



The Global Language of Business

## Panel: Implementation of the EU FMD – it can be done!

Stefan Artlich, Director Track&Trace, Bayer, Germany

Jean-Michel Descoutures, Hospital Pharmacist, Argenteuil Hospital, IHF, France

Andreas Fischer, Pharmacist, University Hospital of Dresden, Germany

Moderator: Christian Hay, Delegate Healthcare, GS1 Global Office

Wednesday 27 March 2019, GS1 Healthcare conference,  
Noordwijk

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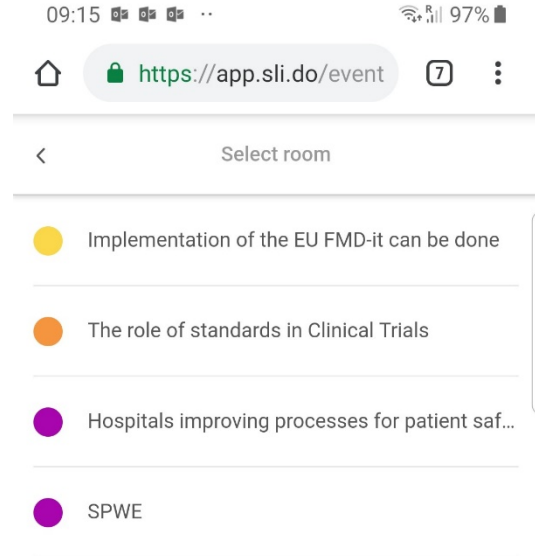
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## Stefan Artlich

- **Director Track&Trace, Bayer, Germany**
- « Father » of the European 'Point-of-Dispense Verification' model
- Played a key role in the design and development of the European Medicines Verification System
- Responsible Program Manager for the FMD readiness at Bayer
- Member of the GS1 Healthcare Leadership Team (LT)



## Andreas Fischer

- **Lead Pharmacist Clinical services, University Hospital of Dresden, Germany**
- Has worked with users and IT providers on clinical system design and safe implementation of new software solutions
- Implemented an electronic prescribing system in critical care
- Projects: introduction of SMART infusion pumps, automated dispensing cabinets, clinical databases to automate collection and feedback of key quality indicators



## Jean-Michel Descoutures

- **Hospital Pharmacist, Argenteuil Hospital, IHF, France**
- Member of the RESAH, one of the major group purchasing organisation for hospitals in France
- Coordinator for the procurement of pharmaceuticals for over 100 hospitals including military in France
- Member of the French Academy of Pharmacy
- Represents the International Hospital Federation (IHF) in the GS1 Healthcare LT



10+ Years of Engagement for  
Patient Safety

# EU-FMD Implementation @ Bayer



Nordwijk /// 27 March 2019  
/// Dr. Stefan Artlich







# Our Purpose: "Science for a better life"





# Our Business Areas



## Pharmaceuticals



- // Prescription products for cardiology, women's health care, oncology, hematology, ophthalmology, radiology and other areas



## Consumer Health



- // Non-prescription medicines in the categories of dermatology, nutritional supplements, pain, cardiovascular risk prevention, digestive health, allergy, cough & cold and other areas



## Crop Science



- // Innovative chemical & biological crop protection, seeds & traits, digital technologies & services
- // Animal Health



# EU-FMD Implementation @ Bayer – Sheer Size of Project was the Challenge

Equipment incl. Automation // Site and Corporate IT // Business Processes // Change Mgmt.

