

Aggregation

Solutions for the Traceability of Products



Contents

- | | |
|----|--|
| 1 | Counterfeit Goods Are on the Rise |
| 2 | Counterfeit Pharmaceuticals |
| 3 | Safety First – Safety Requires Rules and Expertise |
| 4 | How to Implement Full Traceability with Aggregation |
| 5 | Marking, Verifying, Safeguarding – From Cartons to Pallets |
| 6 | Secure Storage of Production Data is Crucial |
| 7 | Solutions – Maximum Possible Safety |
| 8 | Performance – the Expert Partner for Track & Trace Systems |
| 9 | Aggregation Outside the Pharmaceutical Industry |
| 10 | Outlook – the World of Track & Trace is Evolving |
| 11 | References |



1 Counterfeit Goods Are on the Rise

Counterfeiting and illicit trade are a growing problem. Customs authorities across the EU seized an estimated five million more counterfeit items in 2015 compared to the previous year, according to figures released by the European Commission in September 2016. More than 40 million products were detained by EU customs in 2015, with an estimated value of nearly US\$650 million¹.

Cigarettes remain the top category (27%) of goods detained, while food and beverages, toiletries, medicines, toys and household electrical goods account jointly for 25.8% of the total¹.

A report by the Organization for Economic Co-operation and Development (OECD) reaffirms a number of trends that have been evident for more than a decade: almost all brands are being counterfeited, and counterfeit or pirated products originate from economies across all continents, with China remaining the largest producing economy. It also indicates counterfeiters are improving their logistics networks, manipulating transit routes, exploiting governance gaps and taking advantage of the growth in online shopping².

2 Counterfeit Pharmaceuticals

Counterfeit medicines are now a worldwide problem. According to some estimates, more than 10 percent of all drugs in the global supply chain are counterfeit and, in some countries, fake pharmaceuticals account for 70 percent of all drugs in the supply chain³.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) reports that, in one week in June 2013, more than one million doses of illegal medicine worth approximately £2 million were seized in the UK. The UK has also seen an increase in counterfeit medical products, particularly within the medical device sector. The Compliance and Enforcement Manager at the MHRA, Bruce Petrie, had this to say: "These products seriously undermine the safety and quality of the devices and pose a serious danger to patients."

This is far from merely a British problem; the market for counterfeit goods has exploded in other countries across the globe as well. In 2014, Pfizer estimated 60 of their products had counterfeit versions available, up from 20 products in 2008. On multiple occasions, pharmacies have been caught selling off pharmaceuticals on the black market, reporting them as legitimate distribution and billing insurance companies for the expense. Counterfeit medicines are a major threat to public health and safety and have been responsible for thousands of deaths worldwide. In addition, companies are seeing their reputations damaged and their revenues stolen.

The last five years have seen world governments take action in order to combat the increase in counterfeit pharmaceuticals and better safeguard consumers. The European Union, China, Brazil, Turkey, China and the United States have all drafted (and in most cases, implemented) regulations implementing requirements for supply chain visibility.

3 Safety First – Safety Requires Rules and Expertise

As the world faces a persistent and increasing threat from counterfeit medicines, most market players agree that the best solution is the securing of the supply chain. Track & Trace in the form of the clear inspection and tracing of medicines across all stages of manufacturing and packaging is a decisive instrument for increasing quality, safety and trust.

Transparent documentation and data management is a fundamental requirement. Due to the international value-added chains within the pharmaceutical industry, an internationally uniform procedure would be desirable. In reality the situation is quite different: the requirements placed on the consistent monitoring of pharmaceutical products are subject to different regulations and country-specific provisions. In addition, the technological equipment used by manufacturing plants varies.

The EU's Falsified Medicine Directive (EUFMD) comes into force in February 2019 and contains initiatives aimed at protecting both the supply chain and patients. The Directive requires all prescription-only medicines to contain a unique serial number in the form of a datamatrix code, barcode or RFID code and Human Readable Text (HRT). This will enable pharmacists to check, at the point of issue, the source of a product. These codes would be assigned to each individual unit - for example, each box of blister pills in a case would have its own unique identification number.

