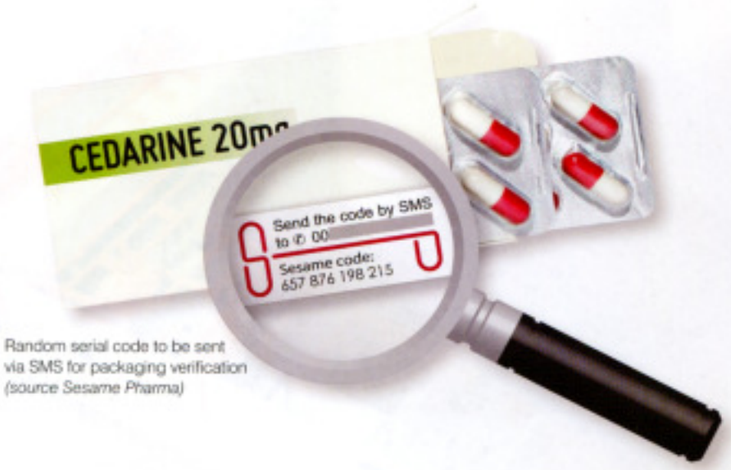
Should we Leave it to Patients to Identify Counterfeit Medicines?

This is a very topical issue in developing countries, but also in industrialised countries, where commercial sites on the internet are increasingly used to buy consumer goods, including medicines - notably those not reimbursed by health insurance and countless others issued without a prescription (OTC – over the counter).

During the recent "Pharmaceutical Anti-Counterfeiting" conference held in Amsterdam on 16th and 17th February 2011, a speaker presented solutions based on a random numbering of secondary packaging of medicine, which would be checked by SMS using a mobile phone, even a first generation phone. Indeed, it is the patient who is given the responsibility for checking his medicine or not. This procedure must however be based on the impossibility of transferring the checking procedure to a pseudo-server that itself is one of the counterfeiters' resources, and furthermore is based on how reliable is the written code sent by the patient to be checked. The argument developed for leaving this responsibility to the patient alone is an acknowledgement that the whole distribution channel is corrupted, including the pharmacist and doctor, not to mention wholesalers or local manufacturers. Owing to this we admit that having reliable intermediaries in such a crucial field as health is not possible and we "make do".

This acknowledgment is a bitter one, however, because it presumes that in these countries, notably in Africa, establishing a basic moral doctrine will be impossible, meaning that we must remain in the jungle stage. Would it not be more useful and profitable to help establish reliable distribution channels, not only for medicine, but also for other goods and services? This is a huge question, all the more so as the introduction quoted above mentioned that although the patient was motivated to check the code by SMS from the start, he seemed to abandon this check gradually, relying solely on the presence of a code concealed by a strip "to scratch" or not, to the counterfeiters' great delight.



Random serial code to be sent via SMS for packaging verification *(source Sesame Pharma)*

What is the Laboratory's Liability in the Event of a False Positive?

An element that raises even more questions is the responsibility of the manufacturer that in fact issues the certificate of authenticity, the SMS question arriving in a database controlled by it or by one of its subcontractors. From that point on, what would the manufacturer's liability be if a false positive is declared or a counterfeit medicine is identified as being authentic? It seems that this question has not yet had enough light shed on it by all possible contributors, notably in the event of a death or serious complication affecting the patient in good faith. Is it to say that once again we depend on the patient's maturity to avoid taking possible complaints addressed to the original manufacturer into consideration? Do we speculate that a patient from a developing country has little chance of asserting his rights opposite an industrial giant?

In developed countries, we noticed the presence of counterfeit medicine in state hospitals or in chemists and of course via the internet. Counterfeiting is thus also present, all the more so as the prices of medicine charged in developed countries provide a greater profit margin to counterfeiters compared with that obtained in developing countries.

Should we therefore give up opposing the manufacturing of counterfeit medicine, and base the whole authentication procedure on either pharmacists or patients, and this on the sole traceability of packaging that mentions a serial number?

There is therefore a danger of counterfeiters tackling the problem and attempting to penetrate the checking chain through corruption or coercion of players from this chain. Likewise it is necessary to expect these same counterfeiters attempting to disturb the procedure by marketing counterfeits before the originals for example, which has already happened in different sectors including the pharmaceutical sector due to leaks or other malpractices.