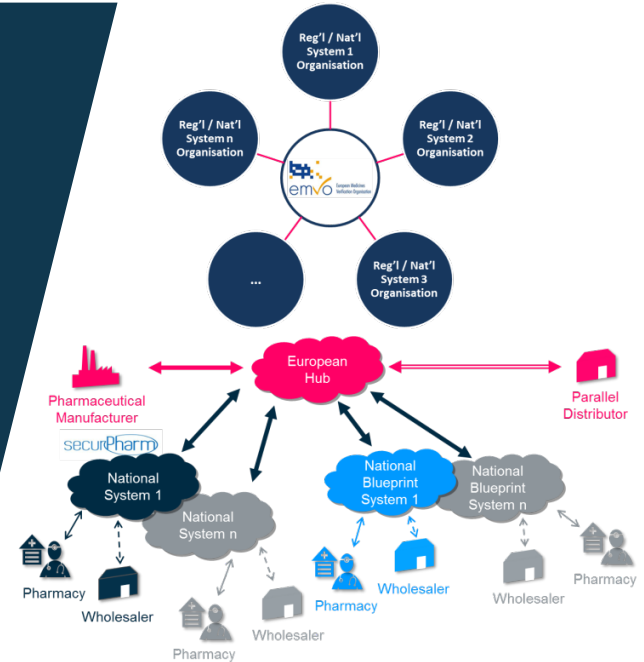
- // Ensure **technical readiness** of **70+ parties**
  - // Approx. 10 Bayer-owned manufacturing sites, 80+ packaging lines
  - // 20+ Contract Manufacturers (CMOs)
  - // Approx. 15 Bayer-operated warehouses
  - // 25+ Distribution Partners (3 PLs)
  - // ## Customers where Bayer acts as Contract Manufacturer (CMO)
- // Establish **serialization data exchange** with all **CMOs** and **Customers**
- // Establish **exchange** of **regulatory** and **serialization data** with **European Hub**
- // **Establish** new/**revise** existing **business processes** for e.g. pack decommissioning, complaint handling, batch recall
- // Execute **change process** incl. **regulatory submission** for approx. **2.000 products** (product-country combinations (Stock Keeping Units (SKUs)))
- // Be ready by **9 February 2019**





# EU-FMD Readiness – Collaborative Challenge for Pharmaceutical Supply Chain Partners

- // **Stakeholders** in EU member states to establish Nat'l Governance Organizations
- // **Nat'l Governance Organizations** to select repository system providers
- // **Stakeholders and Nat'l Authorities** to collaborate and determine coding scheme(s)
- // **Manufacturers** to equip packaging lines with serialization and tamper-evidence capabilities
- // **Wholesalers and 3PLs** to adapt IT systems and establish business processes for decommissioning and risk-based verification
- // **Solution Providers** to provide corporate serialization repositories and interfaces to EU Hub and to integrate verification in pharmacy Point-of-Sales software
- // **Retail pharmacists and hospitals** to integrate verification in workflows



**We Achieved our Joint Goal: Make Medicines Verification Happen in EU  
by Feb. 2019 to Ensure Patients' Access to Safe Medicines**





# What are the Future Coding Requirements in EU Member States + EEA Countries

## Coding of single-country packs in Europe – Some examples

- // EAN-13 coding already established in most EU countries, encoding as 14-digit number in 2D DataMatrix code pretty straight forward
- // Nordics allow for continued use of NTINs for existing products; as of 2019, new products need 'real' GTIN
- // Belgium transitioned from national CNK code to GTIN

## The 'real' challenge: Coding of multi-market packs

- // Easy where packs carry only one EAN code already today
- // Germany to allow for GTIN + NHRN (5<sup>th</sup> data element) e.g. for DE-AT packs
- // Likewise, Spain and Portugal carry GTIN + NHRNs as 5<sup>th</sup> and 6<sup>th</sup> data element
- // ...

PC: 04008500018002  
 SN: 19067811811  
 BATCH BXA6132  
 EXP 02/2019



United Kingdom / Ireland  
 [PCN]

Sverige Vnr 16 34 94 Danmark Vnr 16 34 94 Suomi/Finland Vnr 16 34 94

Norge Vnr 16 34 94 Island Vnr 16 34 94 Malta

Nexavar<sup>®</sup> 200mg  
 Medicinal product subject to medical

България  
 Страна регоратенб  
 По лекарско предписание

Magyarország  
 Sz

România  
 Medicament eliberat pe bază de prescripție medicală restrictivă – PR.

