

Kvalitetsdagen 2017 Quality Day 2017

Oslo, March 30, 2017

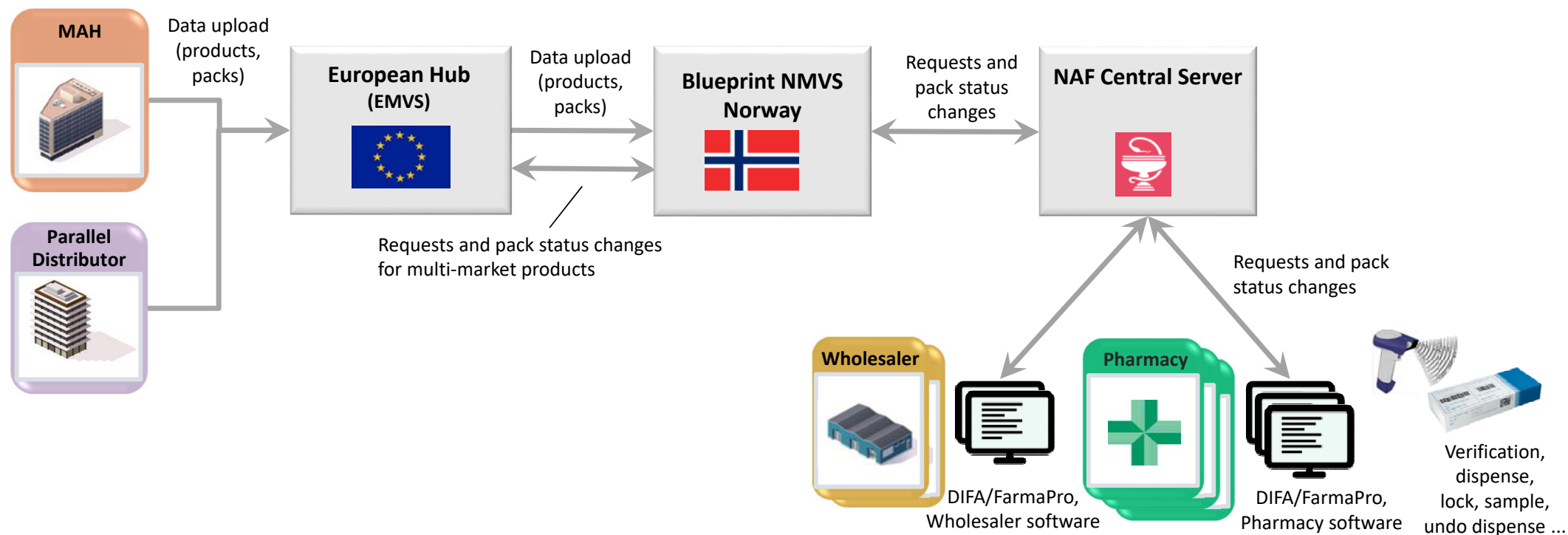
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What is the Norwegian Blueprint NMVS?

NMVS = National Medicine Verification System

All medicaments dispensed in Norway will be checked for authenticity as of Feb 9, 2019.

This is an overview of the planned architecture of the NMVS:



We have to master one central challenge (1)

- **Many stakeholders are involved**

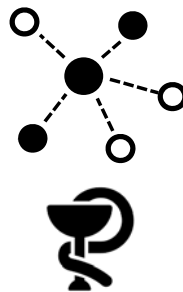
a) Organisers

- NoMVeC
- EMVO



b) Primary distributors

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



c) Software providers

- Solidsoft (EMVS/EU Hub)
- Arvato
- NAF
(Norwegian pharmacists association)



b1) Secondary distributors

- Army
- Prisons
- Airlines
- Nursing homes
- Drug treatment centers
- NGOs
- Offshore platforms
- ...

