

Medication Safety Forum



Swiss initiatives for improvement of labelling and packaging of unit doses

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Worldwide, insufficient labelling and packaging is a recurrent and frequent source of medicine-administration error. An initiative by the Swiss Society of Public Health Administration and Hospital Pharmacists has had some success but Europe-wide collaboration is essential to secure a change in practice.

Labelling and medicine administration errors

Traditionally, in Swiss hospitals and nursing homes, the central pharmacy delivers medicines to the wards in patient packs, and every day nurses prepare the medicines regime for individual patients. Observations on wards have shown that labelling of primary packaging of solid medicines meets only minimal regulatory requirements; this means it does not respond to nurses' needs in institutions or to patients' needs at home. It is usually insufficient to allow a double check before dispensing.

Unfortunately, it is well known that lookalike products are worldwide one of the most frequent causes of medicine-administration errors [1]. Since the publication of Leape's article, "Error in medicine" [2], Swiss pharmacists have intensified their efforts to prevent medication errors, often as a first step towards clinical pharmacy. In 2003, 16 years after the EAHP's recommendations to the pharmaceutical industry [3], a general improvement in labelling of primary packaging had still not been achieved. For this reason, there seemed to be a move towards technical ways around the problem, such as ward stock dispensing machines, e.g. Pyxis, and unit-dose dispensing systems, e.g. PillPick. Nevertheless, these solutions are too expensive or not well adapted to our network of numerous but relatively small hospitals and nursing homes.

Adopting a systematic approach, it quickly became evident that overall,

the most economic solution to prevent medicine-administration errors would be to produce correctly packaged and labelled medicines in the first place.

The IDENTITY study

In 2003, an interdisciplinary national market analysis of solid medicine forms potentially handled by nurses was conducted (IDENTITY) [4]. As many as 1,445 different products from 32 companies were included. This study revealed that only 32% of products were packaged in perforated blisters and only 40% had at least the complete name and strength on every single dose (less than 4% had a batch number and expiry date, and none had a bar code). Following the national belief in market forces, the results were ranked by pharmaceutical company. This ranking showed that the percent-

age of well-labelled blisters depended solely on the company's sensitivity to patient safety.

First, a "soft" educational approach was adopted to try to convince pharmaceutical companies to pack solid medicines in perforated blister packs and to completely label every unit dose. A few companies understood the problem and acted, but most did not, arguing manufacturing costs, market size and the competency of Swiss nurses. We then tried to increase the pressure, but neither the initiatives by professional association nor by mass media were successful. Furthermore, unlike the FDA, the Swiss drug authorities feared imposing standards on the pharmaceutical industry [5].

Free market

Finally, the Quality Department of the

Category	Label	Description
good	6	Category 5 + data matrix bar code
	5	Category 4 + batch number and expiry date
medium	4	Name and strength completely and specifically printed on blister for every single dose
	3	Name and strength complete, but not specifically printed on blister for every single dose
poor	2	Name and/or strength incomplete
	1	No inscription at all

Category	Label	Description
good	X	Perforated blister
medium	C	Blister with solid medicines in parallel lines, necessary to cut
	K	Solid medicines in a calendar blister, necessary to cut
poor	P	Very narrow packaged blister with solid medicine forms, necessary to press
	B	Bulk

The quality of labelling and packaging of unit doses should become a high-ranking selection criterion for hospital medicines lists.

labelling of primary packaging of solid medicine forms.

No doubt, a clear commitment from the European drug authorities (EMA, European Pharmacopoeia) would have as strong an impact on the quality of labelling and packaging as the FDA requirements have done since 2004.

Dr Patrik Muff wrote on behalf of the Quality Department of the Swiss Society of Public Health Administration and Hospital Pharmacists (GSASA), www.gsasa.ch

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Swiss Society of Public Health Administration and Hospital Pharmacists (GSASA) decided to maximise market forces: the quality of labelling and packaging of unit doses should become a high-ranking selection criterion for hospital medicines lists.

For that, we established a table, classified by non-proprietary name, comparing the labelling and packaging of every dosing strength of the original product with the generic product of the most important manufacturers. In order to accelerate the evaluation process and to express clearly what hospitals need, we created only six categories for labelling and five for primary packaging quality (Tables 1 and 2).

At present, this table covers nearly 130 chemical entities and is updated at least once every year after the arrival of a wave of new generics. This tool has been placed on the society's internet homepage [6]. It allows a quick overview and helps hospital pharmacists to rapidly eliminate insufficiently labelled solid dosage forms from the selection process.

By regularly communicating our needs over the last five years, we observed a new trend: good quality of labelling and packaging is becoming a marketing strategy for manufacturers. Nevertheless, improvement is slow. One of the most frequent reasons given for the pharmaceutical companies' inactivity is the (small) size of the Swiss market although several European countries have already made known the same needs for many years [3]. This is why international collaboration inside and between professional societies is essential.

One continent – one voice

At the 37th EAHP General Assembly in

June 2007, the delegates decided to officially support the common European interest in fully labelled unit doses including a data matrix barcode on every single dose. Bar coding is essential if bedside scanning is to be introduced. In daily practice, this means that not only should pharmacological, financial and logistical factors be important criteria when selecting a product for the hospital medicines list, but also the quality of labelling and packaging. This can be demonstrated by comparative tables. And, as this last criterion is fundamental for ensuring the correct administration of solid medicines, it should become the most important one, at least until bar coding of unit doses has become the standard.

On a national level, in order to increase the awareness and willingness of manufacturers and drug authorities, comparative market studies can be made in just a few weeks by pharmacists or nurses with the logistical support of a wholesaler. Finally, where no equivalent alternative is available, the company's representatives should be approached whenever possible.

For the future, the Quality Department of the Swiss Society of Public Health Administration and Hospital Pharmacists is preparing a comprehensive medicines safety checklist, based on Appendix 6 of the Council of Europe's report "Creation of a better medication safety culture in Europe: building up safe medication practices" [1].

Regulatory commitment

Recently, the Swiss drug authorities sent the first positive signal: since 2007, the Swiss Pharmacopoeia [7] has recommended choosing "parallel blisters" with complete labelling on each unit dose in order to promote an improvement in the quality of the