DeLaRue

DE LA RUE
SECURITY PRINT

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28 October 2003

Divisions of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm 1061
Rockville
MD 20852
USA

Dear Sirs

Docket Number 2003N-0361 Counterfeit Drug Meeting

Please find enclosed our response to the Food and Drug Administration's counterfeit drug task force to assist them in finalizing their report.

Yours faithfully

CHingsley

Clive Evans
Head of Sales – Asia Pacific

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An Anti- Counterfeit Technology Review For The FDA ~ A Public Comment

DeLaRue

Executive Summary

- De La Rue one of the largest printers of banknotes in the world currently supplies anti-counterfeit solutions to many brand owners around the world and has experience in supplying such devices into the pharmaceutical companies.
- De La Rue can offer the pharmaceutical industry an unrivalled range of high quality technical solutions developed through hundreds of years experience in the sector. This extensive range of in-house technologies is further enhanced via our technology partner programme, through which we evaluate technology providers across the globe, imposing stringent criteria to ensure that only the best are selected for inclusion in our portfolio of recommended solutions.
- De La Rue have gained further experience working closely with governments around the world in establishing fiscal stamp solutions that combine anti-counterfeit and track and trace functionality. The info-centric solutions, provided by De La Rue, would enable a pharmaceutical company to identify each item uniquely and to check it against a record of past and planned movements.
- Technology solutions are only one part of the jigsaw. For any anti-counterfeit initiative to be effective it is important to understand where in the supply chain the risk lies, the nature of the risk, who needs to authenticate the product, the macro-environmental context and the role of the consumer. This holistic approach to anti-counterfeit solution design ensures the efficacy of the device.

1 Introduction

De La Rue is submitting this report as an initial document that will assist the Food & Drug Administration (FDA) in finalizing their counterfeit drug task force report. The report could also prompt topics for discussion prior to the formation of any working groups.

De La Rue has considerable experience in working with Government authorities as a trusted partner and with Pharmaceutical companies in generating security solutions for their products. The solutions discussed within this report contain recommendations on technology families and are available today from De La Rue.

However, given that this document maybe made generally available, the contents of this document are necessarily generalised and as such does not contain commercially sensitive information. At the appropriate time, De La Rue would welcome the opportunity to have a more detailed discussion on a strictly confidential basis.

1.1 Context

Counterfeit drugs pose potentially serious public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, or even dangerous sub-potent or super-potent ingredients. In the United States, drug counterfeiting is a relatively rare event. Although FDA believes domestic counterfeiting is not widespread, the agency has recently seen an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage counterfeits into the otherwise legitimate drug distribution channels. The FDA has seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about 5 per year through the late 1990's.

In an effort to protect against the rising occurrence of potentially unsafe counterfeit drugs reaching consumers, on July 16, 2003, FDA announced an initiative to more aggressively protect American consumers from the risks posed by counterfeit drugs. As part of this effort, FDA established an internal task force that will develop recommendations for steps the FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs getting into the supply chain.

1.2 Objectives

- To demonstrate the need to recognise where the risk lies in the supply chain, the nature of that risk and who would be required to authenticate the product. In order to design the most appropriate anti-counterfeit device.
- To briefly outline De La Rue's ability to offer solutions that provide supply chain visibility and those that would facilitate the identification of genuine product.
- To briefly describe how anti-counterfeit devices work in the market place.

2 The De La Rue Offering

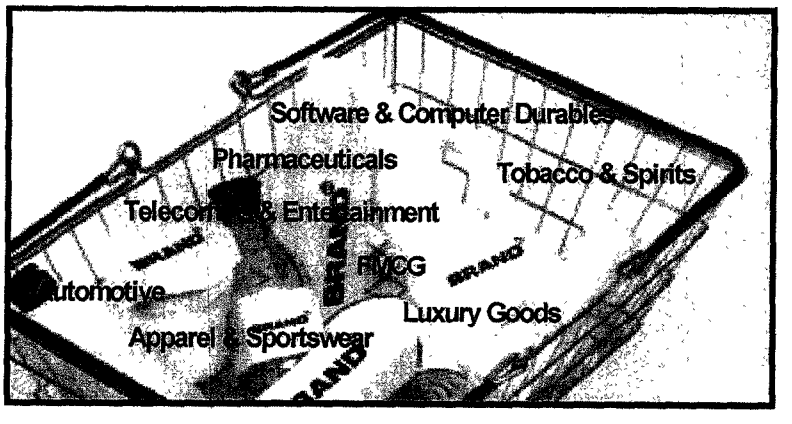
De La Rue is one of the largest producers of banknotes, producing currencies for over 150 markets worldwide. De La Rue is a full function, multi technology, worldwide security company focused to prevent counterfeiting and provide supply chain control to governments, financial institutions and brand owners across the globe.