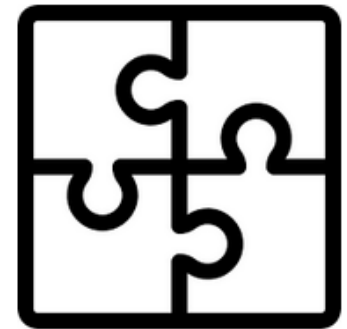


We have to master one central challenge (2)

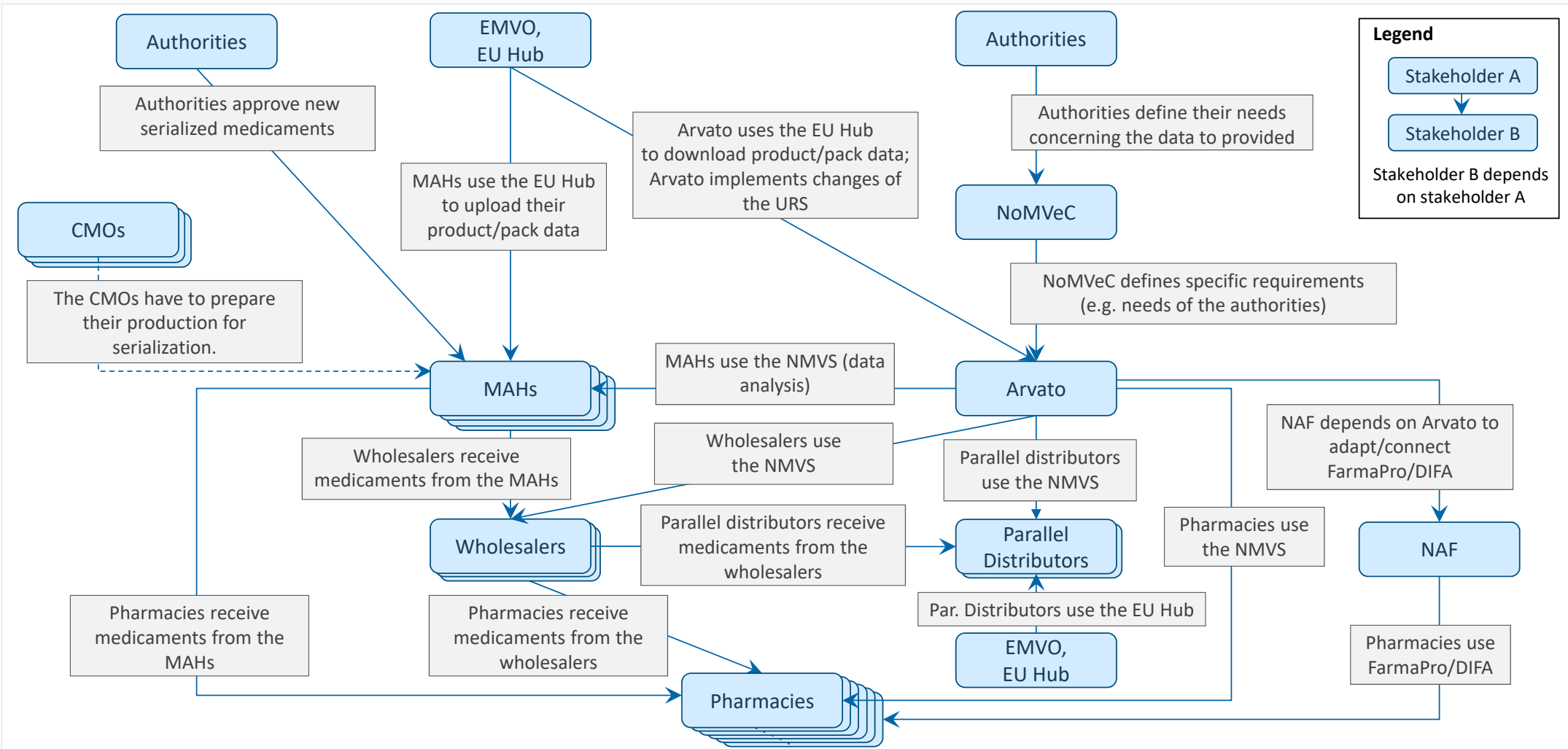
- **Organize Cooperation**

- 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.

