

New Security for US Drug Prescriptions

With new regulations due to come into force next month on the security of drug prescriptions in the USA, Standard Register has introduced *ScripPlus* pads. According to the company, these incorporate a range of security and tamper-proof features that exceed the guidelines laid down by the US Centers for Medicare and Medicaid Services (CMS) to combat prescription fraud, which costs the healthcare system \$5 billion annually.

The CMS guidelines follow the HR2006 Act which requires that states do not pay pharmacies for prescriptions submitted after October 2007 (subsequently extended to April 2008) that do not have at least one of three features designed to prevent three forms of fraud: fraud through unauthorised copying of completed or blank forms;

erasure or modification of information on forms; and the use of counterfeit forms. By October 2008 all prescriptions must carry features to prevent all three.

However, according to Dan Thaxton, manager of document security solutions for Standard Register, anyone committed to establishing a comprehensive defence against fraud needs to go beyond these guidelines. They are, he said 'a step in the right direction, but only a small one'.

Standard Register's solution, by contrast, combines heat-sensitive inks, micro printing, unique background patterns, artificial watermarks, chemical-sensitive coatings and warning bands to provide a defence against criminals modifying, copying and counterfeiting prescriptions.

Contact: www.standardregister.com

Report Exposes Fake Drugs in Asia

The results of an investigation into the extent of the trade in Asia of counterfeit anti-malaria drugs has been made public via a report in the Public Library of Science journal PLOS Medicine.

According to the report, the problem is particularly acute in South East Asia, where researchers first identified counterfeit version of artesunate ten years ago.

The recent investigation, meanwhile, which was coordinated by Interpol, has found that as many as 50% of the anti-malaria tablet samples in Vietnam, Cambodia, Laos, Myanmar and on the Thai/Myanmar border were counterfeit. They were disguised with authentic-looking packaging, including 16 different types of fake holograms, which an expert could distinguish from the genuine hologram but which would certainly fool most patients.

Most of the counterfeits examined

contained no active drug and some had potentially toxic ingredients, including banned pharmaceuticals. Some tablets also contained small amounts of artesunate, possibly to foil screening tests. The doses were too low to be effective but high enough to contribute to the development of resistance in malaria parasites, adding to the problems of fighting the mosquito-borne disease, which claims more than a million lives a year.

The main author of the report was Dr Paul Newton of the Wellcome Trust-University of Oxford SE Asian Tropical Medicine Research Programme. He will be presenting a paper at the forthcoming Global Forum on Pharmaceutical AntiCounterfeiting on how, using novel techniques, scientists, doctors, the WHO, Interpol and the Chinese government collaborated to find the source for some of the fakes, setting new standards for international co-operative investigation.

Fingerprints Offer Alternative for Pharma Protection

CAMO Software AS and InfraTrac Inc have announced a partnership to supply anti-counterfeiting solutions based on near-infrared (NIR) spectroscopy to the pharmaceutical industry. This is used to read spectral tags generated from the formulations of pharma products such as pills, powders and liquids that act as an excipient-based fingerprint. As such, say both companies, it offers an alternative to tagging packaging which, alone, is insufficient in the face of repackaging, legitimate or otherwise.

InfraTrac's technology platform includes the NIR spectroscopy and encryption software that enables substances to be identified down to the batch level. Two versions of the NIR spectrometers are available – either a desktop version for use in laboratories or hand held versions for use in the field, both taking less than a second to analyse the spectral fingerprints.

CAMO specialises in pharmaceutical process management and will provide the delivery of the fingerprints to the pharma products during production.

Contact: www.infratrac.com

RECONNAISSANCE *international*
PUBLISHERS AND CONSULTANTS

Reconnaissance International
2A High Street, Shepperton,
TW17 9AW, UK
Tel: +44 (0) 1932 269917

PO Box 684, Parker,
CO 80134, USA
Fax: +1 303-841-9887

Email: info@Reconnaissance-intl.com

Website: www.pharma-anticounterfeiting.com

Pharma Anti-Counterfeiting **NEWS**

the newsletter of pharmaceutical anti-counterfeiting

www.pharma-anticounterfeiting.info

ISSN 1756-6290

MARCH 2008 | ISSUE 3

Launch of New European Safe Medicines Group

The European Alliance for Access to Safe Medicines (EAASM) was officially launched at the European Parliament in Strasbourg late last year.