De La Rue has a long and distinguished history spanning back to its creation in 1813. Built on the basis of strong values – Security, Integrity and Trust, it has grown into a respected international company with a turnover of $960 million and employing 6,000 people in 26 countries.

2.1 Sector Experience

De La Rue are currently working with a number of brand owners and governments to assist them in their fight against the growing threat of counterfeit goods and the illegal diversion of products.

Sector Experience



In the area of illegal diversion De La Rue have gained further experience working closely with governments around the world in establishing fiscal stamp solutions that combine anti-counterfeit and track and trace functionality. With the aim to increase recovered tax revenues, eliminate smuggling and facilitate identification of genuine product in the field.

Within the healthcare sector we are providing pharmaceutical companies with anti-counterfeit devices for prescribed and OTC drugs. To date we have successfully worked with a number of healthcare companies on proposals for –

- Anti counterfeit solutions
- Stemming illegal parallel trade
- Anti-tamper solutions
- Strategic brand protection consultancy
- Secure documentation to assist regulatory, trademark and patient and submission to health authorities

Having worked with a number of organisations within the healthcare sector, we are aware of the operational procedures and processes that are required to meet the standards required by regulatory bodies such as the FDA, for the supply of such products into a pharmaceutical company.

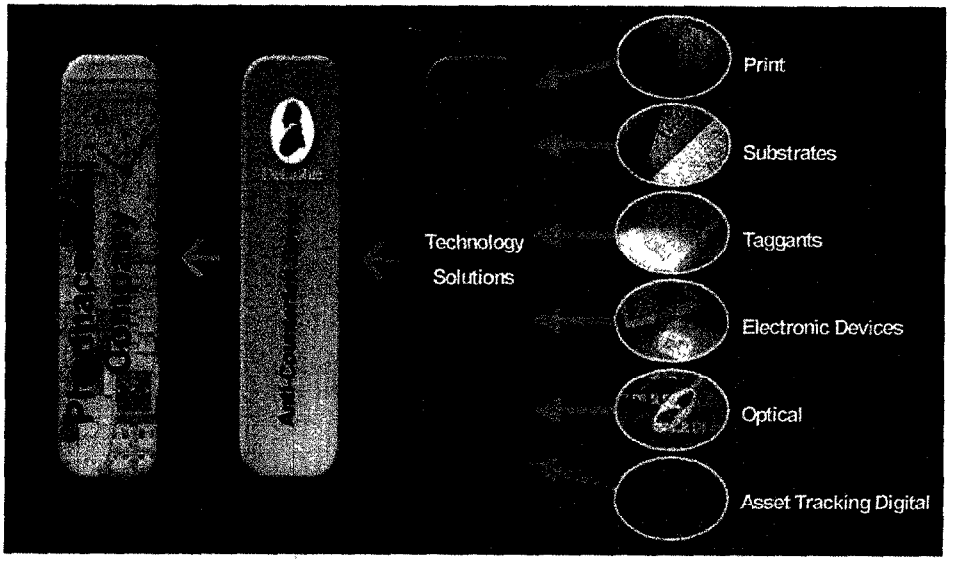
2.2 De La Rue Technologies

De La Rue can offer the pharmaceutical industry an unrivalled range of high quality technical solutions developed through hundreds of years experience in the sector. This extensive range of in-house technologies is further enhanced via our technology partner programme, through which we evaluate technology providers across the globe, imposing stringent criteria to ensure that only the best are selected for inclusion in our portfolio of recommended solutions.

The De La Rue toolbox includes:

- Secure substrates
- Anti-tamper devices
- Covert authentication features
- Secure flexible packaging
- Holograms and holographic foils
- Covert taggants and detectors
- Security print
- Security threads
- Overt features for public authentication
- Info-centric solutions