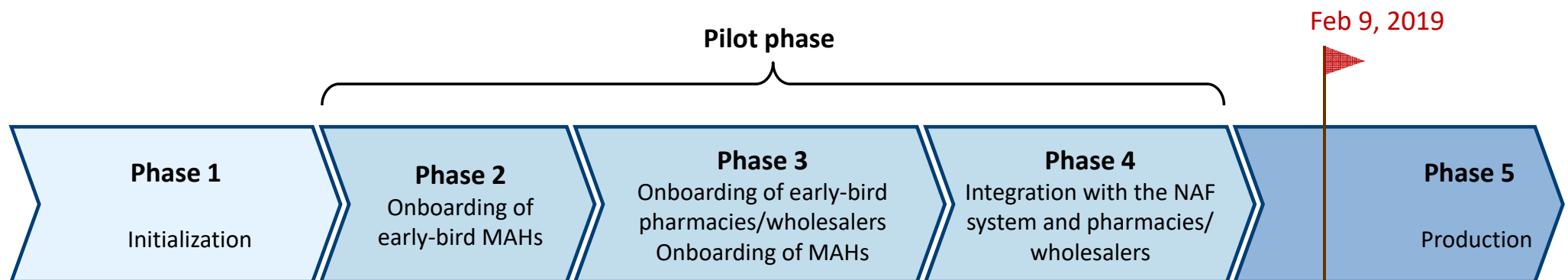


A complex web of stakeholders must learn to cooperate smoothly



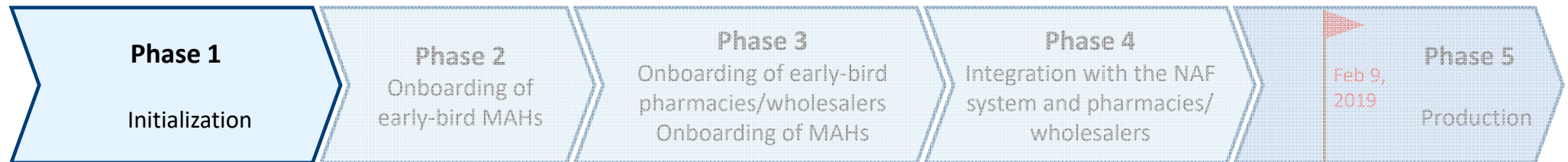
Time Planning, High Level Perspective

- This is our plan to provide sufficient time for alignment among stakeholders and to finish the project within the available time frame:



- What are the results of each phase?
Let's go through the five phases shown.

Planning, Detail View: Phase 1



Results of Phase 1:

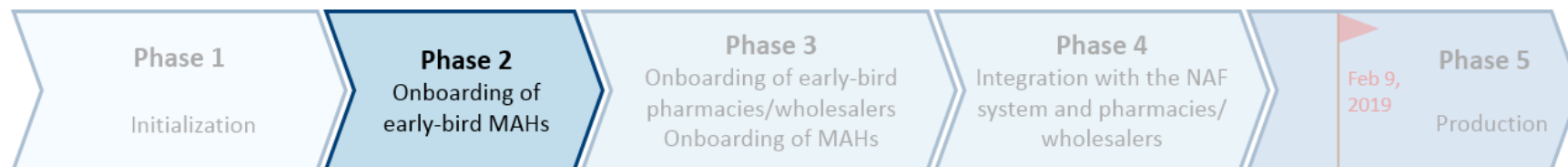
Organization

- The major project decisions have been taken
- The stakeholders and their roles are known
- The planning is complete
- The description of the NMVS web service interface has been made available to NAF

