Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Introduction to GDP and the Supply chain Toolkit

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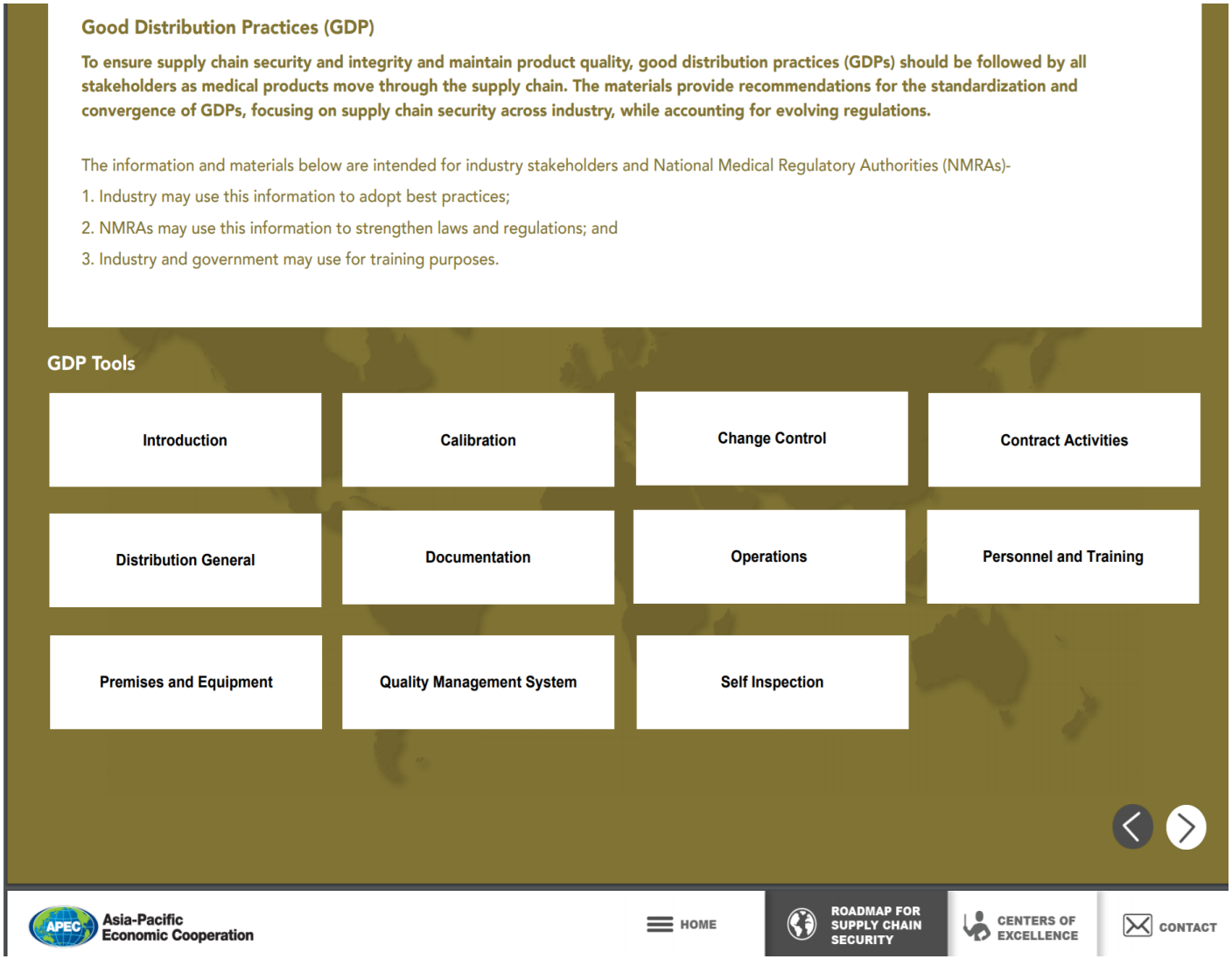
Agenda

- Introduction to the GDP supply chain tool kit using a real world example

http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf


Good Distribution Practices (GDP)
To ensure supply chain security and integrity and maintain product quality, good distribution practices (GDPs) should be followed by all stakeholders as medical products move through the supply chain. The materials provide recommendations for the standardization and convergence of GDPs, focusing on supply chain security across industry, while accounting for evolving regulations.
The information and materials below are intended for industry stakeholders and National Medical Regulatory Authorities (NMRAs)-
1. Industry may use this information to adopt best practices;
2. NMRAs may use this information to strengthen laws and regulations; and
3. Industry and government may use for training purposes.
GDP Tools
Introduction
Calibration
Change Control
Contract Activities
Distribution General
Documentation
Operations
Personnel and Training
Premises and Equipment
Quality Management System
Self Inspection
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Good Distribution Practices

The objective of these guidelines is to assist in ensuring the quality and identity of pharmaceutical products during all aspects of the distribution process. These aspects include,

- procurement, purchasing,
- importation
- storage,
- distribution, transportation, export
- repackaging, relabelling,
- documentation and record-keeping practices.

https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf

THE WALL STREET JOURNAL.