The requirement for medicines to be easily traceable is not restricted to Europe. A number of institutions worldwide are calling for the same procedures. For example, in the US, the Drug Supply Chain Security Act (DSCSA) requires carton and case serialization from 2017. According to industry specialist Tracelink, by the end of 2018 more than 75% of the globe's prescription medications will have legislation covering traceability and tamper protection⁴.

4 How to Implement Full Traceability with Aggregation

Serialization as required in the EU and US enables the verification of a product's uniqueness by comparing it with an entry in the relevant database. However, if serialized products are packed in higher level packaging formats up to pallets with no marking of the higher level package units, it can be more difficult to precisely track the movements of a given package through each step of the supply chain. It is still possible, of course, but it requires each individual package to be scanned at each stop along the way.

Different methods of tracking products exist. In the simplest case, each person in the supply chain documents the movement of goods themselves. Aggregating codes together allows for faster and easier tracking - each package no longer needs to be scanned at each stop as long as the aggregated code is scanned. This also increases process security, as larger containers can remain sealed until they reach their ultimate destination.

The ultimate goal is to have a complete Track & Trace system in place involving everyone in the supply chain. Each step scans a product's code and transmits the data to the next member in the chain. Integrated Track & Trace solutions provide supply chain transparency by ensuring that a product can be traced right back to where it was manufactured and the channels it went through before reaching the consumer from the point of sale or dispensation. The end-to-end solution involves information distribution via a central server which allows the product to be verified at all times. Corporate, national or even transnational databases can act as a central point of reference.

4.1 The Critical Element: the Code

The basic requirement for reliable traceability is a unique code on every product that contains the necessary and prescribed information. At the folding box level, two-dimensional datamatrix codes are the usual method of serialization. Aggregation utilizes one-dimensional barcodes at the secondary packaging level and upwards, as they offer a larger print field.

4.2 Codes and Markings are What Tip the Scales - The World of Barcodes

Linear barcodes are the globally recognized data carrier for Aggregation. In 2009, the Global Trade Item Number (GTIN) replaced the European Article Number (EAN) and along with the Universal Product Code (UPC) became the recognized standards in ISO/IEC 15420, making internationally unique allocation possible. Nevertheless manufacturers can also define their own barcodes. Barcodes may be in ITF-14, GTIN/UPC or, when additional item data is needed, a GS1-128 barcode format.

The Serial Shipping Container Code (SSCC) is the GS1 Identification Key used to identify cartons. It is comprised of an Extension Digit, a GS1 Company Prefix, a Serial Reference, and a Check Digit. A bundle can be any combination of cartons put together in a case or on a pallet where the specific unit load needs to be managed throughout the supply chain. The SSCC will identify any carton uniquely, ensuring that it is always identified correctly anywhere in the world. Combined with GS1 Standards for electronic messaging, the SSCC Code facilitates simple tracking of goods from the carton level all the way up to pallet level.

An overview of the global pharmaceutical industry indicates the various different statutory regulations and their further development will require yet more adaptations to manufacturing plants and basic software requirements for Track & Trace. This is the only way to implement Aggregation successfully across all packaging levels.

With regards to future-proofing Track & Trace systems against upcoming requirements, internationally represented providers have the edge due to experience gained in various different countries.

The following table goes into the particulars of the information that must be stored on a given pharmaceutical product, arranged by deadline. Some of these regulations are already in effect, while others are still being drafted:

Country	Deadline	Serialization	Aggregation
Turkey	2010 - Serialization and Aggregation	<ul style="list-style-type: none"> Packaging Level: Secondary Data Elements: GTIN, Expiry Date, Serial Number, Batch/Lot Number Data Carrier: DataMatrix (GS1) 	Mandatory <ul style="list-style-type: none"> Packaging Level: Tertiary Data Elements: GTIN, batch number, expiry date, serial number (SSCC-18 digit)
Argentina	Deadlines for Serialization vary depending on product class - 2011, 2012, 2013, 2015	<ul style="list-style-type: none"> Packaging Level: Secondary Data Elements: GTIN, Serial number Data Carrier: GS1-128, DataMatrix, RFID Tag (GS1) 	Not Applicable
China	2015 - Serialization and Aggregation	<ul style="list-style-type: none"> Packaging Level: Secondary packaging and cases/carton Data Elements: National product code consisting of: country code, drug category code, drug identification code, check code (14 digits total) 	Mandatory <ul style="list-style-type: none"> Packaging Level: Tertiary Data Elements: Batch number, expiry date, serial number (20 digit) Data Carrier: 1D linear barcode (not GS1 compliant)
South Korea	2015 - Serialization and Aggregation	<ul style="list-style-type: none"> Packaging Level: Secondary Data Elements: NTIN, Batch/Lot number, Expiry date, Serial number Data Carrier: Data Matrix GS1-128 (GS1) 	Not Mandatory: Aggregation is voluntary but encouraged by regulators and strongly requested by supply chain partners. <ul style="list-style-type: none"> Packaging Level: Tertiary Data Elements: GTIN, batch number, expiry date, serial number (SSCC-18 digit) Data Carrier: 1D linear barcode (GS1)

India	2015 - Serialization and Aggregation	<ul style="list-style-type: none"> • Packaging Level: Case/shipper, secondary packaging, primary packaging (exempted till further notice) • Data Elements: GTIN, Batch/Lot number, Expiry date, Serial number • Data Carrier: GS1-128, DataMatrix 	Mandatory <ul style="list-style-type: none"> • Packaging Level: Tertiary • Data Elements: GTIN, batch number, expiry date, serial number (SSCC-18 digit) • Data Carrier: 1D linear barcode (GS1)
USA	2017 - Serialization 2023 - Aggregation (expected)	Item Serialization <ul style="list-style-type: none"> • Packaging Level: Secondary • Data Elements: NTIN, Expiry Date, Batch/Lot Number, Serial Number • Data Carrier: 2D DataMatrix (GS1) Case Serialization <ul style="list-style-type: none"> • Packaging Level: Tertiary • Data Elements: NTIN, Expiry Date, Batch/Lot Number, Serial Number (SSCC - 18 digit) • Data Carrier: 1D Code (GS1) 	US wholesalers and distributors expect Aggregation for supply chain optimization reasons independent from legal regulations, so most pharmaceutical manufacturers plan to implement Aggregation with serialization in 2017
EU Falsified Medicine Directive	2019 - Serialization	<ul style="list-style-type: none"> • Packaging Level: Secondary • Data Elements: GTIN, Serial number, National Reimbursement Number (if applicable) • Data Carrier: DataMatrix (possible QR for marketing purposes) (GS1) 	Not Applicable
Brazil	Timeline under discussion. AN-VISA planning public consultation Q1 2017	<ul style="list-style-type: none"> • Packaging Level: Secondary • Data Elements: ANVISA Number, Expiry Date, Batch/Lot number, Serial Number (GS1) • Data Carrier: DataMatrix 	Not Defined

5 Marking, Verifying, Safeguarding – From Cartons to Pallets

Counterfeiting and fraud can only be eliminated if a product can be seamlessly traced right back to its manufacturer from every point in the logistics chain. Comprehensive solutions designed to ensure patient safety through greater transparency in pharmaceutical logistics are becoming increasingly important. Although approaches differ from country to country and continent to continent, the ultimate objective is clear: **tracking the product's complete journey from the manufacturer via national and international trade chains to pharmacists.**

Serialization begins at the lowest level of packaging (i.e. the individual carton, box or bottle). The serialized packages are then packed into a shipping case which, in an Aggregation scenario, will be given its own code. This code links all the numbers for each individual package in the case - this is the essence of Aggregation. This process may repeat over several packaging levels - starting at the carton level and continuing through to foiled bundles, shipping cases and pallet; i.e. six cartons bundled (children) placed in a case (parent), 12 cases on a pallet, etc.

