COALITION AGAINST ILLICIT TRADE

Business Cases on

Tracking, Tracing And Authentication Systems

To combat Illicit Trade and Counterfeiting

MAY 2017

Contents

Business cases on new TT&A technologies

Introduction

This paper, a collaborative report contributed by the members of the Coalition Against Illicit Trade[1] and based on desk field research, aims to present and analyse practical business cases in different manufacturing sectors and across the supply chain. It demonstrates how technology improves Tracking, Tracing and Authentication (TT&A) processes and outcomes.

For each business case presented below, we look at the industrial and technical requirements and conditions for improving TT&A and highlight inefficiencies likely to occur should such requirements not be met.

Without having the ambition of being exhaustive in covering multiple business initiatives underway in this area, CAIT's report offers a work in progress that aims to encourage the collection and the sharing of business applications which can demonstrate the benefits for companies and public authorities gained through improved TT&A performance. In previous papers, the coalition has addressed the role of new technologies in fighting illicit trade[2], and has looked at the guiding principles for a cost effective implementation of cross-border tracking, tracing and authentication systems[3].

We hope that you find this initial collection of business cases useful and we welcome your comments and contributions of additional cases and industry sectors you may have direct experience of. Feel free to contact us at: enquiries@coalitionagainstillicitrade.org.

[1] CAIT members includes Aegate, Atos Worldline, ArjoSolutions, Domino, Essentra, FATA Logistic Systems, Fracturecode, Nano4U, Scan Trust and Viditrust. For more information visit http://www.coalitionagainstillicittrade.org/

[2] The role of new technologies in combatting counterfeiting and illicit trade, Coalition Against Illicit Trade, 20 May 2016

[3] Governance and Data Management for Cross-border Tracking, Tracing and Authentication Systems to combat Illicit Trade and Counterfeiting, CAIT, 6 December 2016

Examples of industrial TT&A applications

I. Pharmaceutical Products

To fight the growing problem of falsified medicines, which form a major threat to public health and safety, different regions and countries have introduced their own tracking, tracing and authentication legislation. In the EU, the Falsified Medicines Directive requires the introduction of a full tracking and tracing system by February 2019. Medicine packs will need to contain a unique identifier and an anti-tampering device. The product is tracked from the production line up to when it is dispensed to the patient by the pharmacy or hospital. The development of the European Medicines Verification system to ensure the implementation of a functioning, secure, interoperable and cost effective system across Europe has been entrusted to the European Medicines Verification Organisation (EMVO), a joint initiative of EU stakeholders representing the different actors in the distribution chain (manufacturers, wholesalers and community pharmacists), ensuring full industry involvement.

1. Aegate Blueprint

Aegate Blueprint is a solution developed by Aegate, one of the three solution providers listed by the EMVO as preferred providers to implement the repositories system in compliance with the Falsified Medicines Directive.

1.1. Industry requirements

The industry needs a solution that allows them to fulfil all their obligations under the European Falsified Medicines Directive. This means they need to be able to generate and apply a unique identifier, and include the necessary anti-tampering device and safety feature to every product package they produce. This step should not slow down the production speed or in any way compromise the integrity of the product.

Once the individual product leaves their manufacturing facility and enters the distribution chain they need to be able to track and trace it in order to spot potential diversions and allow for efficient product recalls whenever necessary. Finally the authentication solution needs to offer as many guarantees as possible against the introduction of counterfeit medicines in the regular distribution chain.

1.2. System Requirements

The solution offered by Aegate has to deliver on all the obligations required under the Falsified Medicines Directive. For that reason, a 2D data matrix bar code in human readable form is used as a unique identifier on the outer packaging.

The unique identifier is scanned, checked and logged in a central database at all stages of the distribution chain until it is dispensed to the patient/final customer. This is achieved by first uploading all data to a National Repository with an Aegate Blueprint interface and hosted by Aegate on a private cloud. This National Repository exchanges all information with the EU Hub, as required by the FMD.

Since all the National Repositories need to communicate with the EU Hub and need to consult the data in the central Hub, a GS1standard is used as data carrier to ensure interoperability

In accordance with the FMD requirements, the following data are included in the master data on products to be stored in the European Hub: product codes, form, strength, doses per pack, pack type and target market(s) for distribution for each unique product form produced. The data included in the unique identifier at individual pack level are product code, batch ID, serial code and expiry date.

The unique identifier is applied and tracked at the "unit of use" or individual package level. This is also the level at which reporting to the EU hub must happen according to FMD. Although not required by law, Aegate is working with industry partners to explore their multi-level serialization and related aggregation needs with the aim of simplifying tracking and tracing operations and reporting, and product recalls when necessary.

1.3. Business benefits and Impact

The system offers manufacturers a full overview of the movement of products along the supply and distribution chain from production to patient, allowing them to know where any product is at any time. This is important in the case of a product recall due to an incident or the detection of counterfeit products in the supply chain. Such operations can involve very large volumes of product at different steps in the distribution chain, making aggregation at lot and batch level an economic necessity. Conducting authentication at all steps in the distribution chain makes it much more difficult to divert products or introduce counterfeit products into the regular supply chain. This also has important benefits for consumer confidence in the products and the protection of brand value and integrity.

1.4 Consumer/Patient benefits

The system guarantees that the end-consumer receives an authentic product, that has not been tampered with, has not expired and has followed a chain of custody ensuring that it has been handled in the correct way. This is of particular concern for this product category. In Member States where national reimbursement numbers are also included in the data shared with the national repositories, health authorities can introduce automatic reimbursement systems to the patients, or conduct automatic reductions on the prices of the medication sold.

1.5 Public authorities benefits

For public authorities too, the full control and authentication of medicines along the entire supply chain offers important benefits in terms of quality control and health care, since it significantly reduces the risk of counterfeit and expired product being distributed to patients. Linking the Unique Identifier to a national reimbursement number can simplify procedures for reimbursement and allows public authorities to monitor prescription behaviour by doctors and hospitals, as well as consumption of particular type of medications, which can be used to optimize and control health care expenditure.

1.6 Key challenges and concerns

For the manufacturers / logistics / solution providers

Since under the new Falsified Medicines Directive, tracking and tracing will happen at individual package level rather than at lot level, the unit volume of product that needs to be serialized could be as high as hundreds of millions of units a year for a given company. That will require 1,000 times the data storage and 10,000 times the transaction volumes of those for lot level products. This needs to be accounted for by manufacturers, solution providers and national repositories. Without the use of higher level aggregation of products, the time lost in authenticating individual packages in hospital pharmacies can be extremely costly, also when decommissioning a product.

Response time for authentication at pharmacy level is crucial since every product needs to be scanned and authenticated at distribution – Aegate has managed to improve its response times for authentication significantly over the last years (the average response time for pharmacies has been reduced to 135 milliseconds, down from 628 milliseconds ten years ago).

Since every member state has the flexibility to add its own unique requirements to the data which need to be tracked and traced such as national reimbursement numbers – this further adds to the complexity of the database interfaces that solution providers need to offer, and increases the volume of data that needs to be transferred.

For public authorities and consumers

The system goes a very long way to securing and regulating the official supply chain of medication via pharmacists and hospitals, and is as such a very important step in combatting illicit trade and counterfeit medicines within the official supply chain. But as the very recent "Serious and Organised Crime Threat Assessement 2017" (SOCTA 2017) by Europol shows, this also moves the battleground for public authorities to fighting illegal online distribution channels which are increasingly used to distribute counterfeit medicinal products including cancer medication and various types of medical devices.[4]

Consumer involvement is of course crucial in fighting the illicit medicines trade outside the official distribution channels. This requires information campaigns targeting the general public, alerting them to the dangers and health risks of buying medication online via unlawful channels.

The introduction of a common logo under the EU Falsified Medicines Directive for legitimate online retailers of pharmaceutical products is a very important step in the right direction. From 1 July 2015 onwards, all online pharmacies in the EU are required to display this logo in accordance with the rules of their national regulator. The latest On Tap Europe study from RUSI (the Royal United Services Institute for Defence and Security studies)[5] correctly points out that this can, however, only work if accompanied by major public awareness campaigns so customers know what to look out for. It also cannot address the growing practice of sale via social media, where other measures are needed.