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 Bayer  
 Bayer Pharma AG  
 13342 Berlin  
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 Germania

Members of GS1 Healthcare were always up-to-date through access to EU-FMD Coding Tracker



# Industry Collaboration with Authorities was Key to Success

## Conceptual Phase (2010 – 2013)

- // Advocacy for stakeholder-driven Point-of-Dispense verification model
- // Bayer supported EFPIA team in presentations across Europe at
  - // EU and nat'l Health Authorities' public hearings
  - // Manufacturer Association workshops

## Implementation Phase (2014 – 2019)

- // Industry focus group under EFPIA umbrella responding to EU Commission's Q&As
- // Meetings with EU Commission outlining industry needs and constraints
- // Achieved to convince EU Commission to step back from its already published ban on serialized stickers and cellophane wrapping
- // At Bayer, wallet packaging for contraceptives in Weimar could be kept thus
  - // Enabling timely implementation of EU-FMD for wallets
  - // Avoiding considerable one-time investment plus significant increase in COGS p.a.





# Serialization @ Bayer: Implementation Challenges

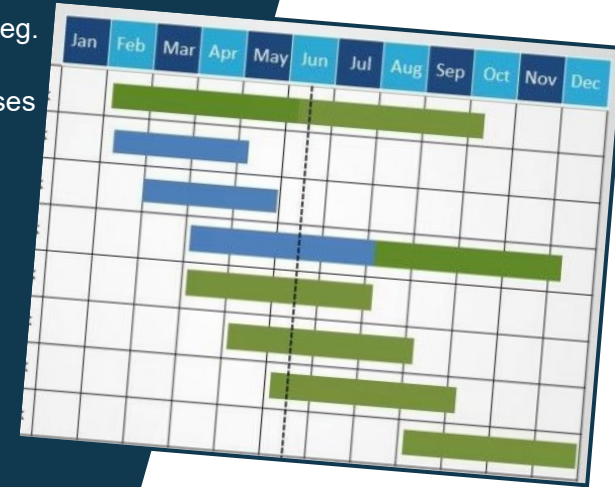
## Steps Towards Readiness for Requirements of Another Country

### Describe Scope

- // Translate country reqs. into implementation reqs., clarify missing details with Country Reg. Affairs manager
- // Highlight particularities w.r.t. e.g. code content (new (AI) ?), reporting, business processes to be revised
- // Determine (i) products in scope, (ii) affected own supply centres, (iii) affected Contract Manufacturers (CMOs)
- // Consider upcoming manufacturing transfers, launches, and product withdrawals

### Pitfalls in Implementation (Examples)

- // Packaging line not ready for serialization or aggregation (in particular if OTCs are in scope) → 12-15 months
- // New CMO in scope → up to 24 months
- // New Application Identifier (AI) required → 6-9 months
- // Usage of 2D code other than GS1 DataMatrix code → 12-18 months
- // Execute change per each SKU → 9+ months
- // Reporting interface to be built → 6+ months (clock starts after publication of interface specs. !)
- // Requirements on 3<sup>rd</sup> Party Logistics Providers (3PLs) → 18-24 months
- // Packaging transfer to new supplier including regulatory re-submission → ## months or years



Regulations in line with requirements in other countries contribute to timely implementation by all supply chain partners



*Thank You !*







## ‘Possible Counterfeit’ Alerts – Root Cause Analysis after 6 weeks

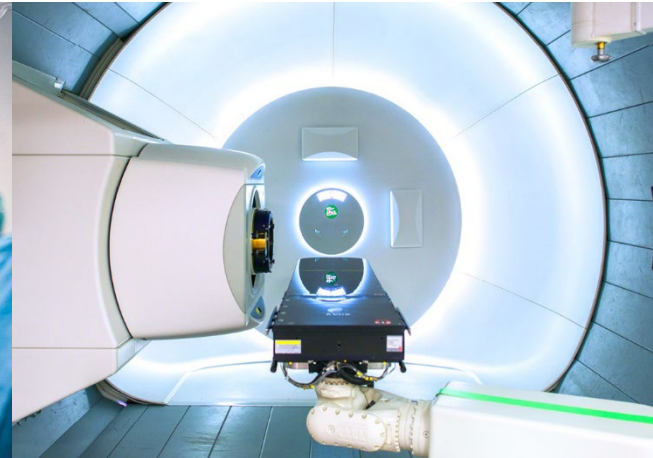
	Received Data	Correct Data	Root Cause	Error cause by
A52 Expiry Date Mismatch (2.200 Alerts)	311221	211231	Wrong data order	End-User System
	211201	211231	First day of month	
	010101	211231	Completely wrong date	
	190316	211231	Date of tomorrow	
	210530	210531	Wrong last day of month	
	211031	211130	Last day of previous month	
A2 Batch Not Found (250 Alerts)	210BXJ06L1	BXJ06L1	AI (10) for batch ID transmitted in verification request	End-User System
	bxj4bf5	BXJ4BF5	Batch ID characters not considered case-sensitive	
	6688132995	???	S/N instead of batch ID transmitted	
	YY02KYI	YY02KYI	S/N upload missing	Bayer

