Project responsibilities

Tallinn
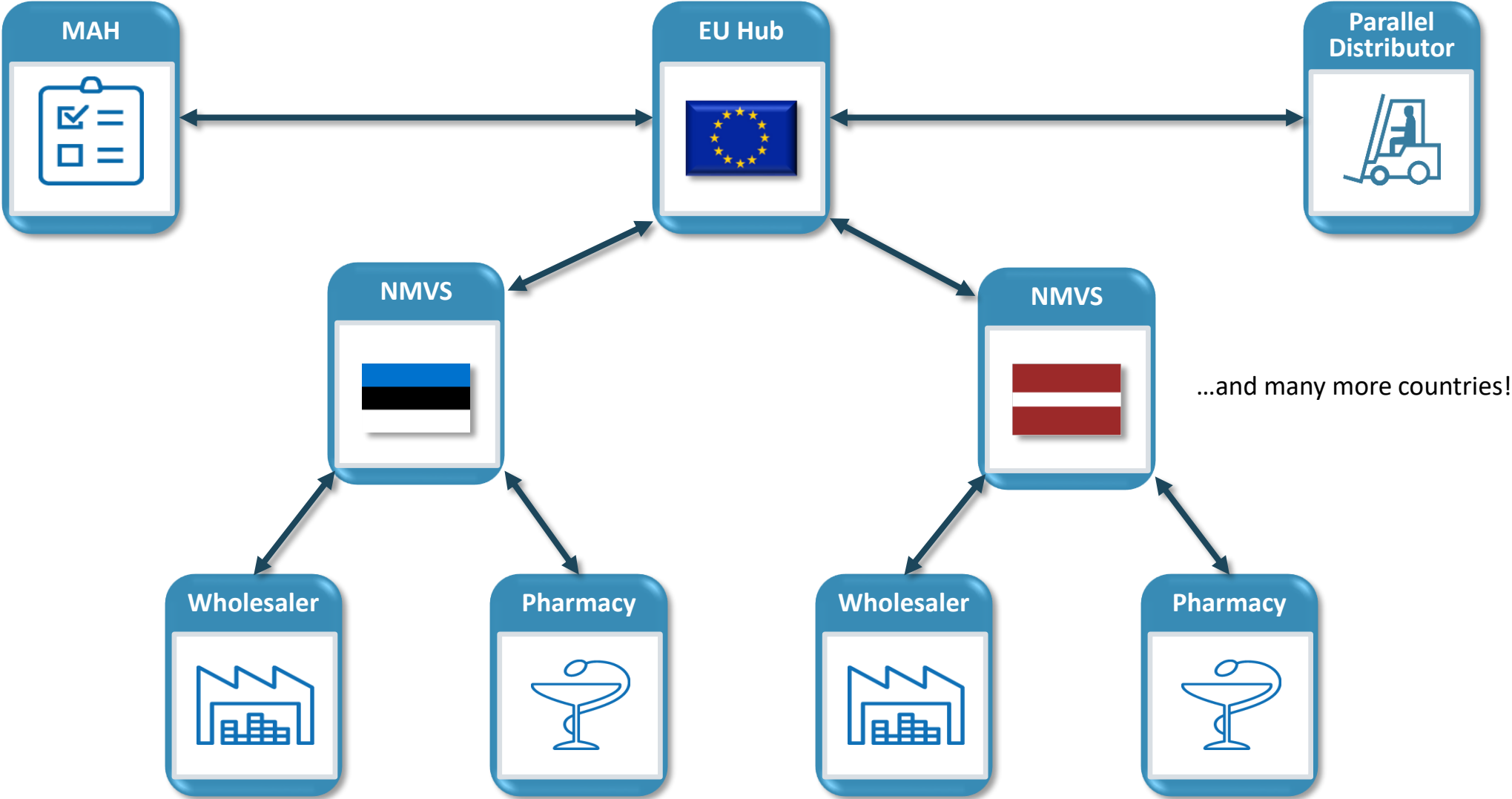November 24th, 2017

Our Mission

- Falsified / counterfeit medicines are a serious risk for the citizens all around the world
- New legislation published on the 9th February 2016 as delegated act
- This new legislation is mandatory for all EU members
- Pan-European strategy to fight illegal medicine products
- Based on a "Point-of-Dispense Verification"

Manufacturer → **MAH** → **Wholesaler** → **Pharmacy** → **Patient**

Where the data goes

…and many more countries!