2. Nanothicate® Solutions

Nanothicate® is a solution by nano4U AG in Switzerland capable of authenticating pharmaceutical dosage forms and their primary packaging along the entire supply chain. Nanothicate allows overt, covert, cryptographic and forensic authentication. It does not require any access to centralized databases (although it is compatible with those) and it does not introduce any additional materials for marking (e.g. inks, labels etc.) into the production and distribution lines.

2.1 Industry requirements

The European Falsified Medicines Directive (FMD) requires that the secondary packaging (carton box marked with a 2D-barcode) of any pharmaceutical dosage forms have to be shipped back to the manufacturer and be destroyed if errors in reading the 2D-barcode are encountered along the supply chain.

In the longer run, this will mean that the industry needs authentication solutions for pharmaceutical dosage forms (in the primary packaging e.g. blisters and/or the dosage forms themselves) and not only for their secondary packaging, as otherwise manufacturers and distributors will potentially be obliged to destroy valuable products in large quantities. Such authentication solutions should be highly secure and easy to apply/read anywhere along the supply chain. The introduction of safety features on the products themselves, including their primary packaging, has to be compatible with existing production lines and should not in any way compromise or change the integrity of the product itself. If possible,

[4] SOCTA 2017, EUROPOL, March 2017, page 46. It also gives as example the following case : The distribution of counterfeit pharmaceutical products online is particularly dangerous. In 2016, Operation Pangea IX
specifically targeted online vendors of counterfeit medicines. The operation resulted in the seizure of potentially dangerous medicines worth more than EUR 50 million.

[5] On Tap Europe : Organised Crime and Illicit Trade in Tobacco, Alcohol and Pharmaceuticals, RUSI, 23 march 2017

the solution should not slow down the production/packaging speed(s) or require any additional hardware investment. Finally, these authentication features have to be compatible with the unique product identifiers on the secondary packaging to allow full identification and authentication.

2.2 System Requirements

Nanothicate Solutions typically emboss or engrave microscopic markers onto the pharmaceutical dosage forms and/or their primary packaging (e.g. blisters) without changing the chemical composition of the product in any way using existing equipment and processes. The changes to the products are normally within established production tolerances. Nanothicate Solutions therefore avoid additional regulatory approval or investment in additional equipment/machinery. Nanothicate Solutions work at normal production/packaging speeds, as these are already established today.

Once pharmaceutical dosage forms are packaged on the primary level (typically in the form of blisters or bottling), individual markers within the package are cryptographically linked to the individual product identifier (2D-barcode) that is printed onto the secondary package. This 2D-barcode is then logged in a central database as required by most international serialization directives. It can then be scanned at all stages of the distribution chain until it is sold to the final customer.

However, because of the special capabilities of Nanothicate Solutions, accurate authentication on the level of the pharmaceutical dosage forms is now possible anywhere along the supply chain by checking the individual product markers against the unique product identifier (2D-barcode) on the secondary package. Such checks can easily be carried out with a dedicated smartphone app. For forensic authentication, special portable measurement devices can be used at strategic points along the supply chain, such as customs or distribution facilities. All authentication checks are fast, highly secure and leave the medication and its primary package fully intact.

2.3 Business benefits and Impact

Nanothicate Solutions offer pharmaceutical companies fully secure authentication of pharmaceutical dosage forms anywhere along the supply chain. The system is highly cost effective, as it does not require any changes to existing production or packaging lines. As all information required for authentication is on the product and its package, Nanothicate Solutions do not need access to any external database for authentication. The authentication works anywhere in the world where there is access to a smartphone with the correct cryptographic authentication software installed on the device.

Fast and fully secure authentication is especially important in cases of product recalls. For instance, where counterfeit products have been detected in the supply chain, Nanothicate Solutions can allow the manufacturers to distinguish between illicit and legal products anywhere in the world. Manufacturers and distributors can therefore avoid shipments and destruction of large quantities of legitimate products because their authenticity can be established on the dosage form level. Nanothicate Solutions also work in glass packaging (liquid dosage forms).

Using cryptography to link the actual dosage forms to their packaging also allows pharmaceutical companies to combat illegal reimports. Individual cryptographic keys can be provided to each manufacturing site and quickly changed should a problem be detected. Nanothicate Solutions can, for the first time, provide the owner of the medication, i.e. the pharmaceutical company, with complete control over its supply chain, even in the case of problems with contract manufacturers or contract packaging companies being used.

2.4 Consumer/Patient benefits

Nanothicate Solutions also allow the customer/patient to check if a pharmaceutical product is authentic or not by using a smartphone app. This is of particular importance in times where more and more pharmaceutical products are sold over the internet, often illegally. In cases when products are sold or dispensed individually, such as in the U.S. (bottling by the pharmacist) or also very often in hospitals, Nanothicate Solutions offer an easy solution to the pharmacist/nurse to check if they are actually dispensing an authentic product in the correct quantity, that has not expired and has not been tampered with. The patient in this case benefits from more reliable medication, in particular if he/she needs to take specific mixes of particular medications.

2.5 Public authorities benefits

Society as a whole benefits from authentic pharmaceutical products through improved levels of health care and the number of lives saved. Nanothicate Solutions also offer public authorities an easy way to authenticate pharmaceutical products, allowing for easy identification of illicit activity, be it forgery or illegal re-imports on site. Customs officers typically only have about 1-2 minutes to decide if they stop and inspect a shipment more closely or let it pass. Nanothicate Solutions give the customs officers an easy-to-use tool that allows them to make informed decisions quickly.

3. StellaGuard

StellaGuard is a new security label developed by serialization specialist Covectra at the request of their pharma clients. It is deployed in connection with their AuthentiTrack platform for serialization. Both technologies are compliant with the provisions of the European Falsified Medicines Directive.

3.1 Industry requirements

Convinced that 2D barcodes and holograms alone are not secure enough and can be replicated on a label thousands of times by counterfeiters before being detected, Covectra was tasked by their clients to develop a label that was copy-proof and could be used for reliable authentication and true track-and-trace and serialization. One added challenge was that this label had to be applied in a highspeed production environment and on different types of packages and materials. It also had to be compliant with the obligations set out in the European Falsified Medicines Directive and must be verifiable by anyone, even without the use of a special reader.

3.2 System Requirements

The StellaGuard label that was developed combines a standard GS1 2D barcode with a unique film incorporating holographic “stars”, which are distributed at varying depths and positions within the substrate. The pattern is unique from label to label, and is almost impossible to replicate because of the way the film is manufactured.

It can be applied in a high speed production environment at full production speed (up to 800 pieces per minute) to virtually all packages or materials. As soon as the label is applied to the packaging, three different images of it are taken on the production line to determine the unique “signature”. This is linked to the serialized 2D barcode in the StellaGuard Database to create a double layer of protection.

By using GS1 standards for the barcodes and uploading data to a EPCIS-Certified database called AT Cloud, the database can easily interface with the EU Hub as required by the EU Falsified Medicines Directive.

The label can be authenticated at different steps in the distribution process and by consumers by making use of the StellaGuard mobile application on a cell phone, rather than necessitating a specialized reader. Every time it is authenticated, its location is also recorded in the AT Cloud Server. Brand owners can make use of the StellaGuard Portal to access all information on the movements of their products.

3.3 Business benefits and Impact

StellaGuard allows the industry to meet the safety feature regulations under the European Union Falsified Medicines Directive, since it can be used with any existing serialization platform. Because it also provides integrity to barcodes, it can improve common business services like recalls, returns processing, new product tracking, grey market trade detection, tracking sample products, supply-demand balancing and uncovering trade in unauthorised channels.

3.4 Consumer/Patient benefits

The system allows customers to verify the authenticity of the medication they buy via a dedicated app on their smartphones. When combined with an FMD approved tracking and tracing solution, it gives an added level of security against the possibility of buying counterfeit medicines.

3.5 Public authorities benefits

As stated above, the full control and authentication of medicines throughout the supply chain offer important benefits in terms of quality control and health care since it significantly reduces the risk of counterfeit and expired products being distributed to patients.

II. Medical Devices and Cosmetic Products in Turkey

Over recent years several initiatives have been taken internationally to develop work on tracking and tracing systems for medical devices. In April 2013 the European Commission issued a Recommendation on a common framework for a unique device identification system of medical devices in the EU[6], setting out guidelines for member states working on projects until the EU sets up its own future identification and traceability structure. The International Medical Device Regulators Forum also adopted an International Guidance on a Unique Device Identification – System for Medical Devices in December 2013 [7].