**Reading and processing a DataMatrix code is much more complex than a linear EAN-13 code in retail. All stakeholders depend on subject matter expertise of solution providers.**



# Implementation of the EU FMD at University Hospital Carl Gustav Carus

Noordwijk, 27. March 2019, Andreas Fischer, Lead Pharmacist – Clinical Services



# EU FMD – Should we bother?

## EU-Market

- 18bn packs of Rx medicine
- 1:20,000 pack are fake

## Developing countries

- Up-to 70% of certain medicines are fake

## Medication risk

- 6.7 serious adverse drug events per 100 admissions, 0.32 fatal events  
(Lazarou, JAMA, 1998)

Phantom fakes

Europe's vast new anti-bogus-drugs system will not find many

*Because counterfeits are not a big problem in the EU*



Print edition | Europe >

Feb 7th 2019



TEETHING PROBLEMS are to be expected with an online system linking more than 150,000 organisations in 28 countries to one



# University Hospital Carl Gustav Carus

## Department and Institutes

- 26 Clinical Departments, 14 Interdisciplinary Centres und 4 Institutes
- 1.295 inpatient beds, 164 places for day case and over 5,200 employees

## Activity:

- Admissions: 55,076 **-0.4%**
- Bed stay 386,363 **+0.9%**
- CaseMix Index 1,588 **+ 3.2%**
- Average lengths of stay 7 d **+ 1.1%**

## Turnover

- UKD (AöR und MF): 516 M € **+1.6%**



# Pharmacy Department

## I Department

- 119 Employees (84 WTE)
- Supply to the CGC and ~3,000 beds in hospitals in and around Dresden
- Clinical-pharmaceutical and unit-dose service to over 900 beds CGC
- Facilitation of clinical research studies (284 per annum)
- Manufacturing of aseptic, parenteral nutrition and non-sterile products (ca. 40,000 cytotoxics, 11,000 parenteral nutrition bags)
- Procurement and supply of in-vitro diagnostics for the CGC and other institutes



# Medicine distribution

## ■ SAP – System / KHT Robot

## ■ Pharmacy distribution

- Manufacturers 400
- Wholesalers 2
- Direct orders 17,350 (+5.8%)
- Order line 46,393  
(+2.0%)
- Pack numbers 4 million
- Turnover 103 Mil. €  
(+26.5%)
- **Direct deliveries 95%**





# Implementation EU FMD

## Local SAP IT solution

- Design of SAP solution by SNAP!
- Based on the Austrian SAP solution
- Additional cost for development
- Up and running (just) in time

## Additional staff (2WTE) needed

- Est. scanning time 3s per pack
- Reality 2 to 10s per pack

## Point of scan - goods receipt

- Point of reference for all packs in store
  - Internal distribution to unit-dose and manufacturing unit
  - Robot KHT™
- "Clean" store
  - Avoiding missed doses for infrequent medicine
- Avoiding bottle necks in the process
  - Uninterrupted distribution as alerts picked up at goods receipt
  - Avoiding delays for time-critical request of medicine



# Current problems

- Reliability of scanning process
  - Failure rate
  - Black vs white bar-codes
  - **Legacy stock vs. new stock**
- Error messages; what do they mean?
- If it's fake; what should I do?
- Parallel / Reimport





# Global challenges

- Role out of the successful implementation across Europe
- Optimising of current processes
- Additional cost for further development and ongoing support
- Digital transmission of invoices with electronic codes
- Medicine shortages and delays