Aggregation defines the data relationship between the parent and child, and allows the product's receiver to scan one code and understand exactly which serial numbers are in the whole shipment, i.e. which numbers are in every case, bundle, or individual carton. This makes tracing products through each step of the supply chain much simpler - a scan of the top-level code registers each individual package. This in turn means that should one of those individual products show up elsewhere, it has been either stolen or counterfeited. It is possible, of course, to do this without parent codes, but that would require individually checking in each package in a shipment.

6 Secure Storage of Production Data is Crucial

An efficient and cost-oriented Serialization/Aggregation solution ensures that multiple lines are connected to a central database. A central server forwards all device data to the standard SQL database, ensuring secure archiving. This data pool later provides the basis for creating corresponding reports and logs. This makes it easy to meet both official and in-house requirements. The use of industrial standards such as Java and SQL facilitates the integration of various different solutions in existing customer IT structures. Linking to existing „back-end“ systems such as ERP, MES or cloud systems is possible via standardized interfaces, providing the solution provider can demonstrate they have the necessary experience.

For complete e-pedigree verification, each part of the supply chain is also required to pass along the information regarding the respective intermediary to the next dealer/reseller. This allows seamless tracing of the product's route to the end consumer. For the end-to-end solution, only the producer reports to a central server. The intermediary stages are not taken into account which means it is only possible to check whether a product has been produced correctly.

Complete Track & Trace systems/Aggregation solutions providers have the edge and offer the following advantages:

- Compact standalone systems which are easy to integrate into the production line
- Alternative OEM kit solutions to upgrade existing packaging lines, including case packers, bundling machines and palletizers with Aggregation capabilities
- A unique range of services covering all affected systems
- Coordinated and fast delivery of ordered components
- Guaranteed compatibility of individual components
- Minimized operation errors due to a reduced number of operator interfaces, as well as faster and more efficient product changeovers and reduced downtime

7 Solutions – Maximum Possible Safety

It is important that any implementation of tracking fits seamlessly into the existing production process. Those seeking to bring transparency to the supply chain must have the required technical experience and industry knowledge needed to ensure smooth implementation. A common information base must be created that can be accessed by all those involved. In this way, consistent quality management can be ensured in order to prevent counterfeits and errors. For manufacturers this means the assurance of complying with statutory provisions and their own prescribed compliance requirements, as well as cost reductions, brand protection and supply chain transparency. For consumers, this means safety, increased confidence in manufacturers and product integrity.

7.1 What does a solution for Track & Trace across Aggregation levels look like?

The statutory requirements are that the smallest sales unit must be marked with a unique serial number by a datamatrix code, barcode or RFID code. Depending on the relevant requirements, this may have been generated randomly or consecutively. The marking is then read in by a camera system or scanner and the data is archived in a database.

The next level of Aggregation follows: several drug units are combined into a bundle or a cardboard box. For this, new Aggregation codes are generated and applied within the production line. In the database, the codes are linked in with the serial numbers of the individual sales packages. The individual codes for these units are read in and stored in the database.

It is now possible to clearly trace the units that are inside this packaging. A pedigree or parent-child relationship is created, and the sequence continues into whatever Aggregation level follows right up to the pallet. This procedure can be fully automated or may involve manual support, e.g. when scanning in the package data from the pallet using a hand-held scanner.

With the use of sophisticated marking and control systems, an effective Track & Trace process can be ensured, starting at the serialization of individual products through Aggregation into bundles, shipping cases and pallets. Intelligent software ensures smooth system control and data exchange with higher-level systems and is a crucial element in the implementation of marking tasks. A complete Track & Trace process is the combination of hardware to mark and verify cartons and the software to record serial numbers and transmit that data to the necessary parties.

7.2 Marking of Packaging and Control in Practice

There are a few questions which newcomers to the Track & Trace process generally have regarding the first step of serialization (and, by extension, Aggregation):

What is the ideal solution for recording data in the production line of a single production facility?

