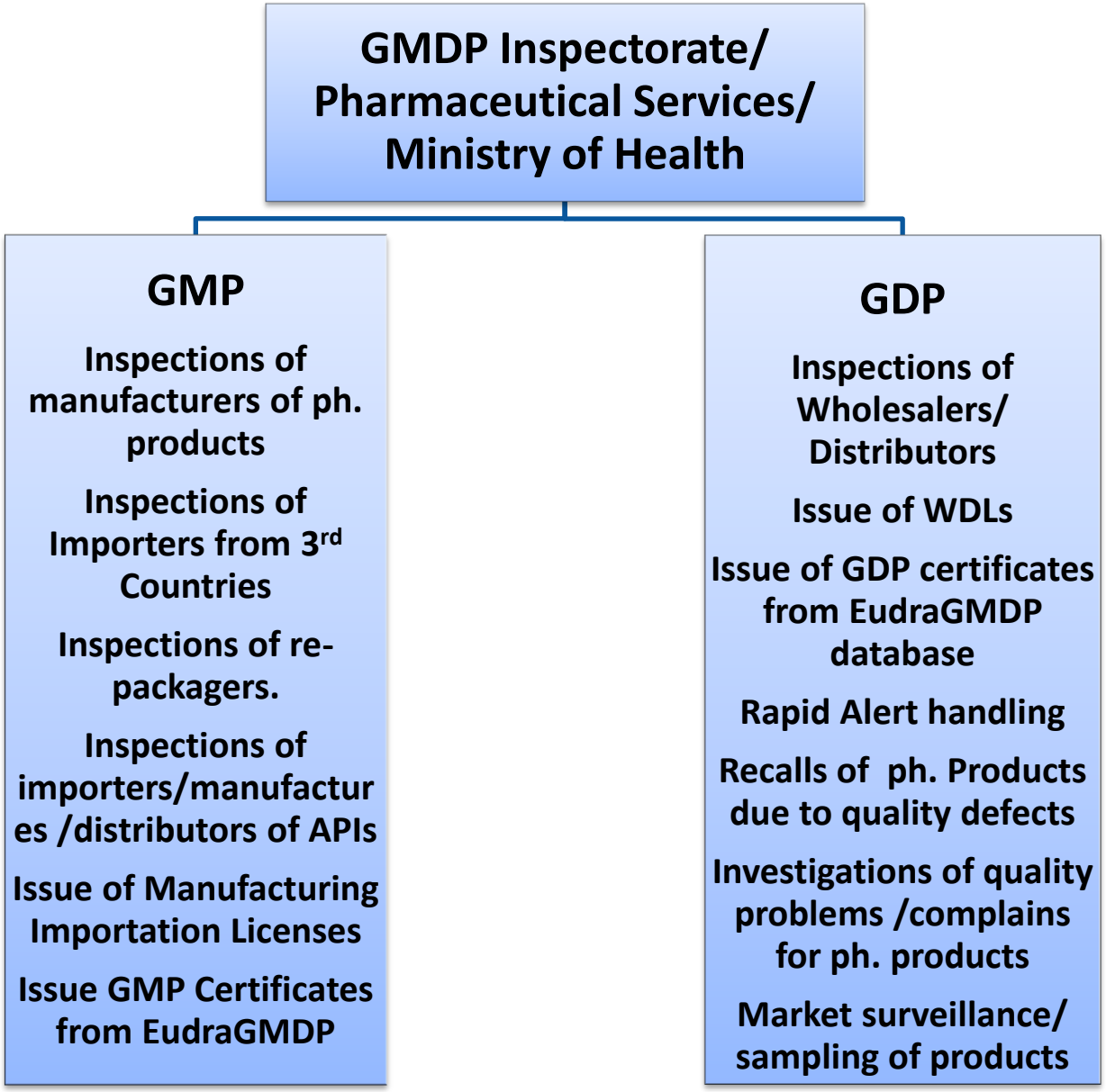
CYPRUS STRATEGY AGAINST COUNTERFEITING OF MEDICINAL PRODUCTS

CYPRUS: in the crossroad of 3 continents

Some facts about Cyprus

After the Turkish invasion in 1974:

- The Republic of Cyprus is *de facto* partitioned into two main parts; the area under the effective control of the Republic, comprising about 59% of the island's area, and the north, administered by the self-declared Turkish Republic of Northern Cyprus, which is recognised only by Turkey, covering about 36% of the island's area. The international community considers the northern part of the island as territory of the Republic of Cyprus occupied by Turkish forces
- Cyprus joined the European Union on 1 May 2004. On 1 January 2008, the Republic of Cyprus joined the eurozone.


