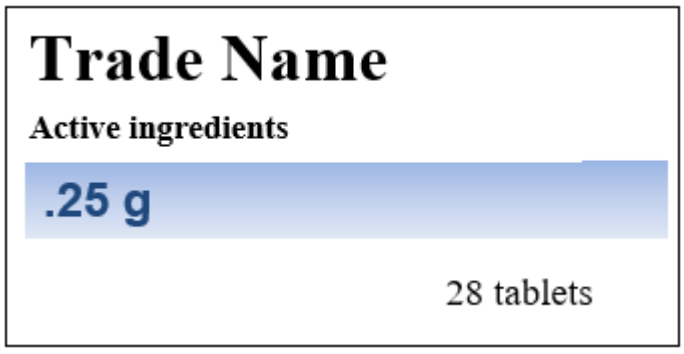
X

3.7 Use of leading zero

For an amount less than one, always use a leading zero to avoid any confusion in the concentration (for example use 0.25 not .25).

√

X



3.8 Information size

Use the largest possible size font for that package so that the information is readable and clear.

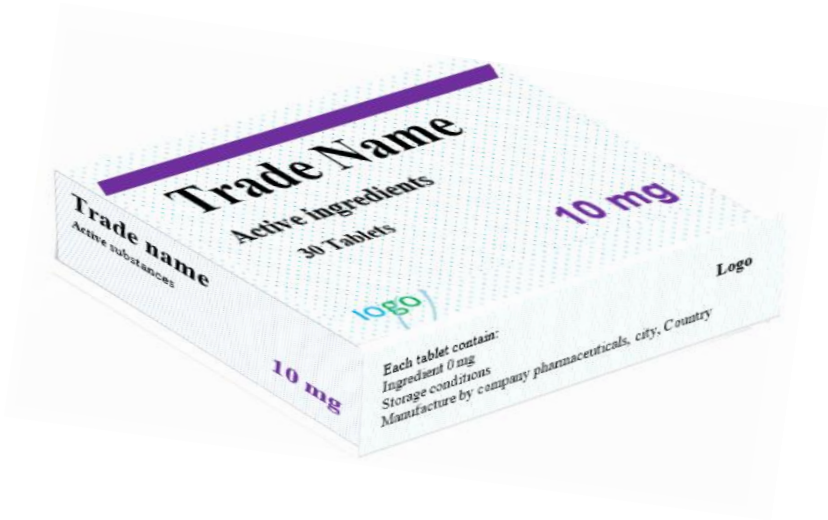
√

X

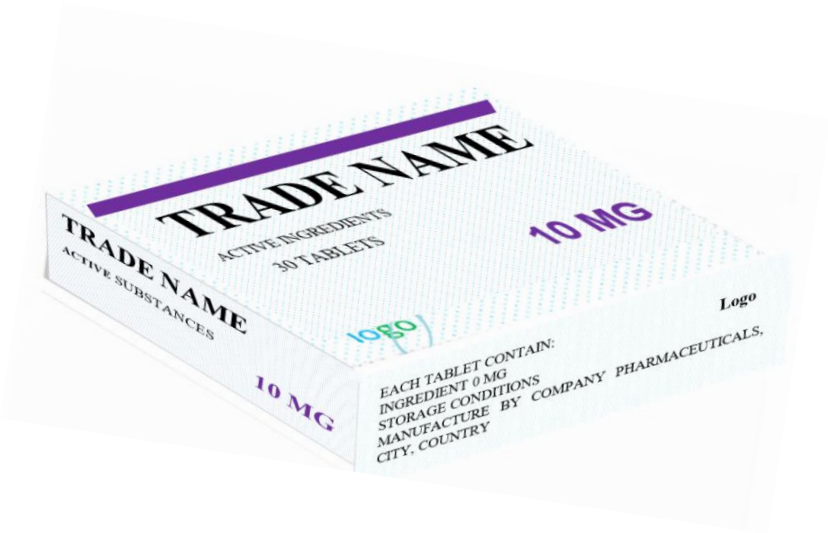
3.9 Use upper and lower case lettering

Entire sentences written in upper case letters or italic type are hard to read. Use the lower case except for the first letter of the generic names, brand names, sentences or paragraphs. Italic types should not be used where there is an alternative method of emphasis such as bold type. Mixed case lettering should always be used for sentences.

√



X



3.10 Use sans serif typefaces

Use a sans serif typeface, such as Arial, Helvetica or Universe. The choice of typeface influences legibility. Ornate typefaces are difficult to read. They are not suitable for medication packaging, where clarity, accuracy and legibility must be paramount.

√

X

3.11 Use bold or semi-bold type

Lightweight type reduces legibility. Patients, especially those who are partially sighted, find bolder type easier to read. Use bold or semi-bold type and avoid lightweight type for all important information.

