Dual branding of drugs by the industry is confusing and should be stopped

By **Stein Lyftingsmo**, a hospital pharmacist from Elverum, Norway, who has a special interest in packaging and medicines information

Before the medicine was withdrawn from the worldwide market in 2004, there were two MSD brands of rofecoxib on the market in Norway: Vioxx and Vioxx AC. The tablets had the same active ingredient, and the same shape, colour and excipients. The brands had different information. Vioxx was for arthritis and chronic pain, and Vioxx AC for acute pain. This difference was apparent both in the patient information and in the drug catalogue.

The situation was and is the same for bisprolol, which Merck markets as Emconcor and as Emconcor CHF. Emconcor is marketed for hypertension and prevention of angina, and Emconcor CHF for coronary heart failure.

Norway has a list of generic medicines that can be substituted. Emconcor and Emconcor CHF are not on this list even though the tablets are identical. But most physicians and pharmacists do not realise or ever think about the difference between Emconcor and Emconcor CHF. We are used to generic competition between companies. But to most people it is unexpected and illogical that a company should appear to compete with itself.

Doctors are confused. I know this because I see their prescriptions. Pharmacists are also confused. And having called the company for information, I discovered that company staff themselves seem to be confused. Most patients are not confused, but only because they do not know about it.

When I looked across the Atlantic I discovered other examples. Bupropion from GlaxoSmithKline is marketed as Zyban for smoking cessation and as Wellbutrin for depression. Fluoxetine from Lilly is the iconic brand Prozac. Lilly also marketed fluoxetine as Sarafem (which has been licensed to another company.). The colours here are not identical. Prozac is green and cream. Sarafem, however, is pink, which may be considered a better colour for a medicine for the treatment of premenstrual tension. Allowing for different strengths, other dual brands are Yentreve and Cymbalta (duloxetine), and Propecia and Proscar (finasteride).

Dual marketing (or brand splitting) increases the risk of double medication. The US Institute for Safe Medication Practices (ISMP) has even reported a case of triple dosage of bupropion: Zyban and Wellbutrin and generic bupropion.

Brand splitting may increase total sale. But each brand will have reduced turnover. Low-turnover packages are not kept in pharmacy stock, and the patient may have to wait hours — even days in rural areas — for his or her treatment. Brand splitting may give simpler and more case-specific information for the different patient groups. But if a patient gets a medicine that is intended for a different patient group, he or she will also get information meant for that other group.

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Brand splitting may reduce people being put off by a particular brand name. If a brand name is strongly linked to a special use of a medicine, this may affect other uses of the same medicine. Prozac is an example of a brand with a very strong position in people's minds, to the extent that some patients will refuse to take it.

There is another substance that is old, but interesting in this connection: thalidomide. Leprosy is the only indication approved by the US Food and Drug Administration — but leprosy is not common in the US. The main uses of thalidomide are off-label for tuberculosis, cancer and AIDS.

Thalidomide's patent ran out long ago, but a company, Celgene, has patented a thalidomide distribution system (as Pharmion has in some European countries.) The information about thalidomide from Celgene does not mention other uses. Information from Medmaster and USP DI (two American organisations delivering information for dispensing from bulk) is more generic and at least mentions other uses.

Another example of mainly off-label use is misoprostol (Cytotec). In Norway, all information in the drug catalogue and patient leaflets is about preventing gastrointestinal ulceration during treatment with non-steroidal anti-inflammatory drugs. But almost all uses of the drug are for gynaecological purposes (abortion, cervical priming, labour induction).

It is possible that if Vioxx had not been withdrawn there could have been more chapters to its story. For example, there are patents and clinical evidence for rofecoxib having an effect in preventing colorectal cancer, in preventing Alzheimer's disease and in the treatment of HIV. MSD chose to use one brand name for chronic pain, and another for acute pain. So it is not difficult to imagine another three brand names here.

Now look at an older substance: atenolol. The FDA has approved three uses for atenolol; the Norwegian medicine authorities, another three. There is good evidence for the use of atenolol for another five indications — altogether 11 different uses for one active substance. Imagine 11 brands, each packaged with information for only one indication.

For patient packs the information in drug catalogues and package inserts usually comes from the manufacturing company. There are several examples of manufacturers claiming copyright on patient information. In the US where most medicines are dispensed from bulk, the PILs mostly comes from companies specialising in providing information.

Different patient groups need different information. How do we solve this dilemma? Do we have one different brand for each indication or information that covers all the different uses? Each solution has its advantages and drawbacks. It is important that a risk analysis is made, since different substances will present different risks.

Is it possible to differentiate information in generic packages? Perhaps there should be two setss of PILs. Maybe there could be separate frames or sections in the PIL for each patient group. Perhaps there are other solutions.

Generally, brand building is the opposite of generic medicine; building double brands certainly is. I believe that the issues around information here are so confusing and obscure that it takes us back to the old days of patent medicines and secret formulae.

I want regulatory restrictions to stop pharmaceutical companies using more than one brand name on a medicine. But if companies are to be allowed to continue to have more than one brand of the same drug, it should be a requirement that the second brand name should be generic, and that information in formularies and package inserts should not differ significantly.

Broad spectrum
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