The EAASM describes itself as a pan-European patient safety initiative campaigning for the exclusion of counterfeit and substandard medicines from the supply chain. It claims to provide an independent cross-sector voice representing European patients' rights to access safe medicines. Key objectives include raising public awareness of counterfeit medicines and addressing the

shortcomings of current legislation and enforcement.

In line with this objective, the EAASM is currently undertaking an independent study on online trading, examining internet-based payment and distribution systems to create data to block this route for fakes. Jim Thomson, the Alliance's chair, will present the findings of this report at the Global Forum on Pharmaceutical AntiCounterfeiting (see page 3).

Further information on the EAASM can be obtained at www.eaasm.eu

MHRA Publishes Strategy for UK

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) has published its first **Anti-Counterfeiting Strategy**, covering the three years to 2010. The document is notable for the demonstration of the MHRA's commitment to fight counterfeits, its openness in doing so and the stated policy to improve communications with the public.

The MHRA strategy has three primary activity areas: communication, collaboration and regulation. It states that its aim is to ensure that 'the public and healthcare professionals have sufficient information about counterfeit medicines, how to avoid them and how to report them', and the agency has established a 24 hour anti-counterfeiting hotline. Collaboration with international organisations, UK enforcement agencies and the industry will play a large part in the MHRA's strategy, with its regulatory actions focused on 'continuous

threat assessment of the risk from counterfeit medicines and devices, based on all known incidents in the regulated supply chain.'

It is also committed to maintain market surveillance and fully investigate all reports of counterfeits. The strategy – which runs to over 40 pages – is summarised in nine succinct bullet points covering the above primary activities.

In two paragraphs on Security Technology Providers, the MHRA states that it will monitor developments in track and trace, but 'any solution would need to be at a European level'. It supports manufacturers using covert and overt security devices.

As part of its new strategy, the Agency will convene a bi-annual meeting of all stakeholders to review developments in counterfeits and anti-counterfeit activities.

Contact: www.MHRA.gov.uk

Bilcare Acquires Pharma Security Solutions

Bilcare Ltd, an Indian provider of pharmaceutical packaging and research services, has acquired Singapore-based taggant supplier Singular ID

Singular ID specialises in magnetic tagging technology. It was spun off from the Institute of Materials Research and Engineering, Singapore, in June 2005, and in 2006 launched the *enxure* enterprise brand security system. This comprises a package of magnetic tags containing unique random arrangements of magnetic features in the micrometer to nanometer range, readers, database hosting and an authentication management service. The tags can be incorporated into labels or embedded into product packaging and each contains a unique signature that is recorded on a central database and is verified using a hand held scanner which connects to this database via a PC or mobile phone.

Bilcare describes itself as a global pharma solutions provider, with services that include material research, clinical trials and drug sensitivity studies, along with packaging design, testing, materials and systems. Its customer base includes Johnson and Johnson, Merck, GlaxoSmithKline, Sanofi, Aventis, Pfizer, and Novartis and its acquisition of Singular ID consolidates its move into drug packaging systems to combat counterfeiting and fraud.

Concurrent with the acquisition,

Continued on page 2

Worldwide Track & Trace Bank

Following its experience in the reported removal of all counterfeit fraudulent medicines from the Italian healthcare system through the use of a unique coded label, a consortium of Italian organisations has established the *Worldwide Track and Trace Bank* (WTTB) as a global system for track and trace.

In Italy all or some of the cost of prescription medicines is reimbursed to the patient by the Ministry of Health. The 1980s saw a dramatic rise in fraudulent claims, with the MoH paying out far more than was needed to cover the cost of legitimate prescriptions. An investigation revealed that both duplicate claims were being submitted and counterfeit medicines were being used to fill prescriptions. Working with the Italian Pharmacy Producers Association, the MOH developed a new tagging system, introduced in 1988, which required a removable, coded label on all medicines, which the pharmacist removed and fixed to the reimbursement claim.