The Technology Portfolio



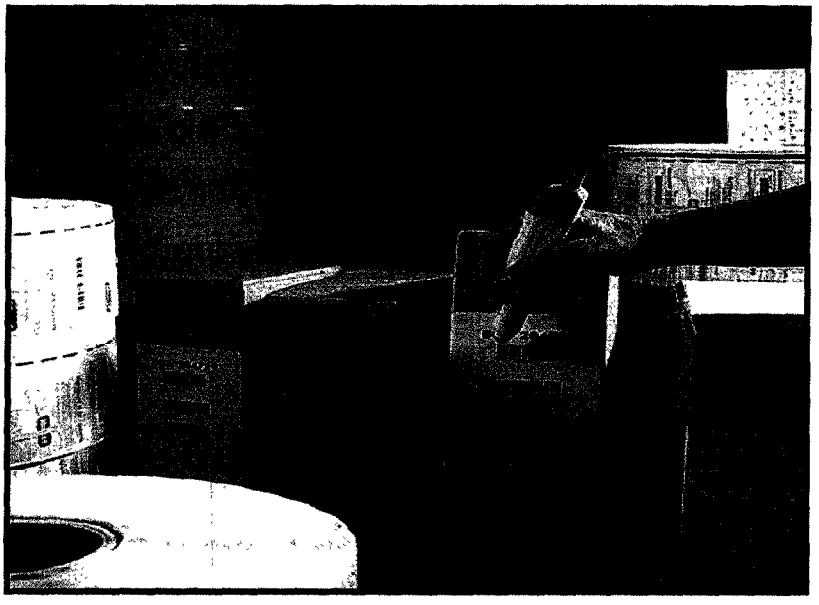
De La Rue advocates the use of a multiple technologies within a single anti-counterfeit device. By adopting such an approach we can facilitate the identification of counterfeit products by the many different stakeholders involved in the supply, prescription, administration and purchase of pharmaceuticals. It also ensures that there is sufficient complexity within the device to ensure that the anti-counterfeit product is never completely mimicked.

2.3 Supply Chain Visibility

The concept of item-level track and trace is not new. The technology exists and is being used for a number of applications, ranging from warehouse management to express deliveries or luggage handling. What is new, however, is that there is a

system that provides pharmaceutical companies with supply chain visibility, security and authentication on a global basis. De La Rue offers such supply chain interrogation systems. These systems combine supply chain integrity with item level authentication.

Interrogating Item Level Data



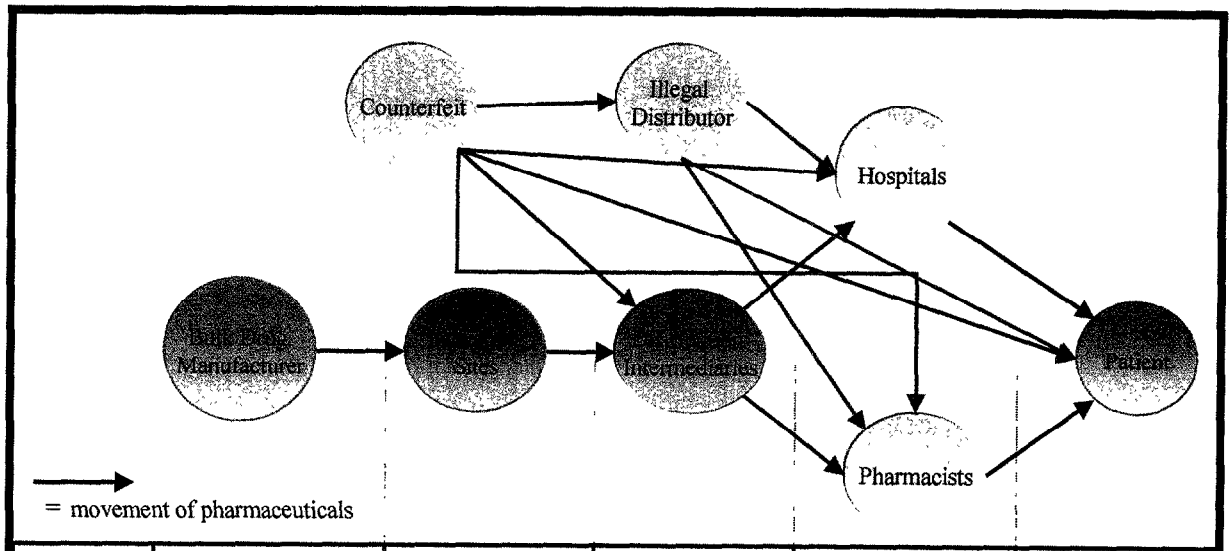
The info-centric solutions, provided by De La Rue, would enable a pharmaceutical company to identify each item uniquely and to check it against a record of past and planned movements. The solution gives accurate real-time information about the identity, status and history of a product. Thus answering questions about authenticity, previous locations, handling agents, assembly and expiry dates. Hundreds of custom-variables can be tracked within the system. The product provides complete supply chain transparency.

3 Where The Risk Lies

In order to design the appropriate solutions, it is necessary determine who would be required to authenticate the product and to review the movement of pharmaceuticals throughout the supply chain, in order to assess where the risk lies and what is the potential risk. Through this understanding the specification of suitable technologies, available today, becomes more relevant to the problem at hand.