GMDP Inspectorate/ Pharmaceutical Services/ Ministry of Health
GMP
Inspections of manufacturers of ph. products
Inspections of Importers from 3rd Countries
Inspections of re-packagers.
Inspections of importers/manufactures /distributors of APIs
Issue of Manufacturing Importation Licenses
Issue GMP Certificates from EudraGMDP
GDP
Inspections of Wholesalers/ Distributors
Issue of WDLs
Issue of GDP certificates from EudraGMDP database
Rapid Alert handling
Recalls of ph. Products due to quality defects
Investigations of quality problems /complains for ph. products
Market surveillance/ sampling of products

Short history of Cyprus GMDP Inspectorate (our values)

- **On May the 4th , 2001**: **"The Medicinal Products for Human Use (Quality Control, Supply and Prices)" Law N.70 (I) 2001 was published in the official Gazette of Cyprus Republic in order to harmonise Cyprus Law with Directive 2001/83/EU**

- **Beginning of 2002:** The GMDP Inspectorate was founded with only 2 GMDP inspectors

- **August 2002: The first Quality System of the GMDP Inspectorate was established**

- **2004: P.I. 716/2004 (Cyprus GMP guidelines) was published, based** on **EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines**

Historical data (2)

- **July the 1st 2008 Pharmaceutical Services/Ministry of Health, Cyprus, becomes a member of PIC/S**
- **On 6/4/2011 Regulatory department of Pharmaceutical Services, including the GMDP Inspectorate, was accredited according to ISO:9001/2008**
- **In December of 2012, Cyprus Law 209(I) /2012 is published in Official Gazette of Cyprus Republic. This is the transposition of Directive 2011/62/EU into Cyprus Law**
- **At the beginning of 2015 the GMDP Inspectorate team was enhanced with two new Inspectors, becoming a group of 5 Inspectors:**

- **The Head GMDP Inspector (10 years experience)**
- **Two Inspectors (4 and 2 years experience)**
- **Two trainee Inspectors (1 year experience each)**

Our Mission

- The mission of Pharmaceutical Services of the Ministry of Health is to safeguard the right of Cypriot citizens and visitors of Cyprus to access high quality, safe and effective medicinal and cosmetic products. The Pharmaceutical Services in order to achieve their mission and upgrade the services offered have set transparency, professionalism, objectivity, direct response and accountability as the basic principles for all of the functions they perform.

Falsified medicinal product

According to Directive 2011/62/EU:

(article 2 of Cyprus Law N.70 (I) 2001)

Any medicinal product with a false representation of:

- (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
- (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
- (c) its history, including the records and documents relating to the distribution channels used.

➢This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

Falsified Medicines

- Could be entirely useless or could be extremely dangerous.
- Falsified medicines may contain wrong quantity of active ingredient (too much or too little or nothing at all)
- May contain poor quality active ingredient
- Or wrong active ingredient
- or sometimes a toxic ingredient

Our Vision: to prevent the penetration of counterfeit/ falsified medicines in Cyprus market, as well as through Cyprus to other countries

How to achieve our mission and realize our vision: Our Strategy

Be committed to the rules

+

Good Knowledge and Supervision of Supply Chain

Close Collaboration with other Relevant Authorities

Raise Public awareness

Be alert and ready to react

Be committed to the rules
(Legislation and Guidelines)

Cyprus **Law N.70 (I) 2001** was amended end of 2012, in order to be harmonised with directive

2011/62/EU

(**Cyprus Law 209(I) /2012)**

API importation

Article 46b: Full implementation

APIs are only imported from 3rd countries, if there is a valid Written Confirmation.

- No importation of active pharmaceutical ingredients (APIs) from 3rd countries is permitted by Customs unless there is a signature of a Pharmaceutical Services' officer.
- A file with all "Written confirmations" is kept in Pharmaceutical Services offices and another one with all "Non-Compliance reports".
- Copies from each invoice signed (with a serial number, date and signature) are retained in our offices

API manufacturing , Importation, Distribution

- **Article 52a:** Full implementation

All API manufactures, importers, distributors, in the Republic of Cyprus, are registered in the EudraGMDP database

They are regularly inspected according to our inspection program and relevant GMP/GDP certificates are issued

Supply Chain (1)

- **Article 85b :** Full implementation
- All brokers in the republic of Cyprus are registered according to a formal SOP. Relevant documentation and information is being checked during an initial inspection.
- A Register is kept by Pharmaceutical Services and is publicly available in our website, with a link to EMA's website.

Supply Chain (2)

GDP Guidelines of 5th of November 2013 are followed and required from all WDL holders.