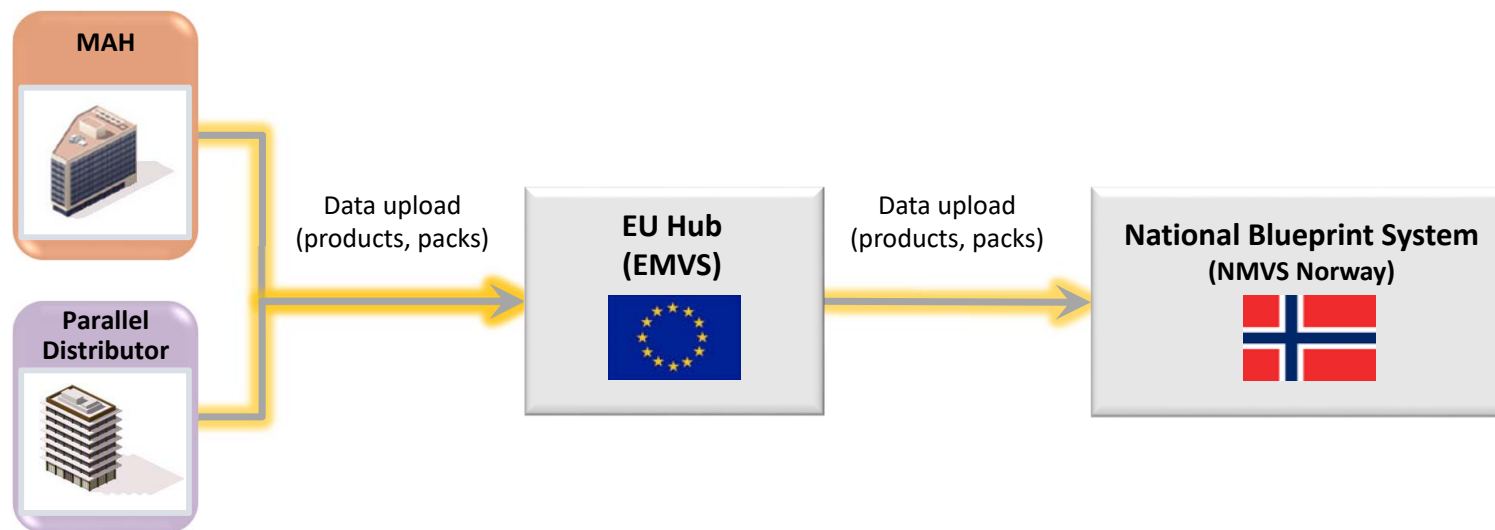
New functionalities

- The first MAHs are preparing the production of serialized medicaments
- The first MAHs are able to upload product/pack data to the EU Hub
- A connection between the Norwegian NMVS the EU Hub has been established
- The EU Hub can upload product/pack data to the Norwegian NMVS

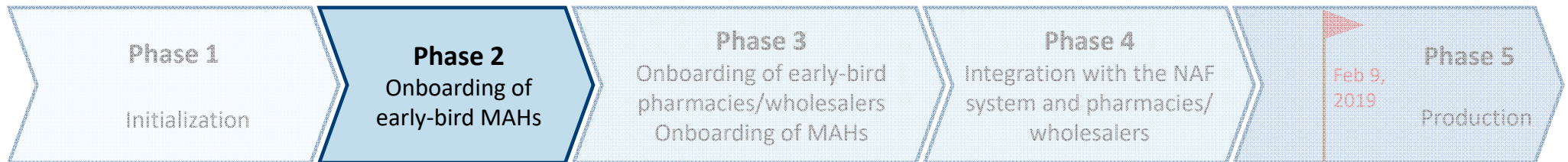
Planning, Detail View: Phase 2



During phase 2, the highlighted information flows will be tested:



Planning, Detail View: Phase 2



Results of Phase 2:

Usage

- The first serialized packs have been manufactured and put into the supply chain.
- Product/pack data have been transferred to the NMVS, i.e. the information flow between MAHs and the NMVS via the EU Hub has been tested.

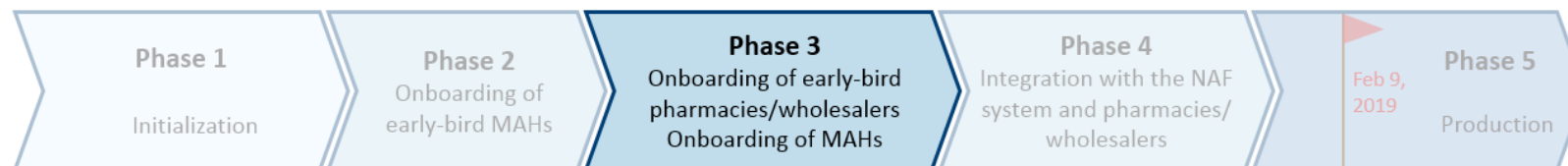
Organization

- A small group of pharmacies and wholesalers („early birds“) has been chosen to test the verification/dispensing of medicaments in Phase 3.

