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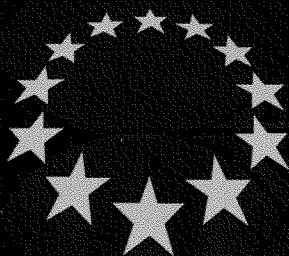
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Barcodes: what's new?

The use of graphics symbols in the form of barcodes to carry information goes back several decades. It has been in the forefront of world news following recent American studies that demonstrated the importance of the number of "medical" errors committed in a hospital setting (the report 'To Err is Human' played a considerable role in this respect).

Since this study, the North American authorities have paid particular attention to this subject, but they are not the only ones. The following reflections aim to illustrate the debate that took place in the summer of 2002 in the USA about this problem. In Europe we seem to be waiting for concrete decisions on the part of the Americans' authorities before we make up our minds.

Too many administration errors with medical agents: is a decision to change the regulations required?

At the start of December 2001, the FDA (Food and Drug Administration) published a "docket" by which it opened a public consultation, indicating its intention of requiring the manufacturers of pharmaceutical and biological substances for human use to affix barcodes to their products.

The objective is to reduce the number of errors made in administering medicines (Federal Register, vol. 66, page 61173). Time limits were fixed for interested parties to express their opinion in writing and by means of a public hearing (late July 2002).

It is in this context that the American Hospitals Association and

other groups of users have asked the FDA to extend the obligation not only to pharmaceutical products, but also to medical devices. These organisations are of the opinion that the voluntary solutions that have prevailed up till now have not been sufficiently tested, as too many articles designed for the hospital market have not yet been identified in this way so it has not been possible to set up an automated handling system.

A recent study by the Wharton Business School observed that the particular structure of healthcare systems had so far prevented standards for identification and communication becoming established. The FDA, in its statement, notes that if it were to leave things up to market forces, it would not be shouldering its responsibilities; hence it feels obliged to regulate in this matter.

A barcode or a system?

The public hearing enabled many

interested parties to make a contribution; positions have essentially crystallised around two questions: is regulation necessary or not? and is it really barcodes that should be imposed or a system?

Those who support regulation are drawn mainly from those in health-care and nursing environments. People who work in these areas have observed that efforts to affix barcodes on medical products have a real effect on cutting administration errors since by using the codes they are able to identify the substance being administered precisely and track it. They want the codes to be added 'at source', as this reduces the chance of labelling errors. In contrast, those who work in the industry indicate that there are technical difficulties in printing sufficiently reduced yet high definition symbols on each article at the end of the production cycle.

Those expressing an opinion who come from technical (developers of customised solutions for the symbols or for reading them) or industrial environments have come out in favour of freedom of choice of the barcodes. These actors have also stated that the future of barcodes probably lies in microchips. On the other hand those who favour a more global approach have encouraged the FDA to adopt a system of identification already widespread in the world, combining tried and tested data structures and novel solutions for the data transport (such as barcodes and plans for a standard chip world-wide).

The debate is over in the USA – but continues in Europe!

The FDA will give its decision according to its own authority. In Europe, there are many initiatives for reducing medication administra-

tion errors. We cannot escape studying the existing alternatives (Which barcodes are most widely used? Are they used as part of a system? Do they form commercial barriers or do they facilitate the free circulation of goods? etc.). Finally, should these initiatives remain voluntary or should they be made compulsory?

Let us hope that those involved will adopt a demanding, neutral and open approach. It is of major importance that the solutions being worked on by the world's leading companies, whatever their sphere of activity, are taken as a model by the healthcare industry and are adopted whenever they meet identified needs.

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