Italian Officials Probe Criminal Ties to Cancer Drug Theft

Investigators Find an Organized Criminal Ring Is Distributing Stolen Drugs in Western Europe

By Benoît Faucon and Hester Plumridge in London and Marta Falconi in Zurich

Updated May 1, 2014 3:40 pm ET

A top Italian enforcement official this week said that a highly organized criminal ring is behind the distribution of stolen and counterfeit cancer drugs throughout Western Europe.

The existence of an apparently organized and far-reaching network is causing alarm among pharmaceutical professionals, as fake or altered drugs reduce drug makers' revenue and can be inefficient or even lethal.

The European Medicines Agency warned in mid-April that vials of Roche Holding AG 's cancer drug Herceptin had re-emerged, contaminated, in the U.K., Germany and Finland after being stolen in Italy. Batches of Eli Lilly & Co. drug Alimta and Remicade, which is marketed by Johnson & Johnson and Merck & Co., have also been stolen, the agency later said.

Rapid Alert Notification of a Quality Defect / Recall

Add Letter Head of Sender / Meldende Stelle

Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit (LAVG)
Abteilung Gesundheit
Dezernat G3 Apotheken, Arzneimittel, Medizinprodukte
Wünsdorfer Platz 3
15806 Zossen
Germany

18. Details of Defect/Reason for Recall:

Falsification fraud because of investigation of the competent authority of Italy (AIFA). They confirmed that every Herceptin batch in italian outer labelling is falsified, when sold outside hospitals in Italy. Moreover the AIFA also mentioned, that the concerned batches are related to hospital thefts. So those batches traded by pharm appear to be falsified. The batches listed below will be recalled.

In addition a delivery in wholesale from pharm to in London (GB) was found at a local center of logistic. The cardboard boxes contained concerned batches. It has to be presumed that more concerned packages have been traded.

Amount	Medicinal product	batch	expiry date
4	Lucentis 10mg/ml IT	SW171	01-2020
19		SAJ97	03-2020
120	Eylea 40mg/ml IT	73519A	08-2019
59		72480C	04-2019
15		64422C	12-2018
5		72475F	04-2019
40	Avastin 25mg/ml IT	B7230H27	03-2019
44		B7230H16	03-2019
3	Herceptin 150mg IT	N6000H01	08-2020
20		H4825H02	02-2021
13		N3008H04	03-2021
3		N7192H03	11-2020
1		N6002H03	08-2020
1	Humira 40mg/0,4ml IT	1092537	09-2019
30	Imukin 2x10^6 UI (0,1mg) IT	606243A	09-2019
170		606243B	09-2019
9	Avastin 25mg/ml IT	B7226H25	12-2018
39		B7230H16	03-2019
108		B7230H27	03-2019
7	Neulasta 6mg IT	1083650A	08-2019
20		1085840C	01-2020

Serialisation of packs


Products stolen from Italy
History unknown
Sold from an Egyptian pharmacy to UK wholesaler
Sold on to German wholesaler
United Kingdom
Ireland
France
Spain
Portugal
Germany
Italy
Poland
Ukraine
Belarus
Romania
Bulgaria
Greece
Turkey
Morocco
Tunisia
Malta
Cyprus
Mediterranean Sea
Black Sea
Tyrrhenian Sea
Bay of Biscay
North Sea
London
Amsterdam
Netherlands
Brussels
Belgium
Cologne
Frankfurt
Luxembourg
Paris
Hamburg
Berlin
Denmark
Prague
Czechia
Slovakia
Vienna
Budapest
Hungary
Munich
Austria
Switzerland
Milan
Zagreb
Slovenia
Croatia
Belgrade
Bosnia and Herzegovina
Serbia
Sarajevo
Monaco
Andorra
Barcelona
Madrid
Valencia
Lisbon
Porto
Seville
Granada
Málaga
Gibraltar
Rabat
Casablanca
Algiers
Tripoli
Rome
Tirana
Albania
Podgorica
Kosovo
North Macedonia
Athens
İzmir
Antalya
İstanbul
Ankara
Bursa
Bucharest
Chisinau
Moldova
Odesa
Kyiv
Kharkiv
Minsk
Lithuania
Voronezh
Rostov-on
Krasn
Cairo
Jerusal
Beir
Adar

Other GDP issues

1.2 Evidence that medicines were transported appropriately was deficient, in that:

1.2.1 It could not be demonstrated that medicines had been transported within label conditions.

1.2.2 There were no processes or agreements in place defining customer collection models.

1.2.3 There were no processes or agreements in place defining importation transportation activities.

2.1 Quality management systems were deficient, in that there were no processes defining, nor documents containing considerations pertaining to change control and quality risk management.