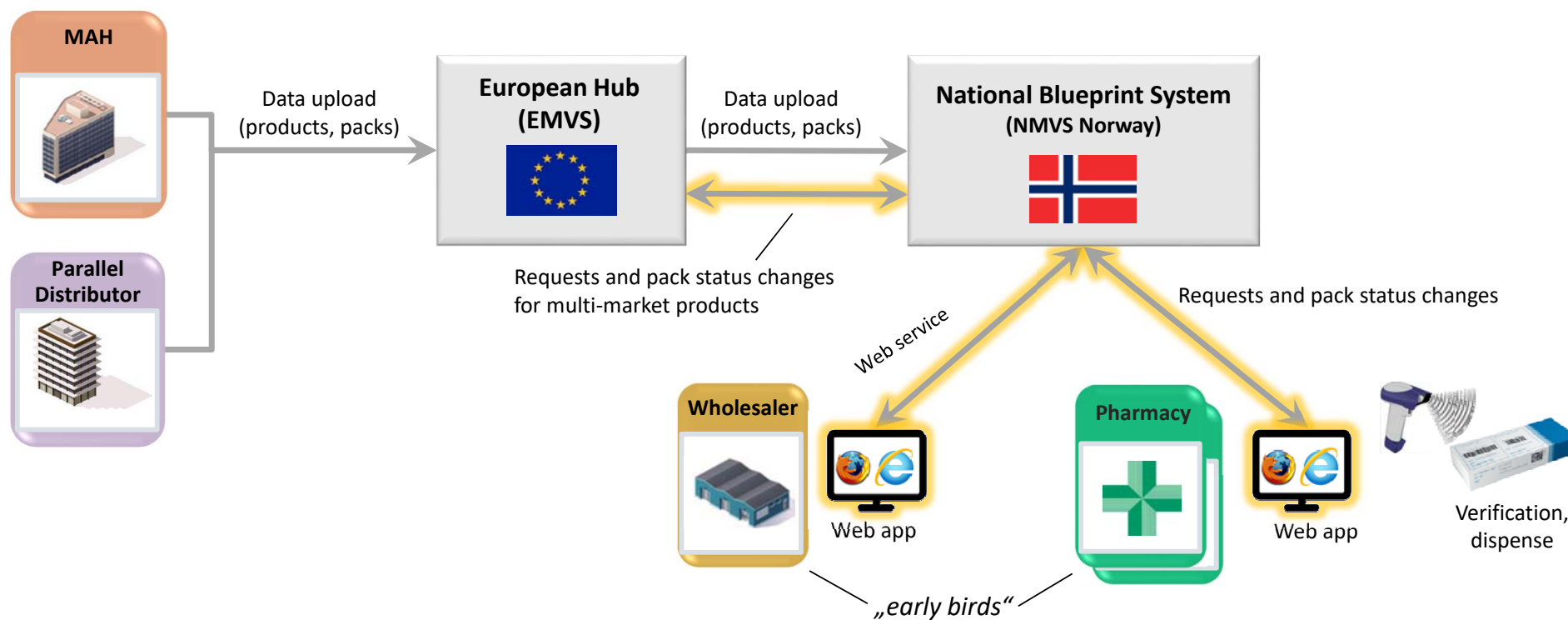
New functionalities

- A web app is being provided for testing in Phase 3, as the NAF system will not have been connected by then.