Challenges

Many stakeholders are involved

- Organisators
  - REKS
  - EMVO

- Software providers
  - Solidsoft (EMVS/EU Hub)
  - Arvato
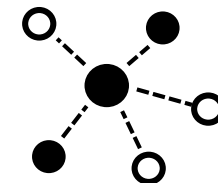 - Pharmacy/hospital/wholesaler SW providers/IT departments

- Authorities

- Primary distributors
  - Marketing authorization holders
  - Contract manufacturers
  - Wholesalers
  - Parallel distributors
  - Public pharmacies
  - Hospital pharmacies

- Secondary distributors
  - Army
  - Prisons
  - Airlines
  - Nursing homes
  - Drug treatment centers
  - NGOs
  - ...

Master the Challenges

- Organize Cooperation

- The stakeholders must learn to act together in a new context.

- New overarching processes must be established.

- Stakeholders are depending on each other,
  i.e. delays and errors will propagate and accumulate downstream.

=> Let's have a (very) short look at which dependencies exist.
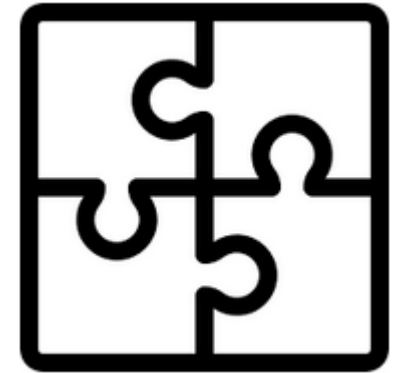
We have to master one central challenge (2)
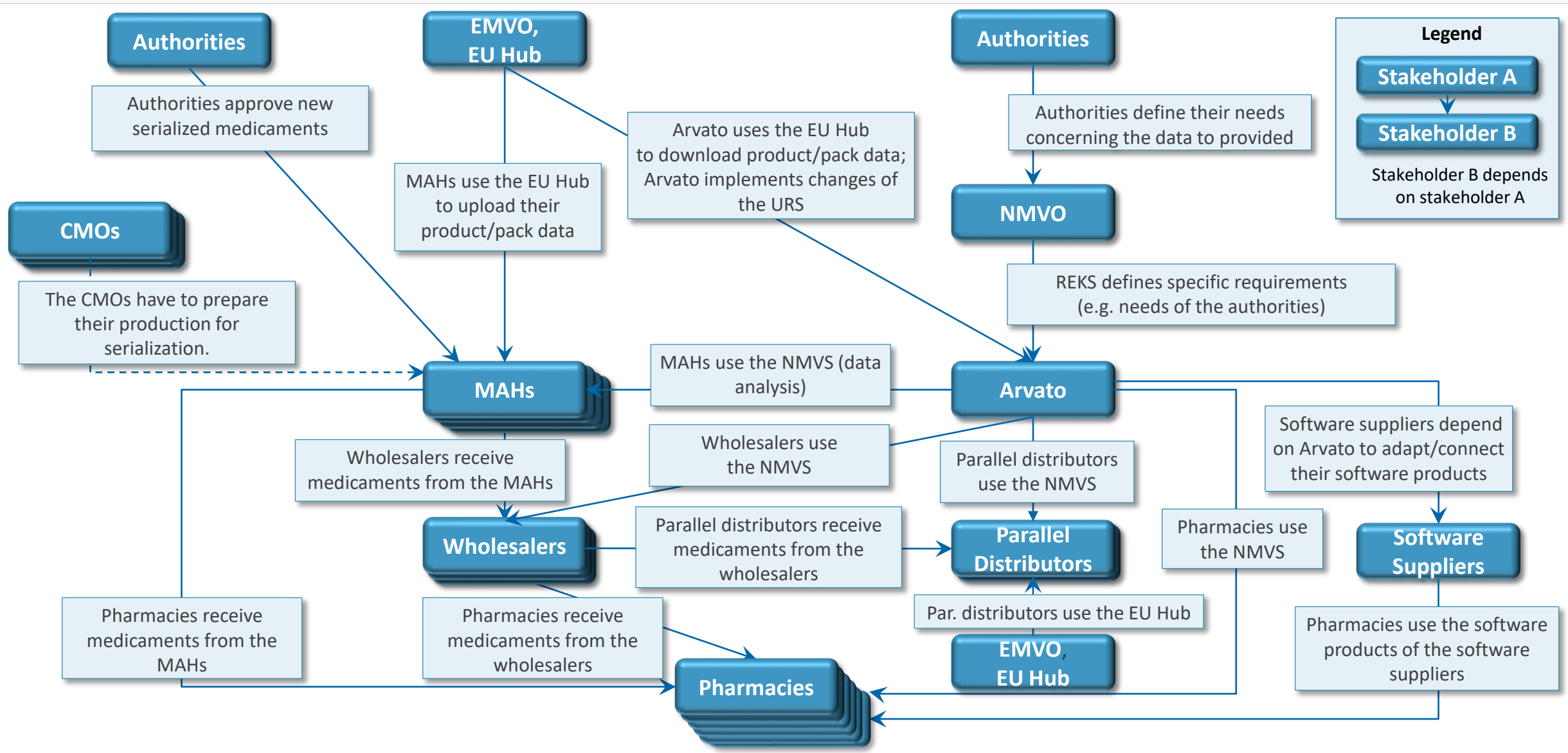
- Organize Cooperation

