

“BUILDING OF DATABASE OF BRANDS OF PHARMACEUTICAL FORMULATIONS AND STUDY THE CASES OF MISBRANDING AND SALA DRUGS RESPONSIBLE FOR MEDICATION ERRORS IN MAHARASHTRA AND GUJARAT STATE”

INTRODUCTION & BACKGROUND:

Introduction:

In this era of consumer awareness, the field of health care is still an area of concern. The common person in India who purchases medication at the chemist is inadequately informed about the contents of the medication. Also as detailed in draft National Pharmaceuticals Policy, 2006 (Part-A), the present system of brand approvals in the country appears inappropriate for the pharmaceutical sector. There are two kinds of problems that are commonly encountered. First, even a casual look at the list of brands existing in the Indian pharmaceutical sector reveals that a number of products have either the same brand name or names which are very similar both phonetically and written. Second, there are a number of recorded instances where the composition of a particular brand has been changed without any change in the brand name - a phenomenon termed as 'misbranding'. Both these have the potential to cause immense harm through misprescription and/or wrong dispensing. Therefore, MSPC's Drug Information Centre undertook the project in collaboration with CDSCO, MOHFW, GOI and WHO Country Office for India and created a detection tool to study the cases of Misbranding and SALA drugs responsible for Medication Errors in Maharashtra and Gujarat State”

Background:

The national co-coordinating council for medication error reporting & prevention defines a medication error as, "Any preventable event that may cause or lead to inappropriate medication use or patient harm". A pharmacist is a primary healthcare provider, plays a critical role in assuring the appropriate use of medications and reducing medication errors in the healthcare system. Misbranding is one major factor responsible for medication errors which adversely affect patient's well being and need to be strictly avoided. Reducing medication errors is a process of continuous quality improvement.

Misbranding is the unethical trade practices the Indian pharmaceutical industry has been indulging in for some time now and there has been hardly any action against such practices from the regulatory authorities in our country. Misbranding is a dubious way of exploiting a well-established brand name for a totally different product. The temptation is because of the massive build up of goodwill a brand attains over a long period of time. And this tendency can only grow to dangerous levels considering the intense competition existing in the formulation sector.

Misbranding can occur because of same name (identical), similar-looking (orthographic), and similar-sounding (phonological) names of brands and also because the composition of a particular brand has been changed without any change in the brand name. Also to be noted are the following practices: (a) the continued use of brand names of banned drugs (example Baralgan to Baralgan Plus); (b) brand drugs in price control: if Becosule is put under price control, changing it by adding a small ingredient and calling it Becosule Plus; and (c) the use of brand names across sectors.

Other area is Sound-alike or Look-alike (SALA) health products which refer to names of different health products that have orthographic similarities and/or similar phonetics (i.e. similar when written or spoken). These similarities may pose a risk to health by contributing to medical errors in prescribing, documenting, dispensing or administering a product. These medication errors may be more likely to occur because

of contributing factors such as identical doses, dosage forms or routes of administration, similar packaging or labeling, incomplete knowledge of drug names, illegible handwriting, verbal order errors and even lack of an appropriate knowledge-base. Some of the brand names may not sound-alike when read out or look-alike when in print, but when hand written or communicated verbally they can cause confusion. Confusion regarding drug names is thought to account for 25% of all medication errors.