2.2 Premises and equipment were deficient, in that:

2.2.1 There was evidence of uncalibrated temperature monitors in place to record ambient temperatures.

2.2.2 The refrigerator utilised to store cold chain medicines had not been mapped.

2.2.3 There was no calibrated temperature monitor in place to record cold chain functions.

Quality Management System

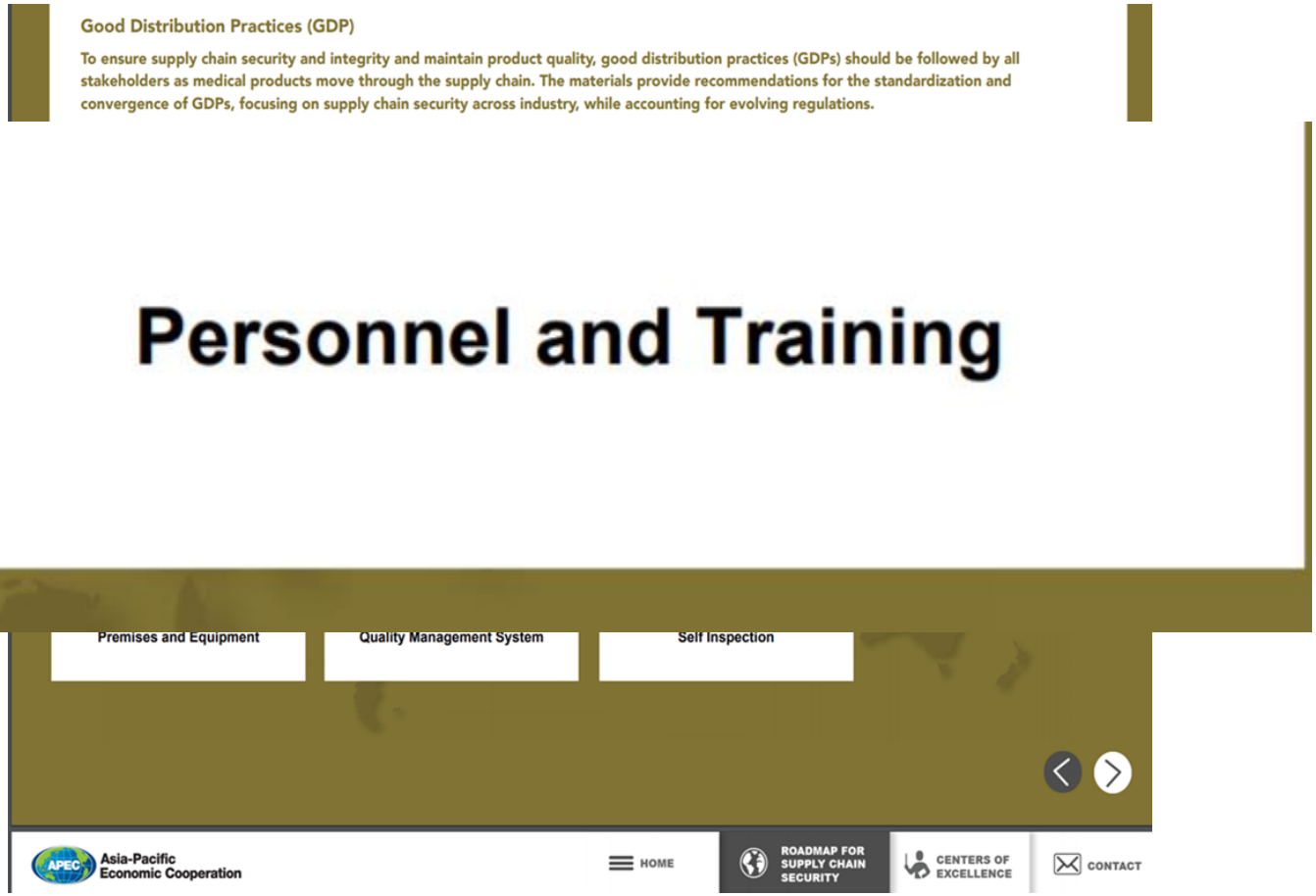
Change Control

Documentation

Asia-Pacific Economic Cooperation

How does the toolkit help?

- Define company quality policy and objectives
- Risk assessments
- Manage change from agreed business plan
- Approved suppliers
- Regulatory compliance
- Importance of SOPs and documents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How does the toolkit help?