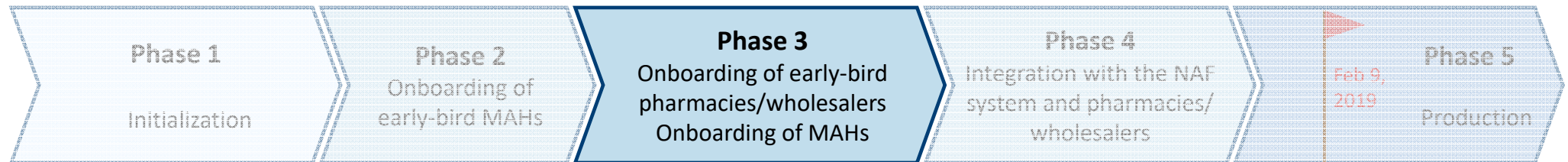
Planning, Detail View: Phase 3



During Phase 3, additional data flows will be tested:



Planning, Detail View: Phase 3



Results of Phase 3:

Usage

- The early-bird pharmacies/wholesalers have verified/dispensed the first serialized medicaments, i.e. the information flow between the MAHs and the NMVS has been tested end-to-end.

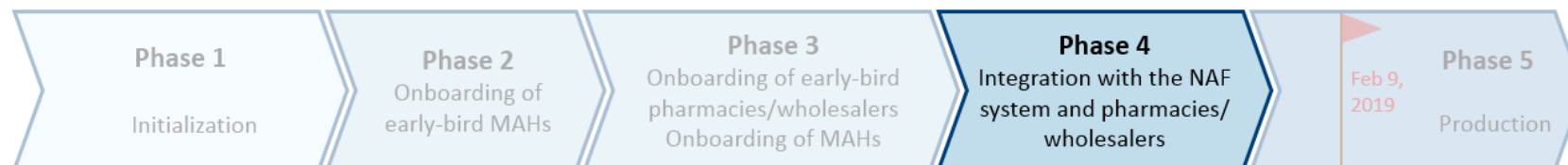
Organization

- The onboarding of the NAF central server including the major part of the pharmacies and wholesalers has been prepared.

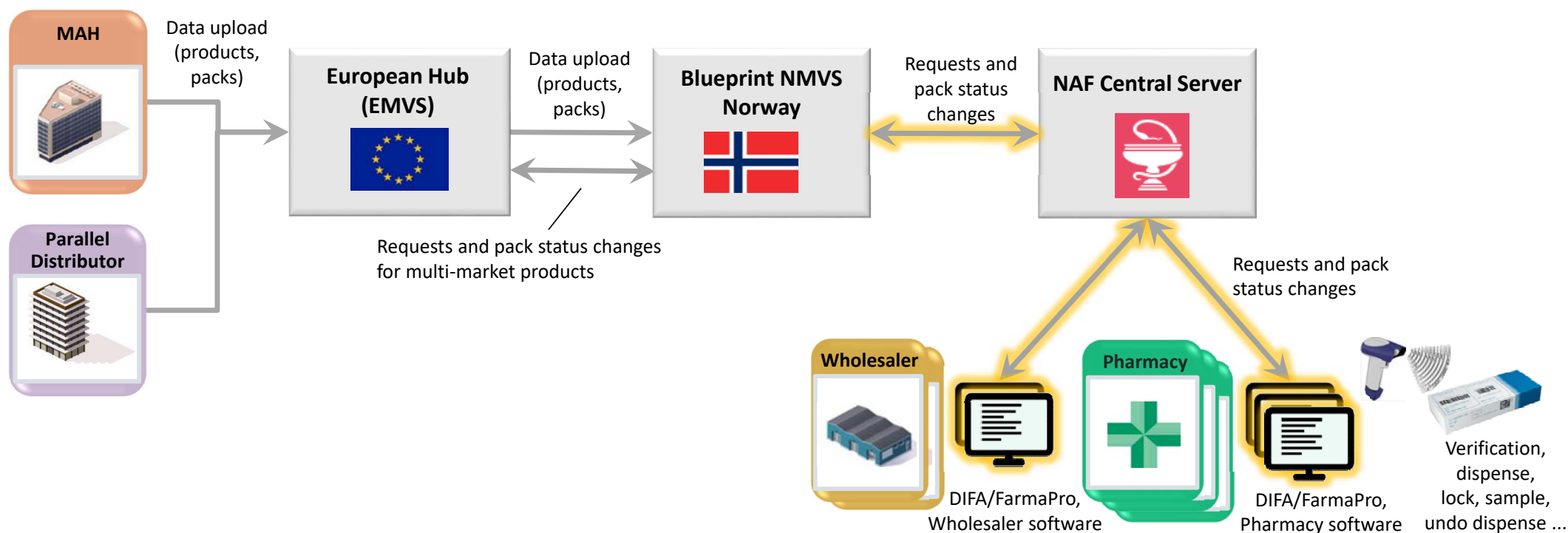
New functionalities

- The NMVS web services are fully functional, including multi-country transactions.