All wholesalers in Cyprus are registered in the EudraGMDP database and hold a valid WDL (wholesale Distribution License) according to the official format of the "Compilation of Community Procedures".

107 Wholesale Licenses were issued so far, since 2003,

but only 90 of them are currently active.

We maintain strict supervision and deep knowledge of the supply chain. Each wholesaler is regularly inspected according to a 3-year periodic program –and of course on a risk basis. Relevant GDP Certificates (or non-compliance reports) are issued from EudraGMDP database after each inspection.

Safety features

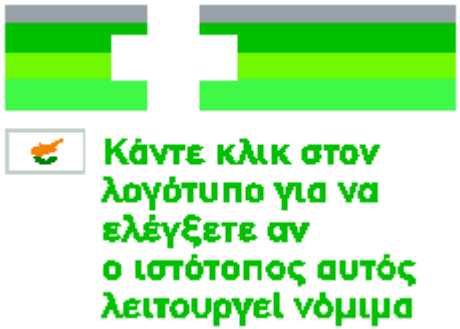
- **Articles 54 & 54a:** Still on going. Delegated Regulation is not yet published in the Official journal of the European Union We are currently in discussions with our stakeholders for the implementation

Distance sale to the Public

- **Article 85c:** For the moment there are no authorised internet pharmacies in Cyprus, because our National Legislation does not allow the distance sale to the public.
- Our Legislation explicitly indicates that all medicinal products must be given to the public by hand of a pharmacist
- Nevertheless all relevant information for distance sale of drugs is available on our website and there is a link with EMA's website

Buying medicinal products online - the Common European Logo

In this modern era of the internet the public have the opportunity to purchase medicinal products online. The public must therefore be informed of the dangers associated with purchasing medicinal products online. ***How can the public ensure that an online pharmacy is legitimate and trustworthy?***



Please visit the portal of the Pharmaceutical Services where you can find information about the medicines registered in Cyprus
https://www.phs.moh.gov.cy/web/guest/drug-search

More information about falsified /Counterfeit medicines
http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000186.jsp

According to article 99 (1) of Cyprus Law "**The Medicinal Products for Human Use (Quality Control, Supply and Prices)" Law N.70 (I) 2001:**

(δ) Any person who produces, distributes, brokers, imports and exports falsified medicinal products, including the distance sale to the public of falsified medicines, commits an offence

And in case of conviction the person committing these acts may be punished up to a 5 -year imprisonment or a penalty of 85000 euro or both punishments!

Close Collaboration with other relevant authorities in Cyprus and abroad

- We have a formal agreement with **State General Laboratory** for sampling and testing of pharmaceutical products for market surveillance and for investigations of suspected quality defects (including counterfeit products)

- A recent example is the investigation of a case of a sex shop advertising and selling illegal- non authorised medicinal products from India (unauthorised Vardenafil –Sildenafil, containing products).

*in this case there was a collaboration with the police as well. Products were confiscated, with the help of the Police and send to SGL for chemical analysis. Now the case is following the path of Justice!

The “LOVERS SEX SHOP” case

ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ

Αρ. Φακ.: Φ.Υ.5.21.02.01
21.6.31.5 ok

5 Μαΐου 2014

ΣΥΜΒΟΥΛΙΟ ΦΑΡΜΑΚΩΝ

ONLINE PHARMACY !

φαρμακευ

AMERICA PHARMACY

VIAGRA (SILDENAFIL)
25mg, 50mg, 100mg
15 Τεμάχια Μόνο € 50,00

CIALIS (TADALAFIL) 20mg
15 Τεμάχια Μόνο € 50,00

Cialis
(tadalafil)

Levitra, Kamagra, Malegra είναι αποτελεσματικά ανδρικά φάρμακ
θεραπεία της στυτικής δυσλειτουργίας.
σκληρότερη στύση όπου

Police Collaboration

- **The Herceptin case**: In 2014 a huge Falsification case shocked Europe! Herceptin and other very expensive drugs (Alimta, Avastin, Remicade, Humira, Mabthera etc) were stolen from Italian hospitals, manipulated (diluted) and re-entered the legitimate supply chain- mostly in north countries (Germany, Finland, UK, Italy) through fake- unauthorised wholesalers.
- **Cyprus had it's role! One of the main players in this illegal supply chain was CARNELA LIMITED, a company established in Cyprus!**

CARNELLA LIMITED

- Was established in Cyprus, in 2012, as a company selling Petroleum products.
- CARNELA never applied and was never granted an authorisation as a Wholesaler by Pharmaceutical Services/Ministry of Health/CYPRUS
- Falsified medicinal products never entered Cyprus. Instead this company was issuing fake invoices.
- Director of this company was a Polish man, owner of a German passport, with a permanent address in Switzerland.
- With the help of the Police we collected all relevant information for this company and we transferred it to our Italian colleagues, in AIFA, who were in charge of this huge investigation.