**42%** of German hospital pharmacists are affected by shortages on a weekly basis



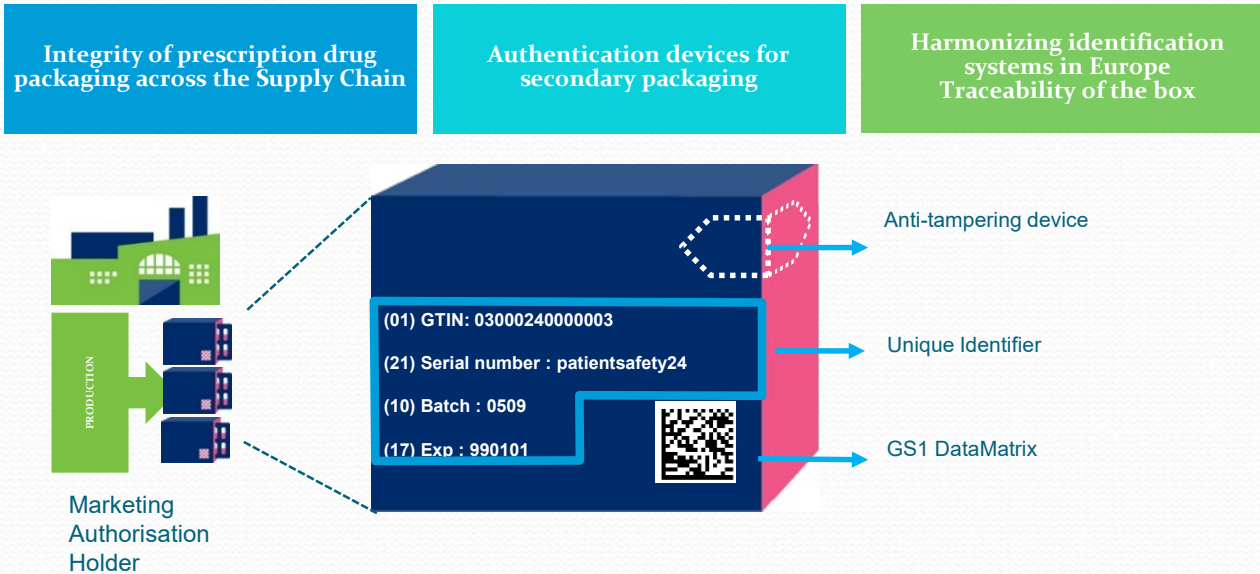
# First month of decommissioning

Implementation of the FMD  
in a French general hospital

**Jean-Michel Descoutures**

*Pharmacist - CH Argenteuil (95)  
Coordinator for Drug Procurement – GPO Resah  
Member of the French Academy of Pharmacy  
GS1 Noordwijk, Mars 2019*

# Context – Regulations - Objectives



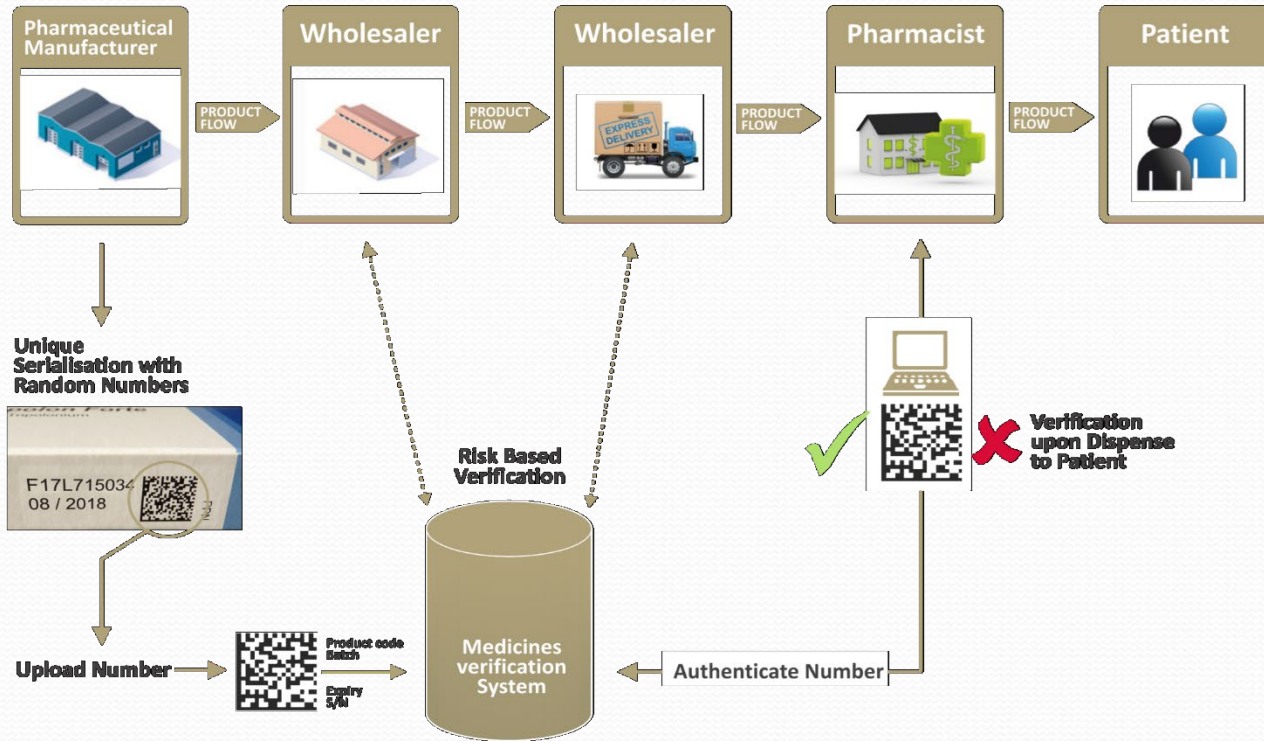
European directive on falsified medicines 2011/62/EU (FMD)