The diagram below, of a simplified supply chain, illustrates this basic concept of recognising the nature of the risk, where it lies and the group of technologies that would be most appropriate for the inclusion in an effective anti-counterfeit device.

The Risk Chain



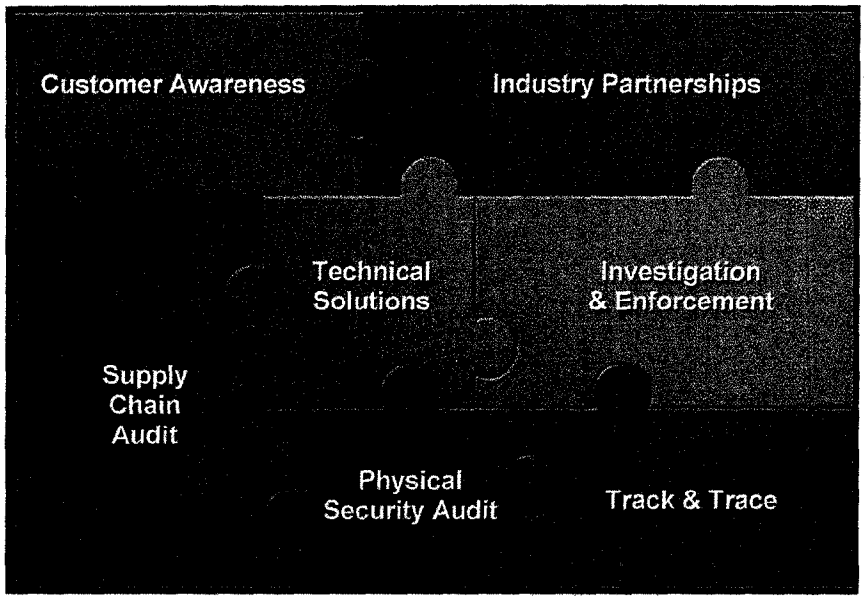
Type of Risk	•Theft of API •Diversion of API •Contamination of API	•Theft of packs •Diversion of packs	•Mixing of genuine with counterfeit •Theft •Refill of used containers	•Theft •Tampering •Purchase from alternative sources	•Theft of API •Diversion of API •Contamination of API
Suitable Technologies	•Overt = tamper evident seals • Covert = taggant & mark for track & trace	•Overt = tamper evident labels secure closures •Semi-covert = UV or IR print on pack • Covert = taggant & mark for track & trace	•Overt = tamper evident labels secure closures •Semi-covert = UV or IR print on pack • Covert = taggant & mark for track & trace	•Overt = tamper evident labels secure closures •Semi-covert = UV or IR print on pack • Covert = taggant & mark for track & trace	•Overt = tamper evident labels secure closures, holograms •Semi Covert = security print & threads

The introduction of anti-counterfeit devices into the supply chain necessitates the need for the pharmaceutical companies to introduce material accounting procedures and secure storage facilities for these products. To prevent the leakage and subsequent misuse of these devices and thus preserving the integrity of the solution. It would also be best practice for bodies such as the Pharmaceutical Securities Institution and American Association of Pharmaceutical Manufacturers to conduct audits on the various manufacturing sites and distribution nodes to maintain high levels of security throughout the supply chain.

4 Making Anti-Counterfeit Solution Work

Technology solutions are only one part of the jigsaw. For any anti-counterfeit initiative to be effective the other parts of the puzzle have to be addressed. Such holistic approaches to combat the threat of counterfeit require the cooperation of many different parties (stakeholders) potentially on an international scale.

The Holistic View



Part of the holistic approach requires the definition of critical success factors and key performance indicators, to ensure that any initiatives, employment of anti-counterfeit technologies etc. is delivering the required results to the stakeholders.

4.1 The Role of the Purchaser

There are a number of different purchasers (consumers) involved in the exchange process of pharmaceuticals namely: distributors, hospitals/doctors, pharmacists and the end user (patient). Each of these consumers interacts with the product in a different manner but all have a requirement to be able to authenticate the drug.

Whilst consumers are key stakeholders in the marketing exchange process, there are no guarantees that the consumer will participate in ethical buying practices. It is not enough to possess the prerequisite knowledge to make an ethical decision; one must act accordingly to that knowledge. Time pressures lead to consumers to make rapid purchase decisions. This places a great onus on how anti-counterfeit devices are communicated and the design of such devices to be "user friendly".

