Max Pharma GmbH
Am Gewerbegebiet 5
95185 Gattendorf
Germany

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Position paper on Article 54(a) of Directive 2001/83/EC

As a wholesaler in medicinal products and a pharmaceutical company, we have set out our position on the above subject below.

Introduction: we attach importance to the implementation of this legislation. Our main aim is to be actively and constructively involved in the process. As a result of our own experience of using RFID in the prevention of counterfeiting and of implementing the technology in practice, we are very keen to see the right approaches taken for industry and consumers.

A comparison between 2D barcodes and RFID shows up some obvious differences. 2D is an imaging technique and requires line-of-sight with the correct side of each individual package. RFID, on the other hand, is a 'radio technology', which is actually based on magnetics. It does not require line-of-sight with the package and the location of the package is not important. The cost of 2D for manufacturers is about 1 cent per package. In Europe the cost of RFID can be estimated at under 10 cents per box. The cost of the numeric code, electronics, software and licences needs to be included in the calculation of the total cost. A 2D matrix performs much worse than RFID in this regard and users ultimately have to pay the additional cost. Barcode scanners cost more than RFID readers because of the camera system required. In other words, wholesalers, pharmacies and hospitals using RFID technology save millions of euros in investment costs. Since many institutions are publicly or semi-publicly owned, there are additional social costs. 2D camera technology also increases labour costs as each individual medicinal product has to be scanned by the camera. This is not a major problem for pharmaceuticals manufacturers following GMP procedures since the packages can easily be read on the production line. However, this is not the case for wholesalers, pharmacies and hospitals, where conditions vary. The existence of many different manufacturers with different kinds and sizes of package poses a challenge.

The 2D matrix is of benefit and can be justified when tablets in a blister pack must be labelled individually. In such a case RFID is uneconomic and technically difficult to implement. However, RFID can and must be used for ampoules.

Regarding the technical requirements of RFID, UHF is preferable to HF as it is less expensive. HF is little better with liquids, is much more expensive and is therefore uneconomic. UHF is an open standard and is already used for bulk scanning. A minor technical adaptation by the supplier enables UHF to read in bulk. As far as possible, data should not be stored directly on the chip in order to prevent the risk of tampering. Only the use of the UID without any reference to the manufacturer, country, substance or time can safeguard against tampering. Standardised numbers may lead to tampering through the use of mathematical processes.

As medicinal products that have been tampered with (term covers all types of alteration) can be smuggled in at any point in the professional process, data need to be collected whenever a product is exchanged/handed over. On account of possible future legal changes or new quality requirements, it must be possible to extend a system and include other options, such as temperature control.

Monitoring arrangements

Data to be collected:

1. Name of the medicinal product
2. INN
3. PZN/authorisation number/registration number
4. Units
5. Manufacturer
6. Batch
7. Optional photo of package

During manufacturing, the available SAP/Oracle data are already combined with the respective package using RFID or a 2D code. Data should be readable from the database only via the UID. The technical/control white paper is provided separately.

Tunnel readers for bulk items are used for processing goods arriving at wholesalers, pharmacies and hospitals. Individual readers are used for smaller quantities. To compensate for the additional security costs, a connection to the respective institution’s ERP is recommended. This can help to offset costs. All those legally entitled are authorised to use the system. The database already being used for the German market can be monitored by the authorities if necessary. This means it would be possible to monitor databases in a similar way to medicinal products and checks could carried out by the local supervisory authorities. A multi-database model should not be used in principle because of the technical investment and the risk of matching errors. Moreover, many functionalities cannot be included in a multi-

database system, e.g. temperature information. A single database is much more stable than several different databases. This is demonstrated in practice by Google, Facebook, Wikipedia, etc.

There are no clear criteria for labelling specific groups of medicinal products. Each impaired or counterfeited medicinal product can pose a threat to a consumer's health. Nonetheless we would suggest a gradual approach. First, specific high-risk medicinal products in small quantities should be labelled to allow the system to be built up. Alternatively the start should be brought forward so as to lengthen the technical implementation period.

In the light of the above, we take the view that, for technical and practical reasons, the RFID system should take preference over the 2D matrix system and should be implemented.

We are at your disposal for any questions.

Michael Kretzer
Max Pharma GmbH
Tel. 00499281-840160
Fax 00499281-84016160
kretzer@max-pharma.de

Black List:

- Oncology
- Infectology
- BTM
- Autoimmune diseases (rheumatism, lupus etc.)

White List: - None