1. ÜRÜN TAKIP SYSTEMI (ÜTS in Turkey)

The Turkish authorities have been working on a system for tracking and tracing Medical Devices and Cosmetic products, produced or imported on their territory, called the ÜRÜN TAKIP SYSTEMI (or ÜTS). The system was fully tested for cosmetic products in 2016 and the medical device section also underwent multiple test runs in a live environment last year.

Since 2014, the Turkish Ministry of Health has involved industry representatives throughout the whole process by requesting benchmark information and documents, organising workshops with industry representatives such as ARTED (Association of Research Based Medical Technologies Manufacturers) on the development of the different modules and by involving manufacturers in testing the technology and systems and allowing them to feedback on possible issues and improvements before it goes live in June 2017.

1.1 Industry requirements

The industry will need to generate and apply a unique identifier to products on the production line or at import. This will either need to be done at individual-product level (mostly for medical devices) or at lotnumber level (e.g. in cosmetics). The full list of products requiring singular product identification is still being established by the Turkish Ministry of Health. This is an important question because of the volumes involved. For medical devices, there are an estimated 4 million product types on the Turkish market, resulting in billions of singular products. For cosmetics, the ministry estimates that there are around 400,000 different product formulas distributed on the Turkish Market, also representing billions of singular products.The list of products requiring direct marking on the product itself rather than on the packaging is also still being finalised.

From June 2017 onwards, only products with a unique identifier will be able to register in the TITCK Electronic Management System and thus fulfill Turkish regulatory requirements. Distribution and sale of all other products will not be allowed in Turkey.

1.2 System Requirements

Interoperability is a crucial issue, since the system will be used, accessed and consulted by all the actors in the production and distribution chain as well as seven different government ministries and agencies, patients and consumers. It will exchange data with 15 different data systems (including the European Databank on Medical Devices, the Global Medical Device Nomenclatura, the Hospital Information Management System, the Central Population register, the Tax Administration, the Market Surveillance

[6] 2013/172/EU: Commission Recommendation of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union

[7] UDI Guidance, Unique Device Identification (UDI) of Medical Devices, IMDRF UDI Working Group, 9 December 2013,

and Inspection, the Cosmetics Products Notification Portal…). This is why it uses internationally recognized GS1 standards for data carriers.

The unique identifier will take the form of 2D barcoding for certain product groups and linear barcodes for other products. It will need to include the data on the product code, production line, where the product will be sold and/or used as well as its manufacturing date.

By scanning the Unique Identifier via an app on a smartphone, patients and consumers will be able to verify whether a product is genuine and indeed sold or distributed at its intended point of sale.

To allow real time access to data, the ÜTS data portal will provide 24/7 single-product tracking and monitoring. Since the estimated number of product movements registered will be higher than 1 billion/day and 400 billion/year.

1.3 Business benefits and impact

Since registration is mandatory for importing and selling medical devices and cosmetics on the Turkish market, adherence to the system is, in a certain sense, a license for economic operators to do business.

However, there are other clear benefits for manufacturers, importers and brand owners. The system allows them good oversight and control of the supply and distribution chain from production or import to patient/consumer. Having the product tracked at all levels along the distribution chain makes it possible to know where any product is at any time, and quickly spot diversion attempts or attempts to introduce counterfeit products into the regular supply chain. From a logistical point of view, it also facilitates product recalls in case of an incident, a faulty product batch or suspicions of counterfeit. This effect is enhanced if aggregation also happens at higher packaging or lot levels.

Securing the distribution chain and allowing consumers to confirm the authenticity of the product they buy is also very useful to protect brand value and reputation.

1.4 Consumer/Patient benefits

By safeguarding the supply chain from counterfeit and faulty products, the system has a clear added value for consumers and patients in terms of product safety and health.

By allowing consumers to verify the authenticity and provenance of the products they buy by smartphone, it also gives them greater comfort when making purchasing decisions.

Since the system will also be used by public authorities to allow them to formulate more efficient health policies, this will ultimately reduce costs for the taxpayers and increase the budget available for government to pursue health or other public policy objectives.

1.5 Public authorities benefits

By introducing much stricter control of the supply chain, the system will support inspection teams in setting up risk based inspections and product withdrawals. This will be an important element in the fight against counterfeit and faulty products and contribute to patient safety and the protection of public health.

In terms of health policy, the system will have clear benefits, since the Ministry of Health will be able to assess how to adjust health policies to make them more effective on the basis of the data. After the Clinical Engineering Legislation is adopted, for example, the system will be used to issue alerts to the administration and manufacturers on which medical devices are approaching the time for calibration, maintenance or standard repairs. These operations will need to be logged, allowing authorities to ensure that they have actually taken place.

Allowing citizens to verify for themselves that a product is neither counterfeit nor being sold

in the wrong market location can help to raise consumer awareness of the risks posed by illicit trade and counterfeiting, and may also discourage the purchase of products online or via alternative distribution channels, where the same guarantees cannot be given.

1.6 Key challenges and concerns

Manufacturers and Logistics

There has been push back from Turkish SME's in the cosmetics sector ("which make for a significant portion of domestic producers" against the "no barcode, no market rule", asking for an exemption for them, since installing barcodes on their products will significantly raise their costs. They complain that this constitutes an unfair disadvantage for them since a significant part of cosmetics sales happens over the internet, under the counter and via door-to-door sales where the respect of the bar code obligation is much more difficult to control.

Public authorities

The resistance from the cosmetic sector's SMEs to joining the scheme poses a big challenge for the public authorities. It illustrates that better regulation and control of the official distribution channels is very important, but only part of the picture. Without government activities to crack down on alternative and illicit or grey-zone supply, channels such as internet and door-to-door sales, it is often an extra burden to brand owners, and only partially addresses the problem of illicit trade. Public authorities must succeed in closing down these supply routes or integrate such channels into the track and tracing obligations in order to audit and control them.

Customers

Another very important element in this is customer behaviour. Public authorities must continue to invest in campaigns to make customers aware of the role they can play in fighting counterfeit and faulty or dangerous products. Only if a significant proportion of customers make use of their smartphones to verify products and the incentive to buy non-authenticated products is removed, will the system makes any real difference.

III. Food and Agriculture

The basic principles for the EU's food safety policy are defined in the EU's General Food Law, adopted in 2002. Its general objectives are to facilitate the free trade of food across all EU countries by ensuring the same high level of consumer protection in all Member States. The EU food law deals with a wide range of issues related to food in general and food safety in particular, including food information and animal welfare. It covers all parts of the food chain from animal feed and food production to processing, storage, transport, import and export, as well as retail sales. This integrated approach means that all food and feed produced and sold in the EU can be traced from 'farm to fork' and that consumers are well informed on the content of their food.

On 15 March, the European Parliament reached an agreement with the EU Member States on a comprehensive overhaul of the existing EU legislation on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. This overhaul concentrates on the frequency and form in which public authorities should verify the integrity of the food chain and respect for animal health and welfare and food safety. It will expand the role of the existing Trade Control and Expert System (Traces System) from managing the data and information on animals and products of animal origin including official controls of all goods for which EU agri-food chain legislation has established specific requirements or practical arrangements for such controls. It also mandates the European Commission to set up and manage, in collaboration with the Member States, an Information management system for official controls (IMSOC), to exchange all relevant data in real time on controls performed by the Member States and which will integrate the existing Traces System. The details of the design of this new system will be defined in subsequent implementing acts.

Even under the new rules, the EU will not implement or impose an end-to-end cumulative traceability system for the full chain, but continue to use the principle of "one step back – one step forward" traceability, which provides information at the level of the immediate supplier and subsequent recipient, not at the level of the product's geographical origin. As such, existing traceability systems often do not gather all the product information that has accumulated through the supply chain ("cumulative traceability"), nor the geographical origin information which would be required for origin labelling purposes[8].

For honey, fresh fruit and vegetables, fish, unprocessed beef and beef products, olive oil, wine, eggs, imported poultry and spirit drinks specific origin labelling rules already exist inside the EU, requiring full traceability of the products.