  - The stakeholders must <u>learn to act together</u> in a new context.

  - New <u>overarching processes must be established</u>.

  - Stakeholders are <u>depending</u> on each other,
    i.e. delays and errors will propagate and accumulate downstream.

  => Let's have a (very) short look at which dependencies exist.

A complex web of stakeholders must learn to cooperate smoothly

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Authorities

EMVO, EU Hub

Authorities

Authorities approve new serialized medicaments

Arvato uses the EU Hub to download product/pack data; Arvato implements changes of the URS

Authorities define their needs concerning the data to provided

Legend

Stakeholder A

Stakeholder B

Stakeholder B depends on stakeholder A

MAHs use the EU Hub to upload their product/pack data

NMVO

CMOs

The CMOs have to prepare their production for serialization.

REKS defines specific requirements (e.g. needs of the authorities)

MAHs use the NMVS (data analysis)

MAHs

Arvato

Wholesalers receive medicaments from the MAHs

Wholesalers use the NMVS

Parallel distributors use the NMVS

Software suppliers depend on Arvato to adapt/connect their software products

Wholesalers

Parallel distributors receive medicaments from the wholesalers

Parallel Distributors

Pharmacies use the NMVS

Software Suppliers

Pharmacies receive medicaments from the MAHs

Pharmacies receive medicaments from the wholesalers

Par. distributors use the EU Hub

EMVO, EU Hub

Pharmacies use the software products of the software suppliers

Pharmacies

What exactly needs to be done? (1)

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- All MAHs must

    - Introduce serialization for their products (package design, regulatory approval, production preparation, production start)

    - Synchronize with their manufacturers (CMOs)

    - Synchronize with their wholesalers

    - Connect with the EU-Hub and start uploading product data and pack data

    - Adapt their IT systems to handle serialized products (incl. EU Hub interface)

    - Manage falsifications including false positives

- All wholesalers/par. distributors must

    - Synchronize with their MAHs

    - Adapt their IT systems to handle serialized products (incl. NMVS interface)

    - Manage both serialized and non-serialized products for a transition time

    - Wait for serialized products to be delivered by their MAHs

    - Manage falsifications including false positives

What exactly needs to be done? (2)

- All pharmacies must

  - Align with their software suppliers

  - Introduce upgraded IT systems for scanning of serialized products

  - Onboard to the NMVS system (certificates, access rights, etc.)

  - Train their employees

  - Adapt their daily business processes

  - Wait for serialized packs to propagate through the supply chain

  - Manage detected falsifications including false positives

- All software suppliers must

  - Understand the NMVS web service interface and specify the required changes to their software products

  - Plan and reserve implementation capacities/efforts

  - Implement and test the specified changes to their software products

  - Coordinate the rollout of their new software product releases to the pharmacies

What exactly needs to be done? (3)

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- The EU Hub will for the first time have to ...
    - ... handle transactions from multiple countries
    - ... handle multi-market products/transactions
    - ... handle inter-market transactions

- REKS will have to ...
    - ... keep an overview of all the stakeholders involved and their respective progress in the project
    - ... align with the Estonian authorities
    - ... manage detected falsifications including false positives

- General aspects
    - Further URS changes by EMVO are likely to occur in the future and will have to be considered

Conclusions

Numerous interwoven processes cause a high global complexity.

The ecosystem as a whole needs sufficient time to settle down.

There is no time to waste until go live.

All stakeholders need to be aware of that.

Thank you