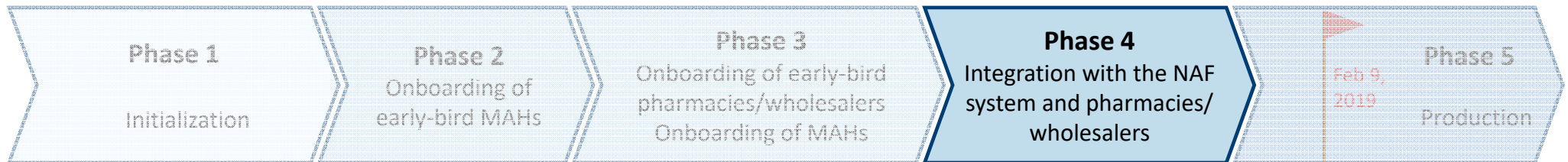
Planning, Detail View: Phase 4



During Phase 4, the integration with NAF and the pharmacy and wholesaler software systems will be tested:



Planning, Detail View: Phase 4



Results of Phase 4:

New functionalities

- NAF have connected their system with the NMVS web services.
- Upgraded pharmacy/wholesaler systems have been integrated with the NAF system and installed at almost all pharmacies and wholesalers.

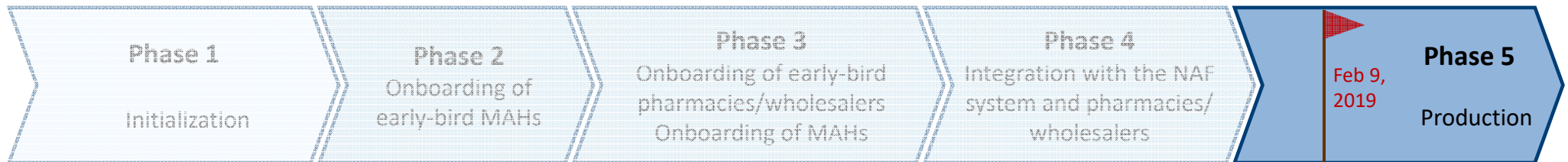
Organisation

- The software suppliers have trained their users at pharmacies and wholesalers.

Utilization

- The new software versions have already been used at the pharmacies and wholesalers.
- The vast majority of medicament packs on the Norwegian market is now serialized.

Planning, Detail View: Phase 5



Results until Feb 9, 2019:

New functionalities

- The new pharmacy/wholesaler software systems have been installed at all pharmacies and wholesalers

Utilization

- The verification of medicaments has become a routine at the pharmacies and wholesalers.
- Almost all medicament packs on the Norwegian market are now serialized.
- The integration between the NMVS and the NAF system works smoothly.

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.



Thank you for your attention !

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Backup slides

What exactly needs to be done? (1)

- All MAHs must
 - Introduce GTINs in addition to VNRs
 - 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
 - Introduce GTINs in addition to VNRs
 - 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 all their MAHs
 - Install check-out procedures for packs delivered to secondary distributors
 - 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
 - Reserve implementation capacities
 - 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)

- The EU Hub will for the first time have to ...
 - ... handle transactions from multiple countries
 - ... handle multi-market products/transactions
 - ... handle inter-market transactions (new requirement)
- Norwegian authorities will have to adapt their product master data management
 - GTINs have to be managed alongside with VNRs
- NoMVeC will have to ...
 - ... keep an overview of all the stakeholders involved and their respective progress in the project
 - ... align with the Norwegian authorities
 - ... manage detected falsifications including false positives
- General aspects
 - The NMVS must be formally validated by the NoMVeC and approved by EMVO
 - Further URS changes by EMVO are likely to occur in the future and will have to be considered