A good example of the complexity of tracking and tracing in the food sector is therefore the tracking and tracing of meat products and poultry. Every day, many consignments of live animals and animal products are imported or traded in the EU. In order for these to be moved safely, strict procedures must be followed. All live animals and large quantities of animal products entering the EU must also be accompanied by a health certificate validated by an official vet, specifying that they fulfil the EU's basic

[8] In a recent survey of the Food Chain Evaluation Consortium less than a third of the sectors/Food Business Operators (FBOs) indicated that they practice traceability beyond 'one step back -one step forward', mostly in relation to existing voluntary quality assurance schemes; over three quarters (78%) of the sectors/FBOs indicated that the current traceability system is not suitable for origin labelling purposes and that significant adaptation or a total change of the system is needed.

animal health requirements. As part of the EU's traceability requirements, cattle, pigs, sheep and goats must be tagged with a lifetime identification number. This helps authorities and veterinary services to track their full movement history in the event of a disease outbreak.

The EU's Trade Control and Expert System (Traces) tracks live animals and food and feed of animal origin as they enter the EU and are traded within the EU. It links veterinary authorities across and outside the EU, and enables veterinary services and businesses to react swiftly when a health threat is discovered. Products can also be withdrawn from supermarket shelves quickly, if necessary.

1. GS1 standards for tracking of meat and poultry

Tracking and tracing of meat and poultry in the EU is the perfect illustration of the complexity of the technology in the food sector. Even without taking into account processed meat (like sausages, ham, salami…), no fewer than 14 different EU regulations govern different labelling and tracing requirements over the whole chain, going from the birth of the livestock, its fattening, slaughtering, processing, and eventual point of sale to the end consumer. GS1 Europe, specialised in setting common industry standards on tracking and tracing and data exchange, in 2015 published an "EU Meat and Poultry Traceability Implementation Guideline", to recommend how best to use the GS1 system in the sector to allow the exchange of data between stakeholders and the creation of a tightly connected information, flow of traceability data while adhering to the requirements of European and member states regulations.

1.1 Industry requirements

The different partners in the supply chain, from the importer of the meat, or the breeder of the animal, the farmer, the slaughterhouse, the processing plants, the distributor and the retailer all have legal obligations to follow under the different regulations that define which data they need to register and transfer. Since the BSE crisis in the beef industry, each beef product needs to be labelled with all required mandatory legal information, starting with half/quarter carcasses and continuing until the final consumer product at the point of sale. For this, several unique identifiers are used which need to be connected with all the relevant information, and need to be stored in the TRACES database.

Several EU regulations such as the Food Information Regulation and its implementing legislation, define the scope of mandatory labelling, with key elements required in "human readable" format for the end consumer (allergen information, expiry date, country of slaughter,etc.).

All actors in the chain are therefore best served by an efficient track-and-trace infrastructure which will provide safe, reliable and comprehensive information on the product to the partners in the supply chain, as well as to the end consumer.

1.2 System Requirements

Allow the exchange of relevant data between different actors in the supply chain according to the "one step forward – one step back principle", whilst ensuring that all necessary data are passed down along the whole supply chain.

The following data need to be reported:

- During the life of the animal: place and date of birth, batch/lot or serial number, place of fattening and fattening period, supplier ID batch/lot or serial number
- At slaughter: slaughter date and place, approval number, new product ID & new batch/lot or serial number for the part of the animal,
- At processing: production date and place, first freeze date (where appropriate), best before/expiry date, approval number, new product ID and

new batch/lot or serial number (for the processed product), ID of the processing unit.

- At wholesale and retail level: storing location, supplier ID, product ID, sales period

To allow for full chain visibility, GS1 recommends an information exchange based on EPCIS as an internationally recognized best practice. This requires a minimum barcode requirement of a) GTIN and a serial number or b) GTIN and a batch/lot number.
For the sharing of master data and allowing a swift exchange of data between partners in the supply chain based on common standards and data carriers, GS1 recommends the use of the Global Data Synchronisation Network (GSDN), which connects to the GS1 Global Registry.
To allow consumers to access the information in non-human readable format, GS1 suggests the use of GS1 Datamatrix and GS1 QR Code. By scanning this code by means of a smart phone or other connected device, the consumer could be referred to the data on the brand owner's website.

1.3 Business benefits and impact

By implementing a full track and trace solution, companies fulfil all their legal requirements under current legislation, and, by integrating the solution with their own supply management software, it gives companies a better view on their whole supply chain and possible opportunities for cost savings.
For all partners in the chain, the system also allows for a quick and orderly withdrawal of affected products from the supply chain, in case of a food alert.
There is also another clear benefit for retailers and brand owners. Since consumers attach more and more importance to the story behind their food, traceability from farm to fork allows promotion of local production, and makes it possible to put a premium on sustainable farming practices, which can all contribute to differentiating brands and building a strong brand identity.

1.4 Consumer benefits

As the European Commission stated in 2007: "The identification of the origin of feed and food ingredients and food sources is of prime importance for the protection of consumers, particularly when products are found to be faulty. Traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products." This of course significantly reduces the risk of health issues from contaminated product and poor handling of ingredients.

A full track and trace solution, documenting all steps in the production process, and clear labelling also provide the consumer with much more transparency on production methods and provenance, informing consumers' purchasing decisions based on more than price alone.

1.5 Public authorities benefits

By having a track and trace solution covering the whole value chain, authorities enjoy more transparency and an easier view on the provenance of products. This can help in targeted controls on production processes, respect for animal welfare and food quality. In the case of incidents, authorities can act quickly to reduce as far as possible the exposure of the general public to health risks.

IV. Wines and Spirits

In the European Union, the Regulation 1308/2013 of 17 December 2013, establishing a common organization of the markets in Agricultural products, lays out clear labelling rules for wine products. This is also connected to the control of their designation of origin or a protected geographical indication. Under Directive 89/396 on indication or marks identifying the lot to which the foodstuffs belong, there is an obligation on the economic operators (producer, manufacturer, packager) to identify the nature of the lot. Regulation 178/2002 on Traceability obliges these operators to have systems and procedures in place that make this information available to the competent authorities on their demand.

1. tesa VeoMark® and the tesa® connect & check online verification platform for the Saint-Emilion Wine Council

The wine and spirits market is one of the sectors most threatened by counterfeiting in France. All the vineyards – from the largest to the smallest – are concerned. Many châteaux have already adopted and implemented individual authentication measures for their wines. Thus, the more modest and less well-known producers often do not have the financial means to ensure traceability and to push counterfeits of their brand out of the market. The Saint-Emilion Wine Council therefore wanted to find a collective protection and traceability solution; one that could give all members the benefits of a mutual cost-sharing efficient, easy-to-implement and affordable solution thanks to economies of scale. The solution was tesa VeoMark® and the tesa® connect & check online verification platform from tesa scribos®.

1.1 Industry requirements

An efficient, easy-to-implement and affordable solution to enable authentication of products and traceability. to the solution must also counter the risk posed by counterfeiters “refilling” labelled bottles to avoid substitution or reuse of security features. The authentication feature needs to be easily consultable by end consumers and members of the distribution chain.

1.2 System Requirements

The unique identifier is encoded by means of a QR code integrated into an adhesive security label that either straddles the capsule and the bottle (to make the security feature tamper-proof and counter the risk of refilling) or is applied to the back label.

Participating wine growers buy the security labels from the Saint-Emilion Wine Council. They activate them via the Saint-Emilion Wine Council extranet and add all the details for the production batch at bottling such as product type, provenance, producer, production date and destination market.
Once the label is applied to the bottle, it is scanned by the producer and its code is activated in the central database. It is scanned at subsequent stages in the distribution chain by scanning the QR code on a smart phone and entering the security code. In case the code is validated by the online verification platform, the user gets a confirmation and is rerouted to the website of the Saint-Emilion Wine Council or the individual producer for all the product details.

Every time the product is authenticated, its location is also transmitted to the central database. Manufacturers can access all those data via the tesa® connect & check online verification platform, which also comprises has a grey market module, automatically raising an alarm if products are checked outside of their destined region. By making use of the GS1 standard, the platform can also be seamlessly integrated into existing distribution processes and identification systems, allowing for smooth interoperability of data.

