

Max Pharma GmbH  
Am Gewerbegebiet 5  
95185 Gattendorf  
Germany

30 March 2012

Dear Sir/Madam,

**Opinion on Article 54a of Directive 2001/83/EC**

As a medicinal product wholesaler and pharmaceutical company, we welcome the opportunity to comment on the above matter.

We wish to point out, first of all, that our company attaches great importance to the Directive's implementation and that our aim is to play an active and positive role in this process. Based on our own experience with RFID in the context of counterfeit security, as well as with the practical application of the technology, we regard it as a priority to ensure that the approaches pursued are the right ones, in the interests of the industry and the consumer.

In a comparison of a 2D barcode system and RFID, a number of differences immediately stand out. 2D is based on image processing and requires a line-of-sight to each individual package, which must be placed the right way round. RFID technology, on the other hand, relies on magnetic-based wireless technology. No line-of-sight to the package is required, and package position is also irrelevant. For 2D, the costs to the manufacturer amount to around 1 cent per pack. In Europe, the costs of RFID are estimated at less than 10 cent per pack. However, full cost accounting must include the costs of the numerical codes, hardware, software and licences. In this respect, 2D Matrix performs much worse than RFID, and these additional costs must ultimately be borne by the users. The scanners required for 2D Matrix cost more than RFID readers, as a camera system is required. For RFID, the investment costs for wholesalers, pharmacies and hospitals are therefore much lower, by several million euros. As many institutions are in public ownership / owned by public corporations, there are additional social cost implications. The 2D camera technology also increases personnel costs, as each pack of drugs must be held in front of the camera and scanned individually. Under GMP conditions at the pharmaceutical manufacturer's premises, this does not pose any major difficulties, as the conveyor belts can read the packages with no problem. However, this is not the case once the packs reach the wholesaler, pharmacy or hospital, where conditions vary widely. There are many different manufacturers using different types and sizes of packaging, and this poses a challenge.

The use of 2D Matrix is justified and advantageous when the individual tablet within the blister must be marked. Here, RFID is uneconomical and beset with technical difficulties. By contrast, RFID is feasible, and indeed essential, when processing ampoules.

As regards the technical aspects of RFID, UHF performs better than HF and is more cost-effective. HF is slightly better for liquids but is far more expensive and therefore uneconomical. UHF is an open standard and is already used on a large scale. A small technological modification by the supplier enables UHF to be used in bulk reading systems (bulk reading ability). As far as possible, no data should be stored directly on the chip; this is to avoid the risk of manipulation. Security against manipulation can be guaranteed only if the sole information stated is the UID number, with no

reference to the manufacturer, country, substance and date. The use of standardised numbers potentially creates opportunities for manipulation based on mathematical processes.

As the infiltration of manipulated medicinal products (meaning all types of changes) can take place at any point in the professional chain, it is essential to log every modification/transfer of the product. With the prospect of amendments to the law and/or further development of quality standards in future, it is reasonable to expect the system to offer scope for expansion and the incorporation of additional functions, such as temperature monitoring, etc.

Monitoring modalities;

Data to be collected:

1. Product name
2. International non-proprietary name (INN)
3. PZN number / authorisation number / registration number
4. Dosage unit
5. Manufacturer
6. Batch number
7. Optional photo of pack

During manufacturing, the existing SAP / Oracle data are linked to the packs using RFID / a 2D code. The data should only be readable via the UID from the database. A white paper on the relevant technology / management will be submitted separately.

The logistics for the handling of incoming goods by wholesalers / pharmacies / hospitals involves the use of tunnel readers for bulk reading. Individual devices are set up to process small quantities. In order to offset the additional costs of security, a link to the organisation's ERP is recommended, as a means of compensating for negative cost impacts. All authorised persons within the meaning of the law have access to the system. The database which is already operational in the German market can if necessary be placed under official supervision. This would enable database monitoring to be managed in a similar manner to pharmacovigilance, facilitating control by the local supervisory authorities. For technical reasons and due to the risk of alignment errors, a multi-database system should be rejected. A multi-database system would also make it impossible to incorporate many additional functions such as temperature data. A single database is also far more stable than separate databases, as numerous practical examples illustrate, e.g. Google, Facebook, Wikipedia, etc.

There appear to be no criteria governing the labelling of certain medicinal product groups. Every counterfeit drug, or drug of inferior quality, potentially puts the consumer's health at risk. Nonetheless, we propose a stepwise approach. First, certain high-risk drugs should be labelled in small quantities in order to support the development of the system. Alternatively, the launch should be brought forward in order to extend the timeframe for technical implementation.

**Based on the above statement, we believe that there are compelling technical and practical reasons in favour of the RFID system compared with 2D Matrix, and we therefore advocate the implementation of RFID.**

Please do not hesitate to contact us if you have any questions regarding the above.

Yours sincerely,

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- Black List:
- Oncology
  - Infectious Diseases
  - BTM
  - Autoimmune Diseases (rheumatism, lupus, etc.)

- White List:
- None