A software program controls and manages the components required for marking and verification: printers, cameras and scanners, if necessary. The software also provides the data required for marking (lot number, batch number, expiration date, serial number, content designations, etc.), pulling the assigned numbers from the manufacturer's ERP or a cloud system down to the printer. The products are then marked in the manufacturing process (inline), with a datamatrix code and plain text. The individual products are detected with the aid of light barrier technology. A countercheck is carried out in order to prevent product bottlenecks at other testing facilities, as well as to document rejected faulty parts. To achieve the best possible print results when marking, the product must pass as accurately and as close as possible to the print head, something which requires a high degree of technical know-how, as well as printers capable of marking up to 400 products a minute.

What happens after the printing process?

The marking is verified via an intelligent camera integrated into the line. To do this, it accesses the data provided by the software. Both codes and plain text are checked, and stored reference codes allow the recorded data to be compared. When it comes to detecting datamatrix codes, the code size, as well as the individual modules that make up the code act as an indicator. Modern camera systems with inline grading functionality can determine the extent to which the code is still to be designated "GOOD". When evaluating the print quality, for plain text the character size and character spacing are checked and for codes the contrasts are assessed. If the defined quality standards indicate that the print quality is "BAD", the product will be rejected immediately. The same also applies to products identified as faulty.

What happens now with the data generated during marking and during verification?

It is stored and saved in the manufacturer's database in real-time and can be used for documentation, as well as for later transfer to comprehensive databases and the next logistics level. In this way, each product can be clearly identified as "GOOD" or rejected. Sophisticated systems also operate logging mechanisms which supply the user administration with data. For example, when users log in or out, this is logged in detail for subsequent evaluation reports and the internal quality system.

Product and process information, as well as the installation of new jobs, can be managed easily with user-friendly configurable software. Very often the software that controls the printers and cameras installed in the line receives the necessary information via an SQL database link to the manufacturer's data management solution (e.g. ERP). New jobs can be configured easily via a terminal and all devices involved can be controlled.

7.3 Integration in Networked Systems with Multiple Lines

The safety and transparency in a pharmaceutical packaging process with multiple lines is also ensured through integration in a networked manufacturing system. For example, a network with SAP interface can be installed, linking data matrix systems to their respective production lines. Experienced manufacturers provide industrial standards such as SOA (with concrete implementation in web services), Java, SQL and XML files to link serialization and Aggregation solutions to existing systems such as SAP or cloud systems. In practice, for example, new print information - which is written to an XML file during operation - is read in via a server and forwarded to the control unit. From here the new print job is issued to a specific production line. If a packaged unit has to be excluded for quality reasons, its code is deactivated in the control unit and forwarded to the ERP, MES or cloud system via the network server.

7.4 Marking and Recording of Aggregation - From Bundle to Pallet

After recording the individual packing units, it is also necessary to document the complex Aggregation of the units at the packing line to ensure traceability. To do this, appropriate modules for recording and marking bundles, shipping cases and pallets are required. Verification of the stored information and print image can be accomplished using LAN smart cameras or HRC systems. To ensure seamless tracking, the recorded units of the corresponding grouped unit (e.g. shipping box) are assigned logically and the grouped unit is marked accordingly (e.g. shipping box label).

In addition to marking all individual cartons, Aggregation involves marking all higher level package units and the storage of the corresponding data.

A proprietary station in the production line provides the basis for the Aggregation of bundles in the Track & Trace process. A high resolution camera system reads the 2D codes of all cartons in a complete bundle. The codes are verified and the allocation of the cartons to the bundle is recorded in an external database. A unique Aggregation number is then printed directly onto the bundle or affixed using a label. This independent unit is registered together with the serial number and the data for all the cartons in the bundle.

From the cardboard box into the shipping case: if cartons have to be packaged in outer boxes, then it's important to verify that all cartons have the corresponding coding. The latter must be verified, documented and stored in a database. A semi-automated system secures a proper process handling and efficient application of Aggregation codes to a shipping case. In a fully-automated process, the shipping case is filled using a case packer and all carton serial numbers are verified using a high resolution camera system. Modern camera technology supports omnidirectional reading which means the orientation of the box is not important. The database comparison indicates whether the correct cartons are present. In the event of an error message, the case is rejected automatically. Likewise the camera verification checks whether incorrect products are present in the case or which products are missing. Here too the case is rejected immediately and this is documented accordingly in the database.

