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The Traceability of Medicines, Medical Products and Food

Swiss workshop on traceability

At a workshop organised a few months ago by EAN (Switzerland), colleagues from the hospital sector as well as their suppliers of drugs and medical devices, discussed the theme of the traceability of health products. During this interdisciplinary meeting, approximately 30 participants were able to learn about the solutions set up in Switzerland, Europe and the rest of the world to respond to the growing demands in this field.

Industry representatives explained how their production sites enable the identification and traceability of drugs through the use of EAN codes, which are placed on individual doses (blisters and ampoules, for example). This was made possible by the new FDA (1) directives, which aim to reduce errors in the administration of drugs.

Moreover, participants were informed of new European regulations which aim to make the traceability of food obligatory from January 2005, both for production within the European Union and for EU imports (Regulation 178/2002).

Factors of influence in Switzerland and the rest of the world

Just when the FDA was looking into the identification of drugs through the use of bar codes on individual doses, an interdisciplinary study (2) was presented in Switzerland in autumn 2003. This study focused on the possibility of identifying with certainty solid drug doses in the hospital surrounding, in medico-social establishments and in institutions for the handicapped, as well as in home care settings. This study underlines the need for important adaptations in the majority of cases. In fact, the doses of approximately 60% of the primary packaging of solid drugs administered by carers can no longer be identified with certainty before being administered to patients.

On the basis of a cost/benefit study (3), the

FDA retained the obligation of placing "linear (4)" bar codes on individual doses. It results that the choice of a simple technique singularly reduces hospital investment in reading equipment, while fulfilling the objective of reducing administration errors. The annual net profit of setting up means of verifying medication is estimated by the FDA to be in excess of four billion dollars (EUR 3.3 billion); furthermore, hospitals can improve other processes (electronic patient record, inventory, etc.) resulting in savings amounting to more than 360 million dollars (EUR 294 million).

The European Union has adopted Regulation 178/2002, which will gradually enter into force by 2005. It compels those involved in the food distribution chain to set up the means with which to follow the progression of products, from their origin to their final consumption. The Regulation holds that each actor in the distribution chain must be in a position to know where the food products in his zone of influence originated, and to which destination they will be dispatched. The processes involved in receiving the goods and stocking the warehouses of hospital kitchens, followed by the processes of preparing meals and finally deliveries to the hospital or to adjoining buildings, are affected by this regulation. As regards the food sector, hospitals will recognise that the EAN.UCC system is already heavily used by their suppliers, and that the development of collaborations as regards traceability can thus be based on available foundations. Of course, this regulation does not directly affect Swiss hospitals, but workshop participants were struck by the adaptations to logistical processes that this regulation imposes. It is very likely that similar measures will soon be developed in Switzerland.

Interactive work

In the interactive part of the meeting, participants were faced with a problem to

solve: how to retrospectively find patients who have received a drug (authorised in the market) of a specific lot. Two mixed groups studied the question from a hospital point of view ("you are responsible for quality in the hospital and you must give instructions for finding these patients"), or from a supplier point of view ("how to help hospitals which have received this lot to find the patients"). This kind of role play allowed the groups to better understand their various ways of working and to anticipate such questions about the safety of patients.

The third workshop of its kind since 1999, the meeting was a great success, with participants realising that without recourse to standardised information throughout the distribution chain, traceability in the hospital setting cannot be assured. Furthermore, feedback from the participants confirmed that one of the objectives of the meeting was fully met: to better understand the reciprocal needs and possibilities in the field of drugs and medical equipment. From the hospital perspective, the identification of individual doses by means of the EAN.UCC standard was welcomed as significant progress, opening essential perspectives in terms of patient safety. ■

References

1. FDA: US Food and Drug Administration
2. Dr. Patrik Muff, Chief Pharmacist and Clinician, *Hôpital Sud Fribourgeois* and Martine Rueger, Graduate Nurse, *Hôpital J. Daler*
3. Federal Register, February 26 2004, Part III, page 9120; see in particular the table on page 9151
4. Linear: the most simple bar codes on a technical level, such as the EAN-13 code which is the most widely used on the mass market. These codes, however, do not allow much information to be carried in a reduced space.

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