1.3 Business benefits and Impact

By looking for a collective solution for their members, the Saint-Emilion Wine Council cannot only allow them to benefit from economies of scale, but also ensure that smaller producers can participate in a collective defence of the reputation and image of Saint-Emilion wines among customers in France and especially abroad. This will lead to higher sales and, by offering an easy authentication solution for customers, much less of these sales will be realised by counterfeit products, thus increasing producers income and the overall brand value of what they produce. The monitoring of grey market activity can help to detect diversions from the official distribution chain, which can be shared with public authorities.

1.4 Consumer benefits

Allowing consumers to verify for themselves whether they are buying a genuine product, protects them against counterfeit and buying products of inferior quality.

By referring consumers to the website of the Wine Council or the producer themselves, they can also be presented with additional background information and details on the wine, such as the story behind it, possible food pairings or promotions.

1.5 Public authorities benefits

The efforts undertaken by the wine sector to secure their distribution chain against the introduction of counterfeit and inferior wines, contributes positively to the image of France and French wines. It also helps to control legally imposed origin labelling obligations. Data collected by the producers themselves on possible diversion or grey market activity can help in identifying and combatting excise fraud. Customs officials and other officers can also make use of the smart phone application to do a quick initial check on the authenticity of a suspected consignment or cargo.

V. Tobacco

Tobacco products are one of the goods most affected by small and large scale illicit trade and counterfeiting, most often financing international and local criminal networks. According to Interpol, the illicit trade in cigarettes is the biggest illegal trade in a legal product in value terms, second only to illegal drugs in terms of revenue generated by smugglers.

Around 12% of the global cigarette market is estimated to be illicit. That is equivalent to some 660 billion cigarettes every year – costing governments more than USD 40bn in lost tax revenues every year. A wide range of measures have been taken by public authorities and enforcement agencies to contrast such traffic given its huge implication in terms of public security and finance. More recently at the EU level, specific requirements to combat the illegal trade in tobacco products based on a pan-European traceability and authentication framework to apply across the EU Member States have been introduced within the so called "Tobacco Products Directive" (TPD) adopted in 2014 (2014/40/EU).

The details for the implementation of the new system are being finalised with a view to apply from 2019. Articulated around an EU-wide tracking and tracing system for the legal supply chain, and a security feature composed of visible and invisible elements (e.g. holograms), the new measures will help law enforcement bodies, national authorities and consumers to detect illicit products.

While the EU legislation is not yet operational, a tobacco products Tracking and Tracing Proof of Concept has been implemented by tobacco manufacturer Heintz van Landewyck (HvL) in Luxembourg in 2015-2016. It uses a tracking and tracing system implemented by the independent technology provider WorldLine, enabling Luxembourg Customs to grant electronic licenses to authorized manufacturers such as the factory of the Luxembourgian manufacturer Heintz van Landwyck (HvL).

1.1. Industry requirements

In order to keep productivity at high level, HvL required a seamless integration and operation in a high speed manufacturing environment (up to 500 packs per minute). A reliable and robust solution was required, running on non-proprietary, from-the-shelve equipment (such as standard industrial printers and vision systems) that HvL could procure in a competitive market and deploy rapidly with the help of a systems integrator assisting from the manufacturing line down to wholesaler's shipments to retailers.

1.2. System Requirements

The systems architecture needed to control, in real-time, the generation of the unique identifiers to be borne by every cigarette packet as required by the TPD. This system has been integrated with the pre-existing Customs and Excise system.

Audited by Worldline, some of these systems provide Customs with permanent and electronic control of the unique identifiers printed on every cigarette packet, while some other components enable the aggregation between the individual packets and the related carton and master case. Once in the supply chain, plug and play tracking and tracing toolkits enable Luxembourgian wholesalers to track inbound and outbound movements of products.

Finally, anticipating a possible systems architecture to be established by the European Commission within the frame of the TPD, an Anti-Illicit Trade portal was required, providing Law Enforcement authorities with 24x7 access to any Track & Trace information available at the

participating manufacturers and distributors.

For this to be effective, it required the use of data carriers in line with international standards, such as AIM DotCode and GS1 DataMatrix, for the unique identifiers borne by cigarette packets, cartons and master cases. Their use enables the use of multiple off-the-shelf coding and reading equipment throughout the supply chain, from industrial printers and vision systems used for manufacturing (industrial printers and vision systems) to the scanners used by distributors and customs up to the last economic operator before retail.

1.3. Business benefits and impact

The overall approach based on open standards supporting effective interoperability and leaving the economic operators with the possibility to select the best fit-for-purpose technologies proved effective and efficient. HvL and the participating wholesalers were able to reach full compliance within a few months despite having no former hardware, software or knowledge of integrating such systems.

Furthermore, the use of the dot-code data carrier, in line with the GS1 EPCIS data exchange standards, the interfaces ensuring the communications between the systems running at the manufacturers, the distributors and the authorities enable every participant to operate the most appropriate technologies fit with its own specific constraints while guaranteeing a seamless interoperability.

Compliant with TPD requirements, the seamless integration of these technologies in the industrial environment enabled HvL to keep high productivity levels and proved that the requirements of TPD can be met by manufacturers large and small if such systems are allowed by the implementing acts.

1.4. Public authorities benefits

This project demonstrated to Luxembourgian authorities how it is possible to implement an architecture for tobacco track and trace that grants Customs with real-time control over the electronic generation of the unique identifiers as required by TPD and includes a central information system integrated with the existing systems used by their Customs and Excise Administration.

VI. Crop Products

The latest report[9] by the EU Intellectual Property Office (EUIPO) estimates that legitimate industry loses about €1.3 billion of revenue annually due to counterfeit pesticides, while 2,600 direct jobs are lost in the EU. Taking wider implications in account, the number of jobs lost could number as much as 11,700. When considering the knock-on effects on other industries and on government revenue, counterfeiting in this sector causes approximately €2.8 billion of lost sales to the EU economy.

1. Supply Chain Track & Trace for BASF Crop Protection

To fight counterfeiting of its products and to respond to current regulatory requirements on labelling in Europe and in certain member states, as well as anticipating new regulations around the globe, BASF, one of the leading Chemistry companies, has introduced its own Supply Chain Track and Trace (SCTT) for its crop protection products filling lines.

1.1 Industrial requirements

The system must be capable of showing and documenting the route the products take from the filling stage until they reach farmers. To achieve this, the product must be scanned at every stage of the supply chain and the data must be easily retrievable from a central database. It also needs to meet current European regulatory requirements and to conform with the industry-developed common CRISTAL standard (Communicating Reliable Information and Standards to Agriculture and Logistics) for tracking and tracing crop protection products and seeds.

1.2 System Requirements

The system generates a unique identification number (UID) in the form of a machine-readable data matrix code on the bottle or the label of the product. The code contains all relevant product information such as the GTIN and batch number, the production date and a unique alphanumeric identifier.

The code is scanned on the production line and at every subsequent step in the distribution line with the data being uploaded to a BASF database. Distributors and end consumers – in this case most often farmers – can verify the authenticity of the product by scanning the data matrix code with a smartphone app called “CPP Verifier”. The app displays the results directly out of the BASF data repository and shows whether the product label is valid, invalid or suspect.

To meet the regulatory requirements and ensure interoperability of the data, the SCTT is based on the global CRISTAL (Communicating Reliable Information and Standards to Agriculture and Logistics) standard supported by sector federations (European Crop Protection Association, Crop Life International) and global standardization organization GS1, on whose standards it is based. It also uses the UN/CEFACT standard to ensure consistency, sustainability and high flexibility in meeting specific needs. By imposing a common language, it allows all actors in the supply chain to exchange data. The CRISTAL standard is an open standard based on voluntary participation but with the commitment of industry to conform to it.

1.3 Business benefits and impact

Implementing this solution on their production lines allows BASF to gain a better insight where and when how a product pass down each step in the supply chain. It helps BASF to meet its legal requirements and to provide the necessary data accuracy to answer documentation requests from authorities.

[9] The economic cost of IPR infringement in the pesticides sector, EUIPO, February 2017

It can also contribute to improving supply chain agility from production to users, allowing for a more efficient management of product recalls and a reduction of product obsolescence along the supply chain.
Additionally, it helps to effectively combat product piracy or brand counterfeiting and protect the brand's reputation.

1.4 Consumer benefits

Allowing farmers to verify the authenticity of the product via the phone app, ensures that they are only using registered crop protection products, which enhances product safety and product stewardship. It equally ensures that they can grow healthy and marketable crops.