In a regular manufacturing process, loading a pallet with shipping cases usually

completes the packaging process: In most cases this process is a manual one. Here too, software is used to supply the individual information for the pallet and simultaneously control the verification of the boxes. Printers place the required codes on the package and a hand-held scanner records the information and gives it to the software to record. The printer creates a label with an individual serial number for the corresponding pallet which is linked with the previously-recorded serial numbers. The label data and the corresponding pallet are read using a hand-held scanner.

8 Performance – the Expert Partner for Track & Trace Systems

A company is only as strong as the partners that support it. Past projects have often shown that although the individual components of a Serialization and Aggregation solution function well, difficulties arise when they are integrated into a manufacturing environment as an overall solution. Companies are therefore advised to tackle this issue at a very early stage and to work with service providers experienced in this field. The route from situation analysis through to implementation, test series, validation and finally start-up of actual manufacturing must be coordinated precisely.

Moreover, this type of solution is not just the responsibility of one division of a company. Normally databases are handled by the IT department and changes in production are controlled by management. Continuous communication is essential to prevent delays. Experienced manufacturers of Track & Trace solutions are aware of these difficulties and can work around problems with the pharmaceutical company and provide appropriate implementation strategies.

When it comes to launching complete solutions – often on an international scale – suppliers need more than just technological know-how and experience: they also need to offer a worldwide service network capable of providing support quickly. In the highly competitive pharmaceutical industry, it is vital that unscheduled downtimes are minimized as much as possible in order to maintain productivity.

A good commercial relationship based on partnership involves ongoing dialogue with customers. High-end suppliers naturally carry out worldwide monitoring when it comes to statutory changes and technical innovations. The knowledge gained is regularly shared with their customers who are actively supported in their cost management and risk reduction strategies. For suppliers, it should be a matter of course that they regularly check their own products for security vulnerabilities and offer appropriate updates or releases.

Experience shows that a partnership founded for the long-term pays off in every way. Due to the global outlook of pharmaceutical companies, projects that involve several international sites can last longer than a year. This should always be borne in mind when selecting suppliers.

When selecting a supplier, it is important to ensure your partner:

- **Is up-to-date:** Worldwide monitoring of statutory requirements ensures state-of-the-art solutions and promotes technological developments.
- **Is capable:** Proven project experience indicates whether a company is able to deliver what they promise and also roll out international systems.
- **Can integrate solutions:** Suppliers who can easily integrate existing manufacturing components into the solution save customers' time and money.
- **Has sufficient resources:** Long-term commercial relationships require companies with a proven track record and not a newcomer with lots of ideas and no experience. Suppliers should have sufficient financial, human and technological resources at their disposal.
- **Is service-oriented:** The current state of the industry makes it essential that a supplier offers an international customer a service and support network.
- **Is a solution expert:** A supplier must be able to integrate existing solutions into their own process without any problems and add new technological solutions in the event of changes. Just saying "we'll manage that" isn't enough.
- **Works with a wide range of components:** Experience has shown that collaboration with a central supplier who has already worked successfully with other providers (outside companies or consolidated companies) and has experience of combining components is the ideal solution.

9 Aggregation Outside the Pharmaceutical Industry

Aggregation is also used outside the pharmaceutical industry. One such use is to provide traceability in the agrochemical industry in order to prevent counterfeit or illegal pesticides.

To ensure the authenticity and legality of chemical pesticides, the CRISTAL standard was developed in Europe. CRISTAL stands for Communicating Reliable Information and Standards to Agriculture and Logistics, and is an initiative driven by the European Crop Protection Agency (ECPA) aimed at establishing a communications framework for the European agrochemical industry. Participation in this initiative is currently voluntary, but with several major players in the agrochemical market involved, it is seeing significant uptake by manufacturers. By doing so, the Standard hopes to achieve complete supply chain visibility to allow easy electronic commerce i.e. buying and selling agrochemicals online. Additional benefits include easier identification of counterfeit products and increased traceability throughout the supply chain.

