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Drug Formulation: Statement on Medication Size, Shape & Colour (1995)

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Drug Formulation: Statement on Medication Size, Shape & Colour

THE CSHP SUPPORTS THE PRINCIPLE OF STANDARDIZED SIZE, SHAPE AND COLOUR OF BIOEQUIVALENT ORAL SOLID DOSAGE FORM MEDICATIONS, WITH UNIQUE PRODUCT IDENTIFICATION MARKINGS FOR EACH MANUFACTURER SHOULD BE VISIBLY IMPRINTED.

BACKGROUND

The legality of using the same size, shape and colour for bioequivalent products is being challenged. CSHP is concerned with the potential ramifications should this "Safety Check" for the patient and health care practitioners be ruled illegal.

Bioequivalent products from different manufacturers usually do have different markings. This is essential for absolute determination of the source of a product should the need arise. However, forcing bioequivalent products to appear different in their size, shape and colour is not in the best interest of public health and safety. Changes to the appearance of a patient's prescription alert the patient and their caregivers to the change. If the change was not expected, it provides a basis to question the change. If the size, shape or colour were constantly changing as a result of changing manufacturers, patients would not be sensitive to the changes and the value of this alert would be lost. The following provide some examples of how standardized size, shape and colour protect public health and safety.

1. **Physician error** - The dose may have been changed by the physician by accident. The change in colour alerts the patient to ask, "Why?". If it was unintended the physician can correct the dosage and prevent the patient from having their already titrated dosage inappropriately adjusted. It would likewise prevent the follow-up visits to re-titrate the dosage and any unfortunate sequalae of receiving a subtherapeutic or excessive dose.

2. **Pharmacist error** - The wrong dose or medication may be dispensed in error. The change in colour alerts the patient to ask, "Why?". If it was unintended the pharmacist can dispense the correct dosage and prevent the patient from having their already titrated therapy inappropriately changed. It would likewise prevent the follow-up visits to re-titrate the dosage and any unfortunate sequalae of receiving a sub-therapeutic or excessive dose or the wrong medication.

3. **Communication error** - The change in dose or medication intended by the physician may be dispensed correctly, but the patient may not have had the change explained with sufficient clarity. The change in colour alerts the patient to ask, "Why?". If it was intended the pharmacist can provide assurance of the appropriateness of the change and reinforce the reasons and expectations of the change. It would enhance the patient's understanding of their therapy and promote improved compliance with the associated potential improvements in effectiveness.

4. **Administration error** - Often a nurse or family member selects medication to be administered at a particular time. In these cases the patient rarely has access to the originally labeled container. The change in colour alerts the patient to ask, "Why?". If it was unintended the nurse or family member can re-select the correct medications and prevent the patient from having their already titrated therapy inappropriately changed. It would likewise prevent the follow-up visits to re-titrate the dosage and any unfortunate sequalae of receiving a sub-therapeutic or excessive dose of the wrong medication.