We also noticed that authentic secondary packaging had been emptied of its contents and probably resold loose and replaced by counterfeit medicine placed in the primary packaging, even with methods used to detect packaging that has been opened that the counterfeiters made every effort to recreate also.

Identification and Authentication: Two Problems that Require Adapted Solutions:

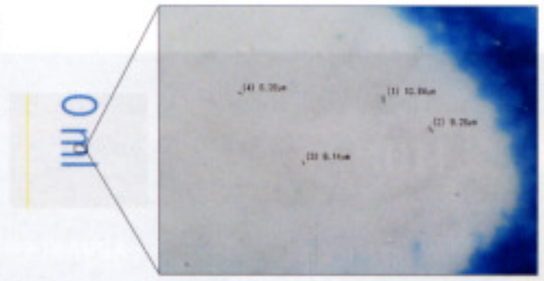
It is therefore dangerous to base the safety chain on a procedure known by the public like a serial number, even a random one, thus also known by the counterfeiters, and to neglect procedures more capable of detecting counterfeits, notably original, primary and secondary packaging, and indeed doses themselves. These secret or covert procedures which cannot be standardised other than according to a resistance scale for replication, combined with other elements, notably a simple serialisation by packaging or by batch, are widely available today. They can detect counterfeits through regular sample checks carried out at different points in the supply chain, even analyses of packaging of medicine consumed and recovered in waste. This is the case for example with Cryptoglyph®, an invisible marking made by normal ink or standard varnish, for primary (blisters) or secondary packaging that can be detected with the help of a simple office scanner or simple digital camera.

We all admit that if a terrorist is in a plane, it is a failing of the safety chain and it is not up to the passengers to carry out checks. A counterfeit medicine in the hands of a patient or honest pharmacist is also a failing in the industrial chain and the distribution chain of pharmaceutical products.

A Visual Examination of Packaging by the Human Eye is Not Reliable Enough to Identify Well-Made Counterfeits:

Introducing means, notably invisible identification means for original medicine, also allows the number of checks to be increased at a very low cost. Checking a batch of medicine not equipped with reliable authentication means is in fact highly costly and can take a lot of time, even requiring a chemical analysis of the substances. In fact, nothing looks more like a real medicine than a "well-made" counterfeit that is visually impossible to tell apart from an original.

This acknowledgment also undermines new systems, reserved for customs or for the employees of the different players of the supply chain,



Cryptoglyph® invisible marking of the carton box made by very small dots printed over the entire surface of the packaging with regular ink, but invisible to the naked eye *(source AlpVision)*.

Genuine or fake? Difficult to spot the difference with good replication *(source AlpVision)*.

that consist in visually recording the key elements of the packaging not likely to be correctly replicated by counterfeiters. Some of these systems call on a 3D depiction of the packaging on a computer screen. There again, it is not simple for everybody, even for a customs employee or a logistics company employee, to determine a real medicine from a fake. It is an either-or situation: either the replica is so badly done (poor brand name, spelling mistakes or other omissions) that there is no need to access this packaging information because the counterfeit is blindingly obvious, or the replica is so well done that the visual examination will be negative and make you think it is a real medicine. These solutions are therefore an illusion as to the possibility of reliably identifying counterfeits.

So this is not a simple problem and should again give a number of conferences and symposiums something to talk about over the next few years. But luckily, more and more pharmaceutical laboratories are now considering the problem by correctly assessing its seriousness and the importance of being able to identify counterfeits as close to their sources as possible, without waiting to see them on the shelves or in dispensaries. They are also motivated by new recently-adopted European directives, notably directive 2001/83/EC, updated in February 2011, that deals with the steps to take to prevent medicine from penetrating legal medicine distribution channels ■

Roland Meylan is the co-founder of AlpVision and today serves as Corporate Communications Manager. He holds an MS degree in signal processing and digital communication from the "Ecole Polytechnique Fédérale de Lausanne (EPFL)", Switzerland, as well as a postgraduate education in Business Administration from IMD Lausanne International Business School. Roland Meylan started his career at the graphic division of Bobst SA, the leading supplier of equipment for the folding carton packaging and flexible materials industries. Roland Meylan also worked in electronic communication over international data transmission networks, the forerunners of the internet. Since then, he has contributed to numerous business start-ups in value added mobile telecommunications services as well as in the digital imaging and visual communication domains.
Email:roland.meylan@alphvision.com