1.5 Public authorities benefits

Counterfeiting crop protection products involves a range of negative effects for farmers, end consumers and the environment. They can be significantly reduced by securing the distribution chain. The solution also fulfils the regulatory obligations and enhances the quality of data and reporting by the company, making it easier to conduct targeted inspections. The use of sector agreed and internationally recognized standards for data collections, contributes to its interoperability.

2. ScanTrust Secure 2D barcodes for seed bags

Standard 2D barcodes have no built-in security mechanism against copying, and therefore will fail to detect a simple photocopy. ScanTrust has invented a copy-sensitive 2D barcode (QR or datamatrix codes) that makes it possible to determine, with a simple scan via a smartphone, whether the product is an original print or a copy. The copy-sensitive barcode only requires standard printing mechanism to be transferred to the product or document to be protected, as the authentication relies on naturally occurring imperfections during the printing process which prevent the counterfeiter from perfectly reproducing an original 2D barcode.

In addition, the SaaS (Software as a Service) platform developed by ScanTrust records every scan event with associated information. It offers real-time traceability and business intelligence to monitor distribution channels & grey market activities.

This case-study presents the partnership between ScanTrust and Ramon Chozas, an Argentinian security printer, to develop a secure tracking and authentication solution for bags of seeds in Argentina. In 2017, 16.5 million labels will be applied to bags of seeds, the number of which may double in the coming years as the secure traceability scheme extends to other crops.

2.1 Industrial requirements

INASE, the National Seeds Institute of Argentina, has established the mandatory use of safety labels for certified seed of hybrid category of oilseeds and for soybean seed. Therefore, each bag of seeds must have a label that serves to prove that the bag is legal and that the relevant taxes have been paid.

To facilitate inspections, enable traceability of the seed bags across the industry, and detect counterfeiting attempts, the safety labels must contain a serialised QR Code with additional security levels against copying that can be verified by an inspector on the field. In this way, the INASE inspectors are able to validate the authenticity of the inspected seed wherever it is located, thus improving the control of the identity and correct labelling of the packaged seed.

2.2 System Requirements

INASE requires each safety label to have a QR Code which contains a unique and non-sequential serial number, making it possible to track and trace the product, to determine to which producer it was sold and on which

product it should be applied. Labels are shipped in reels with quantities that may vary according to the seed producer's need. In addition, the QR code has to demonstrate provable security against counterfeit attempts using variable and copy-sensitive security elements.

Inspectors equipped with a mobile phone must be able to verify the product traceability and authenticity on the field, using a dedicated INASE app. They do no not require additional equipment (such as optical adapter, special devices, etc.). As inspections often occur in remote areas without connectivity, offline authentication is required. Each of the 50 registered inspectors is provided a personal login, making it possible to verify access to the authentication device and monitor the activity of each inspector.

To offer true counterfeit protection, secure graphical elements are inserted in the QR Code at each printing, and are unique to each code. Such secure graphical elements are composed of high resolution structures which cannot be replicated without incurring a loss of details and information, even using a high resolution scanner and the same printer. Furthermore, the graphical elements are bound to the QR Codes and can be authenticated in real time during QR code scanning by inspectors. Authentication works even if there is no Internet connection, which is important because inspections often take place in remote areas with no connectivity.

INASE selected Ramon Chozas to manage all aspects of the system, including safety label production, shipping of reels according to order requests, management of IT infrastructure, secure management of serial numbers, authentication app installation and distribution, management of inspector logins, and storage and visualisation of scan data.

2.3 Business benefits and Impact

The system allows efficient and reliable collection of royalties, and makes the illicit use of seeds easier to detect. This is advantageous for both seed producers and farmers, as it reduces overhead, and eliminates inefficiencies and unfair competition.

2.4 Public authorities benefits

The secure traceability system legitimates the authority of the State in ensuring that intellectual property is respected, and ensures it can collect royalties efficiently. Inspectors can control seed bags and receive feedback in real-time about the product's authenticity. Every scan made by inspectors is geo-located and can be visualized in a dashboard together with associated information (authenticity of type of product scanned, inspector login, etc.). Real-time monitoring of the market is therefore ensured, and if a scan indicates a counterfeit or other issue, an alert can be automatically sent to authorized recipients.

VI. Textiles / clothing

Textiles encompass a wide range of products where tracking, tracing and authentication has been introduced mainly by brand owners for different purposes ranging from quality control and sustainable sourcing to combatting counterfeiting and protecting consumers from fraud.

1. Circular Content Management System (CCMS) for work wear by Dutch aWEARness

An interesting example of tracking and tracing in textile supply chain is CCMS by Dutch aWEARness.

This company has partnered with several manufacturers of workwear, NGOs and IT providers to develop workwear that integrates eco-effective textile innovations. It has developed a full service model for the textile industry, monitored by CCMS, a circular track and trace system in which all the partners in the supply chain are involved. The aim is to develop workwear and corporate wear designed to be reused and offer circular solutions for workwear that cannot be recycled on the same level.

1.1 Industrial requirements

In order to create a full circular solution, all raw materials and products need to be identified and tracked and traced through every stage of development. The exact composition of all clothing items also needs to be encoded to allow for effective recycling. This means that all this data need to be encoded on a unique identifier which needs to be tracked and traced at all stages of the production process.

1.2 System Requirements

As Unique Identifier, the system uses unique bar codes, which are scanned to a central database. This, in turn, operates the track and trace system, and is also used as a purchasing and inventory management tool, with a life cycle analysis of the materials and basis information about the materials used and their possible reuse.

The following steps in the circular process are monitored as data points at which events are tracked: shredding of the collected materials, melting of the materials, making yarns, weaving, interviewing clients on what items he wants to use, preparation of the order, production, customisation of the order, delivery to the customer, collection from the customer for recycling.
Hand-held devices are used for scanning the CR code and consulting the central database to discern provenance and composition of the garments.

1.3 Business benefits and Impact

The CCMS system allows the companies to make the best use of resources by designing for sustainability and ensuring recyclability from the start. This is also a guarantee for the customers that the workwear they lease is indeed ethically produced and sustainably sourced.
The project is also being used as a market test validation for a new circular business model in which workwear is no longer bought by companies, but leased, allowing for efficient organisation of the collections. The plan of the companies involved is to translate this circular business model to other industries and value chains.

1.4 Customer benefits

The complete tracking and tracing of the whole lifecycle of the products reassures customers on the ethical sourcing and sustainable production of the work wear they lease. It also reassures the consumer that they are leasing genuine products that have undergone all necessary quality controls. The system also allows for the concept of leasing work wear, reducing waste for the customers and shifting the onus of recycling onto the provider.

1.5 Public authorities benefits

At a time when circular economy, sustainable production and waste reduction are top priorities for political decision makers at all

levels, the intelligent use of tracking and tracing technology by industries can contribute to building Circular Economy business models.

2. ViseQR

Several solution providers offer high-tech security features that brand owners can use for authentication purposes in the fight against counterfeit. These security features often involve the active involvement of the end consumer, who can verify that he is buying a genuine product and its provenance via a handheld device or smartphone. One example of such technology is ViseQR by ViDiTrust.

2.1 Industrial requirements

To reassure customers that they are buying genuine products and to allow brand owners to keep track of where their products are, clothing items need to be equipped with a security feature that is easily attached or integrated into the clothing and cannot be counterfeited or copied. Verification of authenticity should be done. To allow for the tracking of clothing and its authentication along the distribution chain and by final customers, a simple smartphone based solution is needed to conduct instant verification of authenticity.

2.2 System Requirements

The ViseQR technology is used to define the smart print design and print modelling on the production line. It also controls the redirect service to the company website or any other actions that the brand owners want to occur each time the smart stamp is scanned on a smart phone or hand held device . By integrating the common technology of optical reading with proprietary technology that combines the public information present in the bar code with information invisible to the human eye. a unique stamp image is generated for every product, which is added to the label or tag of the garment during the production process. Once this is done, the smart stamp is scanned on the production line and activated. The data are sent to a cloud-based database, which can be consulted by the brand owner.

Using an application available compatible with most Android and iOS handheld devices and smartphones equipped with a 5mpx camera, end customers and other actors in the supply chain can authenticate the product. If activated on the device, the product is also geo-referenced making it possible to track the location of the product at the time of scanning.

