The Danish Medicines Verification Organization

DMVO Information meeting

16th of November 2018

84 days to 9th of February 2019

What would you like to discuss?

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Agenda

- **Status in DK**
- **Pilot**
  - ☐ How did it go?
  - ☐ Which challenges did we meet?
  - ☐ Completed pack status during the pilot
- **The implementation phase**
- **Onboarding process to DMVO**
  - ☐ MAH's
  - ☐ IT suppliers, wholesalers and 3PLs
  - ☐ Pharmacies
- **Other**
  - ☐ Indian packs
  - ☐ Alert handling
- **Questions**

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Status in DK

Production environment – DMVS and connectivity

- 6 pharmacies out of 450 are 'live'
- 1 IT pharmacy system (private) out of 2 is 'live'
- 2 wholesale systems out of 2 are 'live'
- 0 hospital pharmacy system out of 1 are 'live'
- 0 hospital pharmacies out of 8 are 'live'
- 0 3PL's out of ? (min. 7) are 'live'

Data in the production environment

- 19 out of approx. 250 MAH's have uploaded master data in the system
- 386 batches are uploaded
- 760.518 packs are uploaded
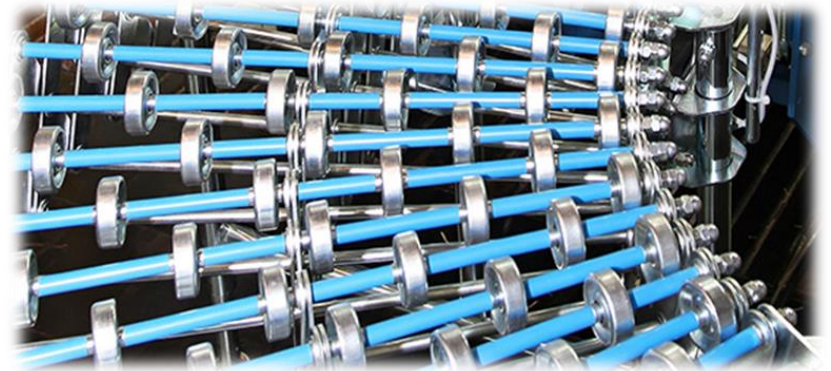
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Pilot

Pilot start April 2018

Consists of:

- 1 IT supplier of pharmacy system
- 2 wholesalers
- 5 manufacturer/parallel distributers
- 6 pharmacies

Pilot evaluation October 2018

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Pilot - Lessons learned, Manufacturer/parallel distributors

- Establishment of internal processes with regards to implementing serialization (more demanding/time consuming than expected)
- Re-design of artwork (2 barcodes on pack)
- Upload of data to Hub
- Diverting experiences of environments – ITE/IQE/PRD
- Lack of receipt for upload
- Response times from the Hub

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Lessons learned, Pharmacies

- Scanners not able to read the new 2D barcodes
- Robots cannot handle the new 2D barcodes – worst case scenario is a replacement
- Too few serialized packs to verify
- Response times

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Lessons learned, Wholesalers

- Positive to be part of pilot
- New return system for packs/flow
- More and more are gaining experience with and "feel" of the new processes
- All return status´ has been tested
- "Real Life" experience of falsified medicine – the system was put to use

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Lessons learned, IT Provider Pharmacy system

- The response time is critical
- Clarification of procedures of the different alerts

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Pack status Pilot

Pack status	Completed	Result	Action
Verify	Yes	Ok	
Supplied	Yes	Ok	
Reintroduce	Yes	Ok	Need to be performed by others – only performed by Nomeco
Locked	Yes	Ok	
Undo mark as locked	Yes	Ok	
Sample	Yes	Ok	
Undo mark as sample	Yes	Ok	
Free sample	Yes	Ok	Needs testing by others than wholesalers
Undo mark as free sample	Yes	Ok	Needs testing by others than wholesalers
Checked-out	Yes	Ok	
Expired	No		
Withdrawn	No		
Recalled	No		
Destroyed	Yes	Ok	
Stolen	Yes	Ok	
Exported out of EU	Yes	Ok	
Undo Exported out of EU	Yes	Ok	

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The implementation phase

- Agreements between DMVO and all MAH`s having products on the Danish market are included in the FMD as of 9th. of February 2019

- End user agreements have to be in place between:
  - End users and DMVO – Pharmacies, hospital pharmacies, wholesalers and 3PL´s
  - IT suppliers and DMVO

- The homepage of "The Danish Pharmacy Association" are handling the agreements for pharmacies

- Other agreements are handled via the contract system of DMVO

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Onboarding process - MAH's

- **All contracts are handled digitally**
  - ☐ To be established in the contract system of DMVO – send mail to info@dmvo.dk
  - ☐ Update contract in the contract system and send mail to info@dmvo.dk
  - ☐ Contract review and approved contract is send for signing
  - ☐ Sign contract
  - ☐ The procedure is described on the homepage
- **Billing**
  - ☐ The invoice will be send end December 2018
  - ☐ Onboarding fee to be paid end January 2019
  - ☐ Yearly fee to be paid end March
  - ☐ PO number is to be send asap to DMVO – no later than primo December 2018

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Onboarding process - IT suppliers/ wholesalers/ 3PLs

- NDA with the IT supplier of DMVO (SSR) to be signed
- Self certification test is to be passed and completed
- End User- and license agreement with DMVO
  - □ Mail to be send to info@dmvo.dk
  - □ Contracts are handled digitally
  - □ Access to an account in the contract system of DMVO is established
  - □ Update contract and send mail to info@dmvo.dk
  - □ The contract is reviewed and send for signing
- End user will have access when the end user- and license agreement between DMVO and the IT supplier is established, given the end user has a user agreement with DMVO.

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Indian packs – OTC products

- Technically we can handle Indian packs in Denmark
- Legislation – they must not be serialized
- The Commission has - in connection with an Expert Group meeting on safety features the 12th of September 2018 - informed:
  - *Membership countries should act as Germany, i.e. in Denmark the recommendation for Danish companies is to contact the Indian partners and request exception from the 2D barcode demand when dealing with packs to the European market.*

- In cooperation with wholesalers, manufacturer, parallel distributers and NCA, DMVO has challenged the feedback from the Commission

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Alerts in the system

General alerts in the system

Type	Description	Sent to Manufacturer/Parallel distributor	Sent to HUB	Sent to NMVO
#A3	Pack not found	√	√	√
#A7	Pack already in requested state	√	√	√
#A24	Status change could not be performed	√	√	√
#A52	Expire date mismatch	√	√	√
#A68	Batch identifier mismatch	√	√	√

➤ A work group has been established to work out process flows on how to deal with alerts in DK

➤ Objective – Alert procedures for Denmark in place ultimo 2018

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Time for questions

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Next meeting

Next info meeting is Friday the
14th of December at: 08.00 – 10.00am

Feedback is welcome – send mail to
info@dmvo.dk

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