- [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir\\_2011\\_62/dir\\_2011\\_62\\_fr.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_fr.pdf)

Règlement Délégué 2016/161 sur dispositifs de sécurité figurant sur l'emballage des médicaments

- [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg\\_2016\\_161/reg\\_2016\\_161\\_fr.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_fr.pdf)

# Organisation of the system







**Serialisation,  
Unique identifier,  
Decommissioning ...  
Kick off : February 9, 2019**

# The situation in France a month after ...

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- 87 gateway providers have been qualified by France MVO
- Number of registered certificates in France MVO for hospital pharmacies : 1360
- Number of hospital pharmacies : 2500
  - **55 % hospitals are registered in France MVO**
- Number of registered certificates for retail pharmacies : 3
- Number of retail pharmacies : 21 535
  - **almost 100% retail pharmacies are NOT in line with the FMD**
- 2,5 billion boxes reimbursed by the Social Security
  - **86,5 % SGTINs through retail pharmacies are not decommissioned today**
- *The main software provider for retail pharmacies is reluctant to develop an application : who is going to pay ?, loans, unit dose preparations ...*
- *Trade unions : special adjustment of the FMD for the French pharmacy, « goods in » decommissioning and not in front of the patient ...*

# Solution portfolio

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- **Level 1 : standalone serialisation solutions**
  - bring a quick and simple response to the mandatory requirements
  - verify and decommission the SGTINs or even tomorrow the aggregated items
- **Level 2 : interfaced solutions with the local IT systems**
  - comply with the FMD
  - avoid duplicating the input transactions. Physical counting, inventory management and output transactions can easily be done by an intensive barcoding lecture
  - scan multiple DataMatrix codes in one go and decommission them when connected with France MVS
  - bring organisational efficiency improvements
- **Level 3 : integrated approach by interfacing the different softwares in the hospital or territory hospital groups**



# ARGENTEUIL Hospital



**General hospital : 1 000 beds**

- short stay : medicine, surgery, OB Gyn,
- long stay and psychiatry
- main hospital of the Territory Hospital Group : Sud Val d'Oise-Nord Hauts-de-Seine – = 5 hospitals
- medicine receipt = 250 000 boxes/year.
  - 80% go in the storage and distribution robot (ROWA)
  - 20% are split between shelves, refrigerator, anti-cancer drug production unit and narcotic safe

**Tomorrow**

- centralisation of the preparation of unit doses for the other hospitals
- medicine receipt = 800 000 boxes/year