Fake Radian cream

Discovered in Cyprus and confiscated with the help of the Police.
It was discovered in a general sale shop (not in a pharmacy).
From the labelling on the package we realised that it was a falsified medicine:It was stated that it was manufactured by ROCHE in 2010.
But ROCHE informed us that it had sold the “Radian Massage Cream” trademark to another company in 2005!!

Collaboration with Customs

The Green Line

The Green Line Regulation for pharmaceutical products: An informal agreement between Customs and Pharmaceutical Services, taking into account Customs Legislation, Pharmaceutical Legislation, as well as the COUNCIL REGULATION (EC) No 866/2004 as amended by Council Resolution (EC) No 293/2005 of 17 February 2005, for people passing through certain check points, from one site to the other carrying pharmaceutical products.

In the Northern part of Cyprus, for the moment EU Law is not applied due to the Turkish occupation

The Green Line Regulation

- Since people passing through certain check- points from one site to the other may carry pharmaceutical products,
- and taking into account that the quality of these products cannot be warranty, since the EU Law is not applied in the Northern part of Cyprus, this Regulation was established:
- Certain categories of products are completely forbidden, like narcotics, psychotropic, anabolic, products with no adequate labelling, or creating the suspicion of being counterfeit. These products are confiscated by the Customs and the Police is informed.
- Other categories of drugs are allowed up to a limit (only for personal use / quantities limited to one month use)
- The Custom's officers communicate and advice with Pharmaceutical Services for such cases.
- A logbook with names, addresses, name of product, quantity etc is kept by Customs.

POST OFFICE CONTROLS

- Once a week officers from Pharmaceutical Services visit the district post offices in every town and check parcels containing pharmaceuticals.
- Narcotics, psychotropic, anabolic are confiscated and the Police is informed.
- Products with not satisfactory labelling or suspected for being counterfeited are confiscated.
- Other products are permitted, up to a limited quantity- for one month use- provided that the citizen presents a practitioner's prescription and he signs a declaration that is for his own use only (not for sale) and he is aware of the dangers created by falsified medicines.

HMA-WGEO (Working Group of Enforcement Officers
THE RAPID ALERT SYSTEM

HMA WGEO – Rapid Alert Form
Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

Reference: **1013/001**		
Date: **18.10.13**	Time: **13:00**	Initials: **ST**
Please complete sections 1 to 5 providing as much information as possible.		

1. REPORTING PERSON

Name: **Ruth Mosimann**	Position: **Head Control Illegal Medicines.**
Organisation: **Swissmedic (Swiss Agency for Therapeutic Products)**	
Address: **Hallerstrasse 7, P.O. Box, 3000 Bern**	
Telephone No: **+41 31 322 04 72**	Ext:
e-mail address: **ruth.mosimann@swissmedic.ch**	

2. PRODUCT DETAILS

- Product name: **Xanax**
- Manufacturer: **Pfizer (= manufacturer of original)**
- Supplier: **Guangzhou Import & Export, Guangzhou, China**
- Legal status: Banned ☐ Counterfeit ☒ Unlicensed ☐ Stolen ☐
- Dosage form: **Tablets**
- Strength: **0.5 mg Alprazolam (API is listed as narcotic)**
- Batch / lot no: **A200768A** Is batch number genuine: Yes ☒ No ☐
- If yes to the above, advise batch destination country: **Egypt**
- Expiry date: **02/2015**
- Language of packaging: **No boxes, just bulk blisters**
- Date of discovery: **02.10.2013**
- Details of discovery: **Discovered by Customs at transit through Zurich Airport. 1'080'000 tablets were in transit from a Chinese company to an Egyptian company.**
- Analysed: YES ☒ NO ☐ **Contains no API!**

3. DISTRUBUTION METHOD

Internet: YES ☐ / NO ☒

Internet:	Non internet, advise full details:
URL:	
Website address:	
Other details:	

- Currency of payment:
- Has product reached patients/consumers?
  No, goods will be destroyed by Swissmedic.