2.3 Business benefits and Impact

By providing the end consumer and other actors in the distribution chain with an easy way of checking the authenticity of the product they buy, brand owners can significantly reduce the risk of counterfeit products being sold to unwitting customers. Geo-referencing of data could also signal locations where counterfeiters attempt to introduce a high number of counterfeit products are into the genuine distribution chain. This can be important if the company or brand wants to further investigate, alert the public authorities or take legal action to safeguard their intellectual property rights.

2.4 Consumer benefits

By being able to verify on a smartphone the authenticity of an item before buying it, consumers are in a much better position to avoid being sold fake merchandise, which is often made of inferior quality materials and design.

2.5 Public authorities benefits

Technological solutions provided by brand owners which allow end consumers to easily verify if they are buying a genuine product or not, help raise consumer awareness and bring citizens on board as allies in the fight against illicit trade rather than just victims of it. Data gathered by brand owners and shared with public authorities on high concentrations and occurrences of counterfeit products can help public authorities to further investigate and take action on dismantling the criminal networks fuelling the illicit trade.

VII. Jewellery

As high value, easily portable goods, jewellery and diamonds face multiple challenges going from ethical sourcing, to fake products and the resale of stolen goods.

The sector itself and individual brand owners concerned with protecting their reputation and brands have therefore undertaken many initiatives from self-regulation to collaboration with public authorities, NGOs and international organisations. An example of this self-regulation in collaboration with other stakeholders is the Kimberly process as part of the fight to stem the flood of so-called “blood diamonds” coming from conflict zones.

1. TrackMatriX, a full tracking and tracing system

Several brand owners are also calling on solution providers to offer full tracking, tracing and authentication services to assist them in their own fight against counterfeit, usually in combination with the use of visible and invisible security features. An example of such a system is TrackMatriX, developed by NanoMatriX.

1.1 Industrial requirements

In order to better control the movement of their product through the supply chain, every product must be given a unique code, which can be easily scanned at different steps in the supply chain and can be used by the consumer to verify the authenticity of the product.
Given the importance of design in jewellery items, companies are looking for unique identifiers and invisible and/or hidden security features which can be integrated to either the product itself in a non-obtrusive way or on the packaging in a secure and tamper-proof way.

1.2 System Requirements

The system generates a unique identification number (UID) in the form of a QR code hyperlink or other 2D bar code, usually applied to the outer packaging of the product, together with visible and tamper-proof security features to ensure package integrity. The 2D bar code is scanned by logistics personnel at every step in the distribution process, allowing tracking and tracing of the product by logistics and brand owners.

All tracking data on the product is sent in real time to a central TrackMatriX cloud-based database that generates regular reports for the brand owners, but can also be consulted in real time by the brand owners via a web-based reporting portal.
The unique identifier can also be scanned by consumers via their smartphone to authenticate the product. Where invisible security features such as laser coding substrates and odour or digital watermarks are added to the product, they can be used by the brand owners to determine whether or not seized or suspect goods are indeed authentic or counterfeit.

1.3 Business benefits and Impact

Installing a full tracking, tracing and authentication system makes the introduction of counterfeit products in to the regular distribution chain almost impossible. It also makes it easy to detect where any counterfeiting is done and by whom. Access to the web-based reporting portal means this can be done in real time.
Enabling the consumer to actively verify the authenticity of the products they buy helps reassure them and helps defend the brand reputation. This also allows companies to actively engage with their customers via the app used to verify the product.

1.4 Consumer benefits

Allowing consumers to verify for themselves on their smartphone if they are indeed buying an authentic product is an attractive option for the average consumer in particular for high value items such as jewellery (often made from precious metals).It is also an extra guarantee for them that they are not being sold stolen goods and that they are buying ethically sourced products. Where the

unique identifier is incorporated into the jewellery itself, it could in future also be used in the identification of stolen goods and their rightful return to their owners when found.

1.5 Public authorities benefits

Efforts undertaken by brand owners to secure their own regular distribution chain make it more difficult for criminal organisations to abuse official sales routes for fencing stolen goods or to introduce counterfeit goods.

VIII. Automotive, Aeronautics and Electronic Industries

The automobile, aeronautics and electronic industries have long battled the serious problem of counterfeit parts being introduced in the supply and production chains. Since these products are often of inferior quality, they can lead to product malfunctions resulting in serious injuries and even death for consumers as well as engaging personal liability for the manufacturers in case of insufficient safeguards and controls on their supply chain. This has led many leading companies in these sectors implementing their own tracking and tracing systems, with a special emphasis on authentication to avoid counterfeit goods entering their production and distribution chains.

1. X'Track and Signoptic™

To allow for digital authentication and tracking and tracing of spare parts and components, leading companies in the sector use the track and trace system X'Track in combination with the digital authentication tool Signoptic™, both developed by ArjoSolutions.

1.1 Industrial requirements

Manufacturers and customers need to be certain that the parts they use on the assembly line or in stock are genuine.
Part of the solution is for the manufacturers and vendors of these parts to implement an extensive track and tracing system of their products based on a unique identifier. But to offer complete assurance to their customers, this needs to be coupled with an authentication feature that cannot be counterfeited. Given the high speed production lines on which many of these products are manufactured, this must happen without affecting production speed and ideally without affecting the substance of the product or the existing packaging.

1.2 System Requirements

For the purposes of tracking and tracing, X'track uses serialization to generate unique identifier codes during production, directly on the product manufacturing line in real time. Each code includes data relating to manufacture (date, time, location, etc.) and also data intrinsic to the product that is marked. To ensure interoperability with other systems, the X'track codes comply with GS1 standards. They can also be applied to any product, regardless of the production environment. To meet the requirements of high speed production, the system can generate up to 1,000 unique codes per minute. The marking of the codes can be done by either using a human-readable code (alphanumeric characters) and/or a machine readable code (Datamatrix, QR Codes, Dot Codeetc.) and can be protected by special, dedicated printing solutions.

Signoptic™ uses the texture of a product itself to generate a unique signature. Because the signature is generated from non-duplicable aspects of the product itself, it allows both identification and authentication. It can be used directly on the product (primary packaging), at the packaging level (secondary packaging) or directly on labels. During manufacturing, each product passes through the Signoptic™ system at the pace of the production line. This process records the product's unique Signoptic™ signature and any visible code carried by the product (traceability code, 2/5, Datamatrix, QR codes, etc.).

This unique pairing of "signature and visible code is recorded in a central X'track T&T database. At this stage, according to the needs of the manufacturer, industry or regulatory authorities, an unlimited amount of additional data may be associated with these two identifiers in the database such as country of destination, distributor, etc. In addition, an online aggregation module is provided to allow detailed traceability of the product, even when it is wrapped in several levels of packaging (product – box – pallet). This can reduce the strain on companies

internal IT networks, by compressing the amount of data to be transferred.

To allow the track and trace platform to communicate with other systems inside and outside the company, it meets EPICS standards as defined by GS1 to track events, locations and movements of products in the supply chain. Product movements are encoded via portable readers throughout the supply chain and can be monitored by brand inspectors and consumers/customers via X'track Control, a mobile and web platform, by querying the codes on a mobile device.

To authenticate a product, a dedicated reader embedding the technology is used to extract the Signoptic™ signature. A query is made on the database with the signature extracted by the device as an input. The output of the query is a binary result (Genuine or Fake) and the visible code that was printed on the product at the "Enrolment" stage. Each authentication is logged. Consumers can do this by making use of "SAFE" (Signoptic® Authentication For Everyone), a smart phone application. Brand experts and logistic providers can either use smartphones, combined with a dedicated Add-On (shell) or dedicated hand held devices to perform authentication operations both on and off line.

1.3 Business benefits and Impact

By taking into account the high speed/high volume production environment of components and spare parts from the start, the TT&A solutions are designed around this production process, which has a significant impact on the cost of implementing the system. The technology is not limited to a specific sector or product category and by using internationally recognized standards for data coding and logging of events, it can easily communicate with other systems inside and outside the company. The product-neutral nature of the solutions also means that the verification app and scanning devices can be used by the distribution sector and customers for multiple products from different sectors, eliminating complexity. The system allows full transparency for manufacturers of the parts and their customers in industry on the chain of custody of the goods and their provenance. The use of authentication based on the physical properties of the product itself makes it extremely difficult to introduce counterfeit products into the production chain. Given the size of the problem and the potentially disastrous consequences of the introduction of low quality parts into critical airplane or car systems, it is also very important to defend brand reputation and shield producers from liability claims.