# Pilot tests – September 2018

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- Gateway provider : OPTEL
- Test : compatibility of EU FMD with OPTEL Certa Software (data base test)
- Training of the two technicians
- Analysis of a fortnight receipt in September 2018
- With hardware devices : vertical scanner, optic station, handheld wire scanner
- Results for « Goods In »
  - number of scanned boxes : 830 per day
  - scanning time : 5 seconds per box or 56 minutes per day
  - Optel Certa is easy to use but the hardware takes place and the scanner uneasy to handle
- Next steps
  - need for a wireless mobile scanner
  - reinforcement of the wifi hotspot network at the pharmacy
  - measurement of the delay for decommissioning in « real life »

# Cost of the different types of contracts

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- **Standalone solutions : 5 000 – 10 000 euros**
- **Interfaced solutions : 10 000 – 15 000 euros**
- **Interfaced solutions with the storage and distribution robot (ROWA) + the WMS : 20 000 euros**

# Materials and methods on the 4 week study

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- **Collect of different informations**
  - evidence of a tamper-proof device by using a sampling analysis based on the Military Standard 1054-D (NFX 06-022 and ISO 2859-1 standards)<sup>(1)</sup>
  - evidence of a unique identifier
  
- **Quantitative indicators measures**
  - volume of orders → receipt in number of boxes
  - number of tamper-proof devices according to the sampling analysis
  - time to serial numbers authentication and decommissioning
  
- **Qualitative indicators evaluation**
  - serialised boxes rates
  - tamper-proof devices rates
  - non compliance rates

(1) M.DUPOUY et C.GUILLAUDIN « Centre Hospitalier AGEN – NERAC » 21/12/2018

[https://www.synprefn.org/files/file/pharmacie/activites-pui/pui-bpo-0299-1.0-2018\\_controler\\_ma\\_reception\\_des\\_medicaments\\_par\\_echantillonnage.pdf](https://www.synprefn.org/files/file/pharmacie/activites-pui/pui-bpo-0299-1.0-2018_controler_ma_reception_des_medicaments_par_echantillonnage.pdf) (accès le 12/03/2019)



# Results

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- Average of 1100 boxes a day [53 – 2820]
- Average delay for authentication and decommissioning : 2,5 seconds per box or 45 minutes per day
- 78% boxes have no unique identifier
- But 21% have already a tamper-proof device
- Among the 22% boxes with a serialised number **1,6% have no tamper-proof device**

All together only 20% boxes are totally compliant with the FMD after this first month of implementation

- Warnings : unfound batch numbers or expiring dates in the NMVS database → lack of data loading in EMVS
- Fortunately no level 5 alert meaning the presence of a counterfeit box

# Discussion

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- **Evolution of the delay for authentication and decommissioning**
  - from 5 seconds to 15,5 seconds and at last 2,5 seconds per box
  - why ? Traceability of the different movements in the OPTTEL software had to be emptied and the local Wifi network is not powerful enough and too old
- **Only 1/5 receipt medicines are compliant but of course there is a slight increase**
- **Differences in suppliers for the full compliance with FMD**
  - big global pharma companies are totally compliant : 24 suppliers or more generally high value based medicines coming from big pharmas or some important generic suppliers are compliant
  - on the other side 53 generic suppliers or medium /small size companies have not yet started
- **Difficulties in the communication with the different stakeholders : gateway provider, France MVO or the local IT management and the pharmacy**

# Conclusion

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- **The implementation of FMD had to be started → *in France between Sept 12 and Sept 19, 2017 433 000 illegal and counterfeit medicines were seized by the customs***
- **This first phase needs of course adjustments**
  - with the increase in serialised medicines aggregation will become necessary
  - but before scan multiple DataMatrix codes in one go and decommission them when connected with France MVS can have a high impact on the time
- **Interfacing with local IT systems or having a more integrated solution with the different other softwares in use could enhance the whole system from the producer to the patient himself**



# Acknowledgments

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- **Jean-Luc Pons, Chief of the Pharmacy Department**
- **Elodie Ducret and Matthieu Bourhis, senior pharmacists**
- **Charline Manzano, junior pharmacist**

**And ...**

- **Erwann Mondoux and Kamel Dahmani, technicians**







# CONCLUSION

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2204 AH Noordwijk,  
Zuid-Holland

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**Dress code:** Casual.





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