√

X

3.12 Condensed typefaces

Do not use condensed typefaces when possible. Condensed typefaces reduce legibility. Condensed typefaces may be necessary on blister packs on each pocket to fit all the required information, but should not be used when there is adequate space for normal typeface.

√

X

3.13 Do not compress lines of text close together or adjust the space between letters

Reducing the space between lines, known as the leading, and between letters, known as the kerning, affects legibility. Do not compress lines of text close together. Leave enough space between lines and letters.

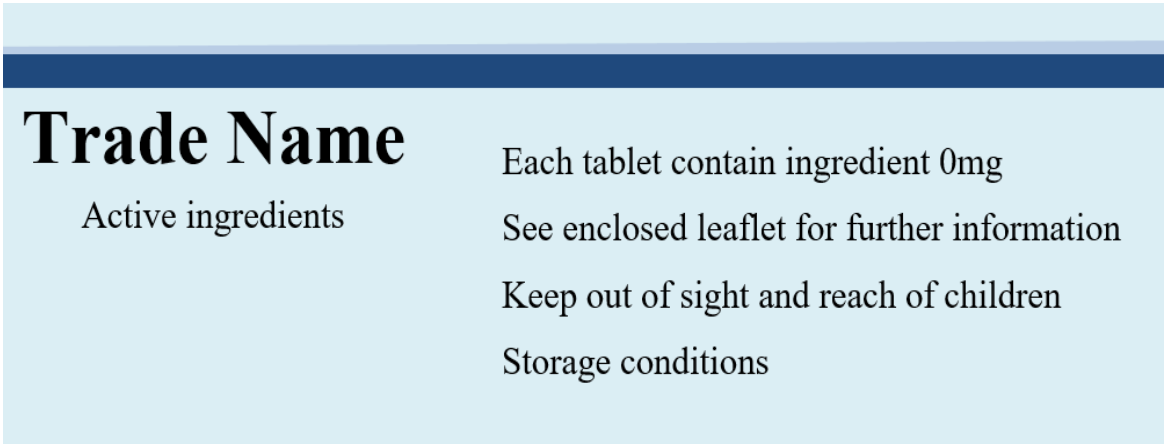
√

X

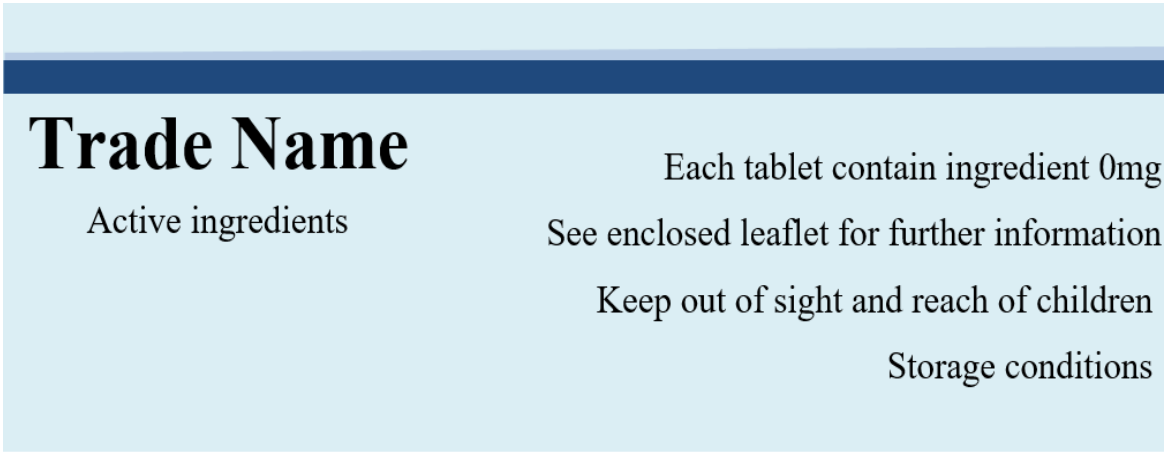
3.14 Align text to the left for English & to the right for Arabic

An irregular amount of space between words affects legibility. Align text to the left hand margin and do not center justify text. Align all English text including the important information to left side (left justified) and for the Arabic version, it should be aligned to the right side (right justified).

√



X



3.15 Images and logos

Images or logos should not be near the text, as it could interfere with reading it, or it may look like it is part of the text. Text should remain unbroken. Fitting text around or over images or logos breaks the flow of information.

√

X

3.16 Create a strong contrast between type and background color

There should be a strong color contrast between the type and background colors. Dark colored type (e.g. black, dark blue) should be on a light colored background (e.g. white, pale pink, pale yellow). The reverse is true as well. Insufficient contrast between the background and the type reduces legibility.

√

X