1.4 Consumer benefits

Since faulty parts can lead to serious malfunctions of products and endanger the integrity and health of consumers, the benefits of the efforts undertaken by industry to avoid counterfeit components entering the production and distribution chain are self-evident. The option of verifying the origin and authenticity of the product by smart phone or web portal is also an important bonus.

Neither technology is product-specific and both use internationally recognized standards which means that the Signoptic™ technology can also be used in other sectors such as perfumes and cosmetics, wines and spirits and the pharmaceutical industry. This means that customers can use the same application on their smart phone to verify different products and do not need to download a dedicated app for every type of product, which could form a huge barrier for customer involvement.

1.5 Public authorities benefits

The initiatives taken by the industry itself to secure its supply and production chain against the introduction of counterfeit parts of inferior quality are very important in reducing mechanical failures or incidents. In the areas of defence and public transport, the public authorities are often the end customers, directly responsible for the safe operation of equipment. The discovery of the presence of faulty parts by industry can also help them in their investigations into criminal networks involved in these activities.

Key challenges and concerns

For Manufacturers and Intermediaries

The purpose of T&T systems is to monitor product movements and changes in ownership throughout the supply chain. This information can only be provided by economic operators handling distribution and administrative accounting procedures in warehouses.

T&T systems should not duplicate, but complement and be compatible with established systems and procedures. Moreover, a business-friendly system would provide an opportunity to leverage data mining and insights on production, distribution and product life-cycle.

“Unique identifiers” are an enabling tool rather than the objective of a T&T system. Meanwhile data carriers become crucial in the context of mass production of goods requiring high-speed manufacture, to avoid disruption in the supply chain.

A clear distinction should be made between system operation and independent control. The identification and operation of the most appropriate system should remain with manufacturers and other economic operators involved. Beyond the internal checks carried out by the economic operator, independent third-party checks should be conducted by public authorities or by agreed bodies authorised by public authorities.

Given the commercial sensitivity and the liability in case of technical failures, stored data should be considered confidential and owned by the manufacturer or brand owner where data is stored locally. This data should only be accessible to certified third-parties such as auditors, law enforcement and public authorities under strict conditions.

Any selected standard for track and trace or authentication features should be an open specification that allow systems that use a range of familiar and proven technology platforms and solutions. Reliance on one or a small selection of solution suppliers will increase the risk of delays in the deployment and effectiveness of any selected TT&A system.

Avoidance of redundant complexity and costs should be built into the design of all track and trace systems from system inception to system management. Such systems must take into account the value of the products they protect and guarantee a level playing field for operators so that the investment required of the operators does not act as a discriminatory barrier for SMEs.

Visible security features can add significant cost, are restricted in supply availability and require education of end users in order to be effective tools against counterfeiting. When overt features are used, the experience is often that counterfeiters will apply a simple copy which mimics the genuine device and confuses the average consumer. These features also require utmost security in supply, handling and disposal procedures to avoid unauthorized diversion. They should be applied in such a way that they cannot be reused or removed without being defaced or causing damage to the package – otherwise components used on genuine products may be recycled with

fake contents, thus giving the false impression of product authenticity. Any overt security feature should therefore be accompanied by a tamper evident feature for added security.

For Public authorities

Public authorities and regulators have a critical role to play in supporting the development of relevant technological architectures to guarantee interoperability across different technological platforms, geographies and industry sectors.

The selection of relevant technologies for TT&A should be left to the economic operators of the supply chain, in compliance with technical standards agreed by public authorities or international standard setting bodies.

For regulated products and processes, non-compliance by economic operators should be clearly sanctioned and associated with proportionate penalties as a deterrent against the non-implementation of the statutory requirements in TT&A.

Regulating and monitoring the regular supply chain and manufacturers can have a significant impact on securing official distribution channels against the introduction of counterfeit products. However this is not sufficient to fight illicit trade and counterfeit. As the "Serious and Organised Crime Threat Assessment 2017" (SOCTA 2017) by Europol shows, this also moves the battleground for public authorities to fighting illegal online and alternative distribution channels which are increasingly used to distribute counterfeit products[10]. A broader and bolder approach is required to ensure consumer involvement and a change in consumer mindset. Communication campaigns targeting the general public and alerting them to the dangers and health risks of buying products via unregulated channels or non-controlled online platforms have so far had limited success. There is a need to continue to raise public awareness on the criminal and terrorist networks which are fuelling and being financed by illicit trade and counterfeiting. However, the design of new, original communication strategies and tools should be explored more thoroughly in order to focus more on grassroots consumer engagement rather than the traditional one-way information messaging that has been deployed up until now. The EU, notably in cooperation with other international organizations such as OECD, WCO and WTO could develop a public-private initiative targeting consumer engagement.

For Consumers

The constant development of smartphone technology should be leveraged by brand owners to empower consumers and ensure their buy-in in the fight against illicit trade and counterfeiting.

A lot of the technological solutions in non-regulated industries try to actively involve consumers by allowing them to use their smart phones to verify for themselves the authenticity of the products they buy. This can be a very important way to raise customer awareness of the problems and help them to make informed purchasing decisions. The effectiveness of this also depends on the ease of use of the applications. Customers will be very reluctant to do this if they have to sign up to a multitude of different applications on a product by product basis in order to be able to verify

[10] Crime in the Age of Technology, Serious and Organised Crime Threat Assessment (SOCTA) 2017, Europol, 9 March 2017

authenticity. Proprietary solution providers should look at how to develop common verification interfaces and apps for end-customers.

Another issue is public attitude and social acceptance of certain forms of illicit trade. As the latest RUSI "On Tap Europe study"[11] points out: "Purchasing illicit tobacco or alcohol is too often seen as a minor, victimless crime, even perhaps as a small victory over the tax agency and government, which are perceived as responsible for high prices in the legitimate market. Moreover, consumers rarely recognise the link to organised crime, as highlighted by research conducted on behalf of the European Commission: when asked about the most important revenue sources for Organised Crime Groups, almost 70% of respondents cited illegal drugs, but less than 15% suggested illicit tobacco[12]".

In the case of illicit pharmaceutical products, beyond price, social embarrassment or the fear of not getting the prescription medicine can also drive consumers to illicit sources, according to RUSI's findings. But in both cases, there seems to be a clear disconnect between law enforcement agencies who recognize illicit trade as an important part of organized crime activity and the public perception that it is a minor, victimless crime. This social acceptability needs to be addressed and tackled to reduce consumer demand and create a more hostile environment for criminal networks who seek to sell illicit goods.

Policy recommendations

The operational experience and learning on the ground across industries and products suggests that public authorities at the national and international level, when designing policy and enforcement strategies or statutory requirements, should take the following points into consideration:

- Identifying methodological standards for applying TT&A to production-supply chain processes, although these may be product-specific.
- Defining technical standards only for basic elements of the TT&A process.
- Applying defined standards uniformly to the products to be tracked, traced and authenticated.
- Supporting, or at least encouraging, producers and supply chain operators to select the most appropriate technologies to fulfil TT&A standards, which best fit their respective industrial environments.
- Allowing outsourcing of the TT&A applications to "certified" third parties.
- Promoting competition and innovation through the establishment of an accreditation/certification mechanism for systems deemed compliant with the regulatory requirements or the internationally agreed standards both for the provision of data and technical standards, irrespective of the technology providers.

[11] On Tap Europe : Organised Crime and Illicit Trade in Tobacco, Alcohol and Pharmaceuticals, RUSI, 23 march 2017

[12] European Commission, 'Special Eurobarometer 443: Public Perception of Illicit Tobacco Trade', July 2016, p. 17.

- Promoting overarching technological architectures, which would enable interoperability across technological platforms, geographies and industry sectors.

- Assessing and benchmarking the cost effectiveness of optional solutions taking into account the value of the products they “protect” and the industry specific objectives in tracking and tracing.

- Considering the affordability of initial TT&A investments required for every company and operator in a given industry and market sector, with a view to avoid discriminatory entry barriers for companies due to lack of investment capabilities.

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