In 2001 a new system was introduced, automating the process of issuing, printing and recording a unique code-number on the dosage pack. The issuing and database

system, which was created by Assistenza Ricerca e Sviluppo SpA (ARES), issues a code to the security printer (Istituto Poligrafico della Stato), which prints the label and supplies it to the pharma manufacturer, importer or other authorised agent or packager.

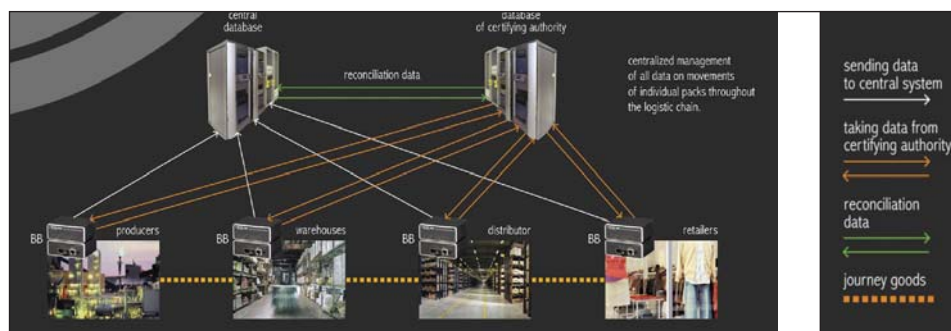
Within two years of the introduction of the new system, Italy was claiming that there were no counterfeit medicines available through legitimate outlets in the country and the number of fraudulent prescription reimbursements was negligible. The system also managed the control and removal from the distribution chain of expired or withdrawn drugs.

ARES is now heading a consortium to expand the system to all products, offering

a system based on a program called SITRIS (for *integral traceability and retracability security system*) and a central database to manage track and trace on a global basis. This system issues and records a unique code which can then be scanned along the distribution chain or by a member of the public, sending the code to the database to check that the product is legitimate. If not, the scanning person and the product manufacturer or brand owner is notified that the item is counterfeit or otherwise not legitimate (see diagram).

Partners in WTTB include public and private institutions, associations, technology and financial partners.

Contact: www.arespa.org



Europe Launches Anti-Counterfeiting Study

The European Commission has launched a study to assess various options to prevent pharmaceutical counterfeiting. At the same time, the EC's Directorate-General for Enterprise and Industry is undertaking a consultation exercise to obtain ideas for amending the regulatory framework for medicinal products.

The moves have been prompted by a sharp rise in counterfeit medicine

seizures at EU borders (up 384% in 2006). There are specific concerns on the trends in counterfeiting so-called lifestyle drugs, classical supply chains being targeted and a blurring between counterfeit and sub-standard active substances in medicinal products. The EC has also expressed concern that attempts by countries to address the problems unilaterally may contravene

rules for the internal market within the EU and displace counterfeiting to other member states with lower levels of protection.

The scope of both the study and the consultation exercise are wide-ranging – covering tighter regulations on manufacturing, distribution and inspection; new rules on transshipment and importation of both finished products and active ingredients; a ban on repackaging; requirements for medicinal products to be effectively sealed; and making mass serialisation together with product traceability compulsory.

Contributions to the consultation exercise can be made by May 9 at <http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new.htm>

Bilcare... cont'd

Bilcare has announced the launch of its own anti-counterfeiting barcoded labels with 'fingerprints' produced by nanotechnology. For verification of the

product the customer is reportedly able to swipe the drug packet in a scanner or at selected ATMs to attain product authenticity. The labels are seen by the company as a cost-effective alternative to RFID product tracking.

In addition to this new product, Bilcare plans to commercialise Singular ID's technology for pharma applications as early as the second half of 2008.

Contacts: www.bilcare.com;
www.singular-id.com

Systems for Safety in a Global Arena

The fourth Global Forum on Pharmaceutical AntiCounterfeiting will take place June 4-6 in Washington DC and, with the theme of *Systems for Safety in a Global Arena*, is designed to promote discussion regarding the developed world's focus on digital anti-counterfeiting systems and the developing world's use of sensory or overt authenticators.