Marketing research indicates that although consumers express a willingness to make ethical purchases the reality is social responsibility is not the most dominant criteria in purchase decisions. The most important purchasing criteria are price, quality and value, which implies that consumers buy for personal reasons rather societal ones.

Ethics only appears to matter to the purchaser if they have a vested personal interest and that they would be personally or negatively affected by the behaviour. Buyers will simply not be engaged by issues that do not directly affect them, or with which they feel no sympathy. Therefore, it is critical that anti-counterfeit initiatives are supported by a communication programme that draws to the attention of the purchaser/user to the risks of counterfeit pharmaceuticals and to encourage them to engage in product authentication.

Given the personal risks for the end consumer within the pharmaceutical environment, it can be assumed they will engage more readily in the authentication process, than

they would in other sectors, if they are properly educated and provided with the means to identify genuine product.

4.2 The Global Economy

Current business practices that capitalize on the competitive advantage of nations, the movement of consumers, the removal of trade barriers and the usage of the Internet to purchase goods from all over the world and provide access to non-traditional sources. Makes it imperative that the FDA views any initiative, at least, on a regional basis and for companies to coordinate their activity across the world.

Therefore, anti-counterfeit technologies utilised in this context need to be successful in the different countries around the world. De La Rue has the experience of providing solutions that are effective in the main product counterfeit areas of the world and have the necessary expertise and competences to assist pharmaceutical organisations to coordinate their activity across regions.

5 Conclusions

The report highlights the key risks that pharmaceutical products face at each of the steps within the supply chain and possible technology solutions. It draws attention to the need for a holistic approach and how there is a need for all parties to be fully aware of the objectives and the importance of measurement against those goals. There is also a requirement to engage the purchaser, be they the distributor, pharmacist, doctor or end user.

Whilst the report identifies some of the risks, it also illustrates a variety of solutions that can be implemented today using existing technologies that can be provided by De La Rue.

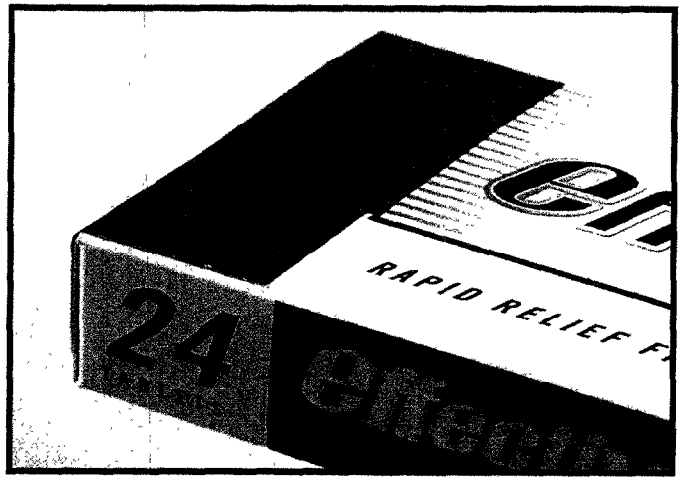
De La Rue would be delighted to work with the FDA in their initiative to combat the threat of counterfeit pharmaceuticals.

6 Appendix ~ Technology Families

6.1 Overt Features

Overt features are aimed at the end user to verify that the purchase is a genuine product. However, because the consumer can easily see them, they are the feature of any anti-counterfeit device that is most frequently mimicked. Therefore, the use of an overt feature on it's own is insufficient to provide adequate protection against the identification of counterfeit goods. Nevertheless, they are a very important part of any anti-counterfeit device as they allow for public authentication. Clearly, the stronger the underlying technology of the overt feature, the stronger will be the counterfeit resistance. De La Rue has an extensive array of suitable proprietary technology.

The Hologram



6.2 Semi-Covert Features

Semi-covert features are invisible or semi-visible with the naked eye and can be detected using a simple device such as an ultra-violet lamp or hand lens. They provide added complexity to the anti-counterfeit device. Such features can be easily communicated to and used by the many different stakeholders within the distribution channels to enable identification of genuine product.

UV Ink

A Security Thread under UV Light

6.3 Covert Features

Covert features are difficult to reproduce and are perfect for pharmaceutical companies who do not want their solutions in the public domain. They provide an ideal infrastructure for supply chain control, law enforcement and enforcement.

A Covert Taggant Within The Pack Design

6.4 Forensic Features

Forensic features are generally used to provide organisations with a means for absolute authentication. They can be used within the judicial system to prove beyond doubt authenticity of the product.

Covert and forensic features should only ever be communicated to very few people within each pharmaceutical company and enforcement agency on a need to know basis.