Staff trained to appropriate understanding

Recognise what they don’t know

Independent Quality Assurance function/person


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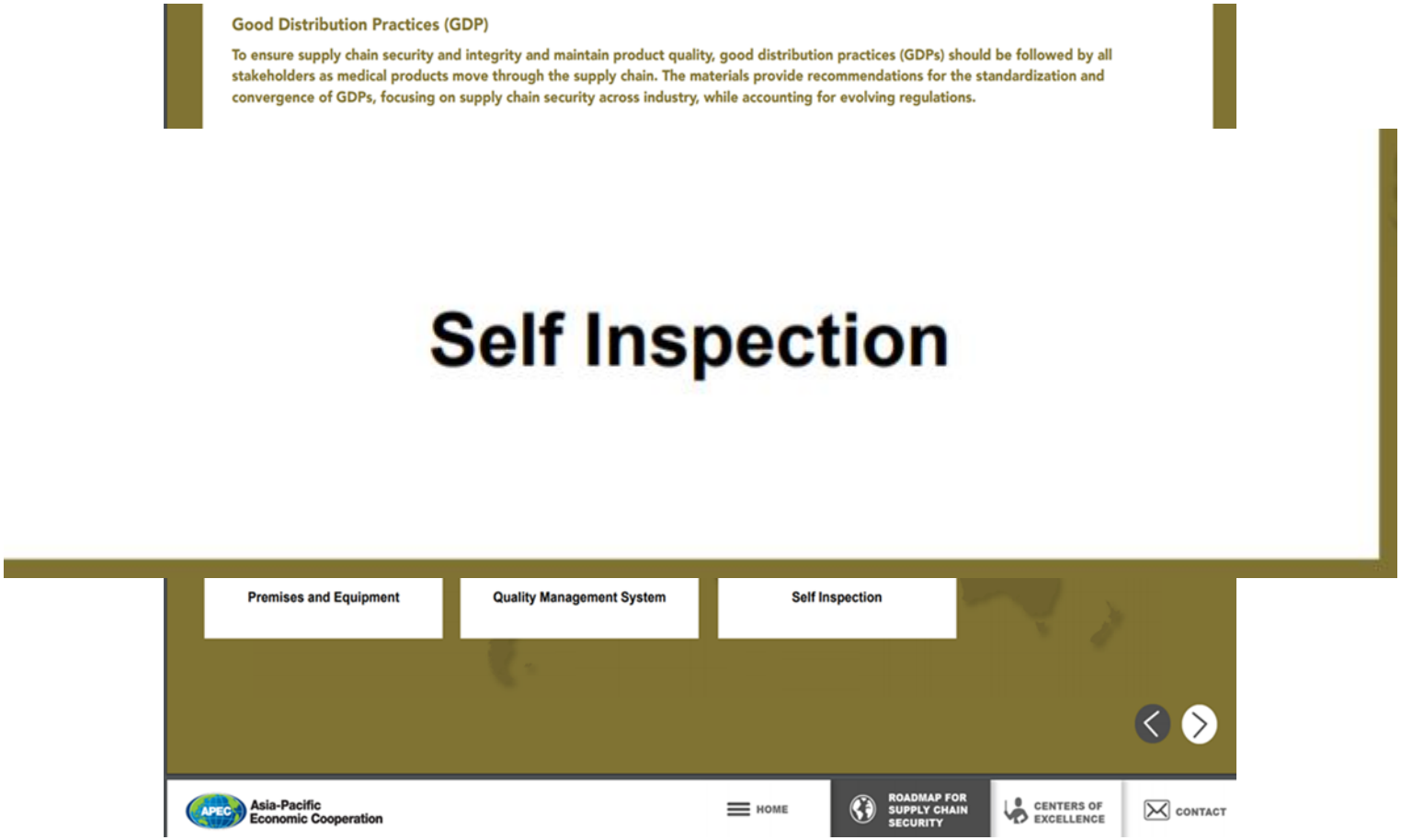
How does the toolkit help?

- Receipt of incoming products
- Product traceability and why it is important
- Checking on receipt
- Returned goods
- Picking, packing and checking
- Dispatch and transport
- Repackaging and relabelling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How does the toolkit help?

- Purpose of self-inspection is to evaluate whether a company's operations remain compliant with GDP
- Assists in ensuring quality improvement
- The programme should:
  - cover all aspects of distribution and quality control;
  - be designed to detect shortcomings in the implementation of GDP;
  - recommend corrective actions;
  - set a timetable for corrective action to be completed.


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How does the toolkit help?

- What are Outsourced Activities?
- Contract Agreements
- Contents of a Written Contract
- Contract considerations

Summary

- Failure to implement GDP puts patients at risk of substandard and falsified products
- Industry and Regulators both needed to ensure GDP is effective
- Communication between regulators is vital
- Use of all available resources to communicate, implement and monitor compliance with GDP to protect patients

Questions?

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