Impact of Pre-registration Evaluation process at Regulatory Authority on Improving Patient Safety Culture at Hospital

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Improving patient safety culture in hospital start before the drug added to hospital formulary and be in Pharmacy. Many articles were written and talking about the errors related to: Lack of patient information, communication, drug storage , delivery , environmental factors , staff competency , work pressure, and patient education , but what about the role of drug packaging and labeling in medication errors and what the necessity to review of drug name before its registered. Many patients and health care professionals rely on product packaging and labeling information; if this information was incorrect or barely reading definitely this will lead to Mediation Errors (ME) and make the patient safety culture at the hospital more badly. Poor packaging and labeling contribute to medication errors .

Errors related to name confusion due to look-alike and sound-alike (LA/SA) are common. In the United States, up to 25% of medication errors related to name confusion and 33% related to labeling and packaging, it causes thousands of deaths and millions of dollars in cost each year.[1]

How Saudi FDA (SFDA) minimizing and preventing error? What is the pre and post marketing strategy ?

When company submits a file for product registration, it goes through several processes from administrative information review to quality, non-clinical and clinical review, manufacture inspection and many others. One of the important roles for SFDA is minimizing medication errors (ME) in pre-marketing stage by reviewing drug name, labeling, packaging and, product design to identify and revise information that may contribute to medication errors.

As post marketing SFDA monitors and evaluates medication errors report, SFDA may require a manufacturer to revise the labels, labeling, packaging, product design or proprietary name to prevent medication errors. SFDA may also issue communications alerting the public and health care professional about a medication error safety issue.

Role of company in improving patient safety culture at hospital

Before the company submits the name of the product and artwork, they need to go through SFDA guidance published in our website. There is several guidance has published by SFDA: submission, variation, SPC, PIL, and Labeling Information. I will focus here briefly on two guides\ guidelines, which help to improve patient safety culture at hospitals and minimizing error by choosing the right name for the product and proper design to prevent LA/SA in names and packaging. LA/SA consider one of biggest factors may lead to ME especially if it combined with other factors like human factors or environmental factor such as: lack of enough light in pharmacy, stress, overload, and shortage of staff.

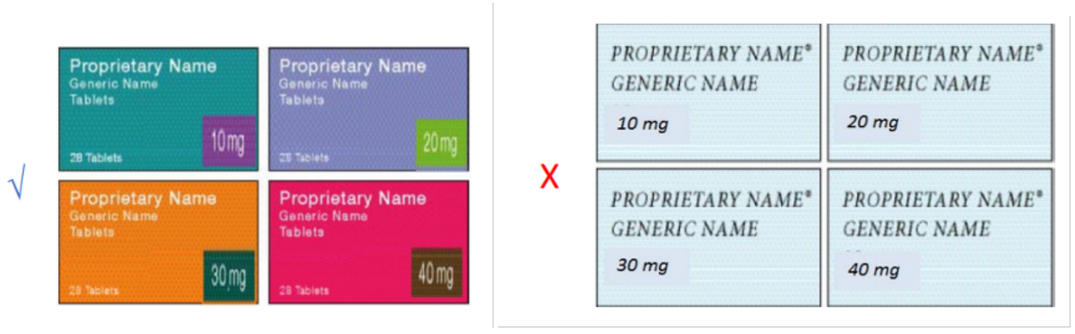
First, Guidance for Graphic Design of Medication Packaging[2]

This guidance is complementary to the GCC Guidance for Presenting the SPC (Summary of Product Characteristics), PIL (Patient Information leaflet), and Labeling Information with more illustrations and details to minimize medication errors. This guidance is applies to SFDA registered or under-registration medicinal products intended for human use in Saudi Arabia.

It contains design recommendations for primary packaging for such as (Blister packs). Design recommendations for secondary packaging. Critical information needs to be added to each outer and inner package.

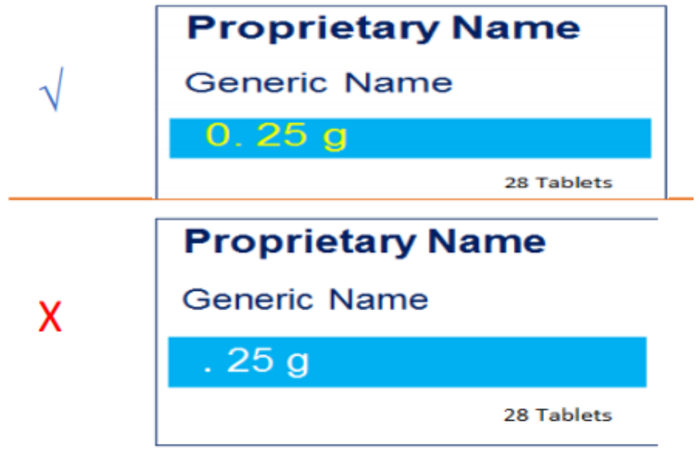
Some points we emphasize the company to follow it:

1- How Differentiate between strengths of the same pharmaceutical product

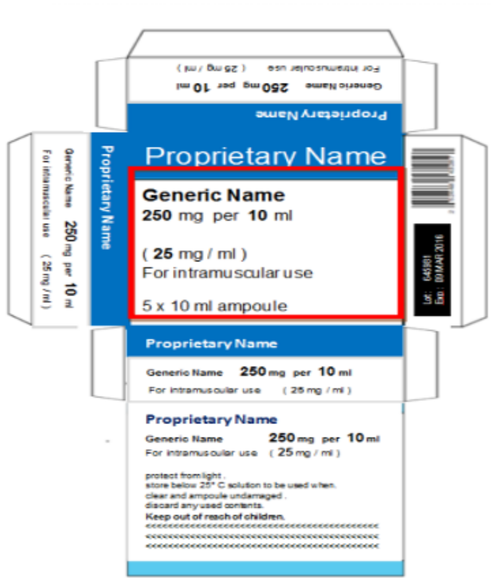


2-The importance of leading zero

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).



3- How to design the Labeling and Packaging of Injectable Pharmaceutical products
Create a front panel that features only the critical information. Subsequent (noncritical) information can be shown on the back panel. Minimum information consists of the trade name, generic drug name, concentration of the pharmaceutical product, total quantity in the container (large font), and concentration per unit volume (smaller font). Administration route(s) and significant Warnings



For more details and information about the Guidance for Graphic Design of Medication Packaging, please check this link:
GuidanceGraphicDesignMedicationPacka/02-2020/https://www.sfda.gov.sa/sites/default/files pdf.gingV3

Second, Guidance for Naming of Medicinal Products[3]
This guidance will help companies determine the factors that need to be considered when selecting an invented medicinal product name to reduce medication errors.

General Principle in name selection:
The applicant should use the principles below to aid in the development of the invented name:

1. The invented name should not be liable to confusion with the generic or the invented name of any other medicinal product.
2. The invented name should not be liable to confusion with other products 'name, which were withdrawn from the market.
3. The invented name should not be misleading with respect to promotional issues and make claims relevant to:
   - Some names may indicate to overstatement of product efficacy, minimization of risk, broadening of product indication, unsubstantiated superiority claims, or being overly fanciful.
4. The invented name of a medicinal product should not incorporate product-specific attributes
5. If the medicinal product contains more than one active ingredient, the invented name should suggest all the ingredients, not just some of them, or it may be considered misleading .
6. If the invented name includes the name of an ingredient, which is not contained in the medicinal product, it will be considered misleading.
7. Invented name should not incorporate the manufacturer's full name or part of the name across multiple products, as this may increase the similarity of invented names by the same company
For more details and information about the Guidance for Naming of Medicinal Products, please check this link:
https://www.sfda.gov.sa/sites/default/files/2020-02/NamingGuidanceV1.pdf

Recommendations to Health care professional to reduce ME and improve patient safety culture :
In case of any similarity between two products we recommend :
1- Separate the medications from each other on the shelves to avoid future errors
2- Add auxiliary labels with different colors on the outer package of the products to minimize medication errors.

We encourage all healthcare professionals to report ME, especially ME related to medication name or packaging issues to SFDA.

SFDA will work together with companies and hospitals to make any required changes to minimize and prevent the error from happening again .

Health care professional can report to us through
Saudi Vigilance System: https://ade.sfda.gov.sa
Call center: 19999
Email: Med.drug@sfda.gov.sa
Npc.drug@sfda.gov.sa

References:
1. Reducing Medication Errors through Naming, Labeling, and Packaging. Berman, Journal of Medical Systems, Vol. 28 No. 1, February 2004[1]
2. GuidanceGraphicDesignMedicationPackagingV3
3. Guidance for Naming of Medicinal Products[3]

[1]Adrienne Berman. Reducing medication errors through naming, labeling, and packaging. J Med Syst . 2004 Feb;28(1):9-29. doi: 10.1023/b:joms.0000021518.60670.10.

[2]SFDA. Guidance for Graphic Design of Medication Packaging. Saudi Food & Drug Authority Drug Sector. Version 3.0.28 January 2019.
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