The programme, which can be viewed at www.pharmaanticounterfeiting.info, features leaders from around the world and from across the anti-counterfeiting spectrum. Papers move from an examination of the issues

4TH Global Forum on PHARMACEUTICAL ANTICOUNTERFEITING

around current topics exercising the pharmaceutical and healthcare communities, to guidance on anti-counterfeiting systems and the relationship between the digital and sensory regimes. The four conference sessions are titled:

- *Pharmaceutical Counterfeits - the Global Issues;*
- *Global, Regional and National Responses;*
- *Creating an AntiCounterfeiting System*
- *Authentication and/or Traceability?*

Parallel Trade and Counterfeits

Speakers and topics include Peter Pitts, former US FDA associate commissioner and founder of the Center for Medicine in the Public Interest, on importation issues – still under discussion in the US Congress – which will be counterpointed by Dr Jonathan Harper, reporting on parallel trade and counterfeits, following his recently-published report on the situation in the EU.

Import issues include those relating to active pharmaceutical ingredients, a topic to be addressed by D'Arcy Quinn, former director of the Pharmaceutical Security Institute and now with

CropLife International, while Jim Thomson of the European Alliance for Access to Safe Medicine will show how the internet allows patients to get around any import controls - putting themselves at danger in doing so (see EAASM article - page 1).

Regularity Measures

There will be papers from the respective drug regulators on new anti-counterfeiting measures in Ghana, Malaysia and Nigeria, while – in a typical 'left-field' Global Forum move – David Kenny, a senior counterfeit analyst at the European Central Bank, will describe the attempts to counterfeit euro banknotes and what the pharmaceutical community could learn from the ECB's experience.

Speakers from the appropriate drug regulators and pharmaceutical companies will cover the state of play in California, at the WHO's IMPACT and on China's newest laws and law enforcement activities to improve anti-counterfeiting and quality control in its chemical and medicines industries.

There will also be reviews and updates on the newest developments in anti-counterfeiting technologies, including a presentation from GS1 Healthcare on the status of its work on supply chain safety standards.

Two Workshops

The two-day Global Forum plenary meeting is preceded on 4 June by two workshops on *Making the Internet Work for You, Not Against You*, and *Integrating Authentication & Tracking for Best Effect* respectively.

The Global Forum is sponsored by Authentix, Nanoink, Sicpa and Tesa Scribos, which will all be exhibiting in the accompanying anti-counterfeiting exhibition (joined by ARmark, Vesdo and Oyster Manesty). There are only three sponsorship opportunities still open, and exhibit space is also available. For further details contact the conference organisers Reconnaissance, or visit the website for early delegate registration.

Contact: www.pharma-anticounterfeiting.com

New 3-in-1 Forensic Tool



Graphic Security Systems Corporation (GSSC) and Aven Inc have developed a three-in-one portable forensic device to capture and verify a range of first, second and third level security features in the field. According to the companies, the *iDetector*[™] is a world first which offers the perfect compact device for collecting affirmative evidence of genuine products at an affordable price.

The *iDetector* is a combination of a 7 mega-pixel digital camera, a digital portable microscope (with a magnification range of 10x to 150x) and an adjustable UV or LED light source to provide specialised illumination, enabling a broad range of images to be captured. The three functions – lighting, magnification and digital camera – can be quickly interchanged and it comes with a variety of software options, which can be linked to a database via a local or web interface to store and match data.

Typical features include images printed with UV or IR inks, including symbologies such as data matrix barcodes, the information from which can be extracted by GSSC's proprietary software and analysed. Other features which can be examined include holograms and halftone screens. The *iDetector* will also decode GSSC's proprietary scrambled indicia, in which hidden images are embedded into print via manipulation of the printed lines and dot structures.

According to GSSC, the *iDetector* is a powerful tool for brand inspectors and law enforcers that enables digital authentication of a wide variety of security features which are already in use in billions of products worldwide.

Contact: www.graphicsecurity.com