



“Do not underestimate requirements”

Russia is planning a very extensive approach to track and trace. In an interview, software specialist Stefan Öing explains what this means.

What is being planned in Russia?

An extremely extensive approach is to be implemented in Russia. It will go far beyond what is planned in the EU and even overshadow Brazil's original intentions, which are still being fulfilled.

Can you explain the approach in more detail?

The Russian concept, codenamed FSIS DCM, is focused on capturing the path traced by a drug all the way from its manufacturer to the end user.

That sounds very much like the track and trace policies that are envisaged in other markets.

Two things distinguish Russia from other markets, the first of which is the abundance of data that is to be captured.

Second – and this is a key point – the difference lies in the express goals of being able both to evaluate the data according to various criteria and to make it available again to the market players according to certain criteria. Fundamentally, Russia's approach envisages intensive monitoring and evaluation of the entire pharmaceuticals market. Its primary intention, of course, is to prevent counterfeit pharmaceuticals from entering the logistics and supply chain.

What other functions will the system allow, beyond the ones already mentioned?

A central element, according to the information we have, is the ability to control the prices of important and indispensable medicines. For example, end users are to be enabled to compare the purchase price with the official price

limit. But the responsible authorities can also acquire a great deal of information from the data.

What might they use it for?

The data is so extensive that the authorities could retrieve information about the storage time of the medicines that are in circulation at a given time. They could also determine what drugs have been removed from circulation because of quality issues, improper authorization, or suspicion of counterfeiting, including information on the relevant dates, places and quantities.

What identification technology is to be used?

According to our information, a data matrix code is to be used for machine-readable serialization. This is indicated by

several statements and presentations on the topic, especially those circulated by official Russian agencies. Moreover, aggregation is to play a key role. Without aggregation, the extensive track and trace approach could not be implemented.

At the beginning, there was some discussion about using RFID technology to make pharmaceuticals counterfeiting more difficult. Does it still have a role to play?

As far as we know, this topic is off the agenda for the time being. But tamper evident measures will play a role. Although not widely discussed in official documents or presentations, there are several indicators that provision for verifying authenticity which will form part of the final regulations. The only question is likely to be whether less expensive medicines are to be disregarded and, if so, exactly where the price threshold will be set.

What is the implementation timetable?

The Russian authorities know that the system they are seeking to establish is very complex. The regulations will therefore apply only to drugs for seven especially lucrative types of disorders at first. The deadline for this first stage is January 1, 2018. One year later, the FSIS DCM rules will be applied generally to 'especially important' medicines. And a further year after that, from January 1, 2020, all medicinal products for human use will have to be serialized. At the moment, pilot projects involving 16 pharma manufacturers and a total of 30 medicines are already under way.

But the timetable is tight, isn't it?

It is certainly a challenge, and one that should be taken seriously. Representatives of the Russian authorities have already warned the pharma companies not to drag their feet with serialization and GxP projects in order subsequently to claim

that insufficient time was allocated. There is a certain sense of expectation on the part of the Russian authorities, which should not be underestimated. Stipulations cannot be met simply by equipping packaging lines with additional devices. Implementation entails developing and interlinking entire information systems.

How well is Atlantic Zeiser prepared for the Russian challenges?

The ability to comply with the very extensive requirements in this country depends to a large extent on the flexibility of the software. We designed our MEDTRACKER from the outset so that it can adapt to as yet unknown, complex serialization regulations. The Russian stipulations are no exception. The extensive interface library that makes MEDTRACKER so remarkable also helps us when it comes to linking various databases, institutions, authorities and manufacturers within a country. Of course, the time required to configure the interfaces in an individual case is not to be underestimated, especially given the need for fine tuning.

What about the hardware?

Atlantic Zeiser designed the software architecture of MEDTRACKER so that it can be connected to existing, even multi-vendor hardware. MEDTRACKER is able directly to control a variety of hardware components, such as camera and printing systems and other units. This means that there may be no need to replace hardware if the existing equipment is fundamentally able to fulfill requirements.

What is to be done if a track and trace module has to be newly integrated?

We can plan and implement a single-provider software and hardware solution. At the Interpack fair, for instance, we have introduced a new track and trace



"The Russian concept, codenamed FSIS DCM, is focused on capturing the path traced by a drug all the way from its manufacturer to the end user," says Stefan Öing, head of Track & Trace Software at Atlantic Zeiser.

module that can perform serialization and, if necessary, be equipped with a check weigher and tamper evident labeler, all within a small footprint – with a built-in MEDTRACKER interface, of course. We are therefore well equipped to stay on top of even the Russian challenge.