CRISTAL relies on pre-existing traceability standards already defined by the GS1 system. The guidelines define three core technologies as necessary for the support of electronic commerce:

- Electronic Data Interchange (EDI) which facilitates the exchange of data between entities
- Identification codes, which are used to link the data exchanged to products in the system
- Barcodes, to link the physical products to the identification codes

10 Outlook – the World of Track & Trace is Evolving

Various efforts are being made by international legislative authorities and organizations to achieve a uniform standard for the traceability of medicines. Despite years of effort, it remains unclear as to when and whether a uniform solution will emerge. What is clear, however, is that the growing danger of life-threatening risks caused by counterfeit medicines is forcing further action from the relevant government agencies. Serialization solutions and associated Aggregation solutions must be fit for the future in order to anticipate statutory requirements and voluntary compliance standards as best as possible. Only then will pharmaceutical manufacturers be able to ensure patient safety and confidence, and forge lasting customer relationships.

In addition, companies will only be able to handle faster manufacturing processes and remain competitive if technically sophisticated components can work together trouble-free in an integrated system. Whether printers, camera systems or IT technology: when trying to balance production rates, safety and time-to-market, real success can only be achieved by sophisticated technology. It is therefore not just a question of using the solutions offered in production lines to comply with legal provisions, but more about strategic considerations which, when considering health in general, have wider economic implications.

11 References

¹http://europa.eu/rapid/press-release_IP-16-3132_en.htm

²<http://www.iccwbo.org/News/Articles/2016/OECD-report-shows-growth-in-counterfeiting,-losses-to-global-economy/>

³<http://www.ncpc.org/topics/intellectual-property-theft/counterfeit-drugs-1>

⁴ <http://pharmaserialisatononline.com/>

11.1 Links to Additional Information Sources:

- Informationsstelle für Arzneispezialitäten
(German Information Centre for Proprietary Medicinal Products) – IFA GmbH
www.ifaffm.de
- Bundesvereinigung Deutscher Apothekerverbände
(Federal Union of German Associations of Pharmacists) – ABDA
www.abda.de
- Bundesverband der Pharmazeutischen Industrie e.V.
(German Pharmaceutical Industry Association) – BPI
www.bpi.de
- Bundesverband des Pharmazeutischen Großhandels e.V.
(German Association of Pharmaceutical Wholesalers) – PHAGRO
www.phagro.de
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
www.efpia.org
- GS1 – Global organization for the development of systems and traceability standards
www.gs1.org/traceability
- International Medical Products Anti-Counterfeiting Taskforce – IMPACT
www.who.int/impact/en
- National Institute of Standards and Technology
www.ts.nist.gov
- United States Food and Drug Administration (FDA)
www.fda.gov
- World Health Organization (WHO)
www.who.int

About Mettler-Toledo Product Inspection:

The Product Inspection Division of METTLER TOLEDO is a leader in the field of automated inspection technology. Our solutions increase process efficiency for manufacturers while supporting compliance with industry standards and regulations. Our systems also deliver improved product quality which helps to protect the welfare of consumers and reputation of manufacturers.



Checkweighing



Metal Detection



Track & Trace



Vision Inspection



X-ray Inspection

Disclaimer:

Information contained in this publication is provided "as is" and without warranty. METTLER TOLEDO disclaims all warranties, express or implied, and makes no warranty regarding the accuracy or applicability of the information contained in this publication, and is therefore explicitly not responsible for any damage, injury or death resulting from the use of or reliance on the information.

No part of this publication may be reproduced or distributed for any purpose without written permission from METTLER TOLEDO.

© 2017 METTLER TOLEDO. All rights reserved. Subject to technical changes.

www.mt.com/pi

For more information

Mettler-Toledo Group
Product Inspection Division
Local contact: www.mt.com/contacts

Subject to technical changes
© 01/2017 METTLER TOLEDO. All rights reserved