4. RISK TO PUBLIC HEALTH

- Adverse reactions: YES ☐ / NO ☐ Not known
- If yes, please advise details:
- Medical assessment details: **Absence of API > inefficacity**

5. NEED FOR PUBLICITY

- Are you making a public statement? YES ☒ / NO ☐
- Are you issuing a press release? YES ☒ / NO ☐
  (Without stating the product name)
- Are you recalling product? YES ☐ / NO ☒
  (No need for any recall in Europe. It is not known yet if Egyptian MoH will recall the genuine batch in Egypt)
- If yes to any of the above, when do you intend to take action? **TBD**

6. DISSEMINATION

- Are you content for this Rapid Alert to be shared outside WGEO membership?
  YES ☐ / NO ☒ (please see below)
- If yes, please specify which of the below you are content for this to be shared with (you may tick more than 1 box)
  Law Enforcement ☐ Industry Security ☐ Trade Associations ☐
  Traders ☐ Other ☐ Please specify

7. PHOTOGRAPH

If possible, please attach a photograph of the product. **Please see attached**

Rapid Alert Notification List

(for EEA, MRA, PICS)

Defective Product Recall

For Immediate Action

Belgium H-V	Séverine Brasseur	+32 2 524 82 56	+32 2 5248257	rapidalert@afmps-fagg.be
Belgium H-V	Josiane Van Der Elst	+32 477 880 336	+32 2 5248257	rapidalert@afmps-fagg.be
Bulgaria V	Antonio Radoev	+359 9 88102978	+359 9 88102978	a_radoev@nvms.government.bg
Bulgaria H	Albena Yordanova	+359 2 8903454	+359 2 8903434	albena.yordanova@bda.bg
Cyprus H	**Anna Paphitou**	**+357 22 608616**	**+357 22 608649**	**apaphitou@phs.moh.gov.cy**
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Finland H-V	Sami Paaskoski	+358 2 95223202	+358 2 95223007	qdefect@fimea.fi
France H	Dominique Debourges	+33 1 55873988	+33 1 55873922	dvs.defauts-qualite@ansm.sante.fr
France V	Laurent Fabry	+33 299 946665	+33 299 946671	defautsqualiteMV@anses.fr
Germany H	Axel Thiele	+49 228 2073232	+49 228 2074636	a.thiele@bfarm.de
Germany H	Dirk Mentzer	+49 6103 771011	+49 6103 771263	pharmacovigilance1@pei.de
Germany V	Cornelia Ibrahim	+49 3018 44430400	+49 3018 44430409	rapid.alert@bvl.bund.de
Greece H-V	Pantelia Goura	+30 213 2040 283	+30 210 6549 500	market-surveillance@eof.gr
Hungary H	Julia Németh-Palotás	+36 1 88 69 334	+36 1 88 69 460	notice@ogyi.hu

Raising Public awareness

- We participate in Operation Pangea every year since 2011.
- We took part in several TV and radio broadcasts, as well as press conferences with other authorities, for public announcement of Pangea results. We have also given some interviews in local news papers.
- In 2012 we issued a booklet for the public, highlighting the dangers of falsified medicines.
- In 2013 and 2014 we gave lectures and presentations for the Consumers Associations in Paphos and Nicosia.
- We are planning to repeat the presentations next year .

Hundreds of dangerous online-ordered drugs confiscated*

- HUNDREDS of prescription drugs ordered over the internet were confiscated yesterday by pharmaceutical services after they searched suspicious looking packages at post offices around the island. The drugs included anabolic steroids, hormones, contraceptives, antibiotics, food supplements and abortion aids.
- A total of 302 packages were checked with seven confiscated as they contained prescription drugs, the state broadcaster said.
- “We located one package in Limassol that contained drugs used for abortion which are very dangerous and can even cause death,” pharmaceutical services official Anna Paphitou said.
- Head of health services, Christos Christou also expressed his concern over the matter as food supplements fall under health services jurisdiction.
- “Some of these supplements contain dangerous and prohibited substances and can put people’s health at risk,” he said.
- The find was part of Operation Pangea which is an international week of action tackling the online sale of counterfeit and illicit medicines and highlighting the dangers of buying medicines online. Coordinated by Interpol, the annual operation brings together customs, health regulators, national police and the private sector from countries around the world.

* Article from CYPRUS MAIL-July 2nd 2013


CUSTOMS
CUSTOMS
CUSTOMS

Be alert and ready to react

- We have a formal SOP for investigations of suspected violations of the Law. **We collect information from every possible source (citizens, newspapers, social media etc)**
- Recently we have completed several investigations/ operations concerning illegal –non authorised products sold in various shops, like mini-markets etc.
- If the mission is expected to be difficult we ask the involvement of the Police from the beginning. If not, we accomplish it and send a formal letter to them afterwards, informing about our findings and asking for prosecution of the suspects.


60 филмирани таблетки
Ранитидин Унифарм
150 mg филмирани таблетки
Ранитидин
Aulin 100 mg

Thank you