

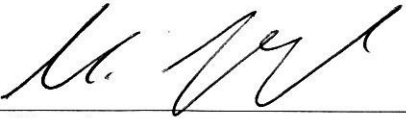
Roadmap to NMVO and NMVS Implementation

Document Number	Version	Effective Date	Page No
EMVO_0028	1.0	1/3/2016	1 of 2

ROADMAP TO NMVO AND NMVS IMPLEMENTATION

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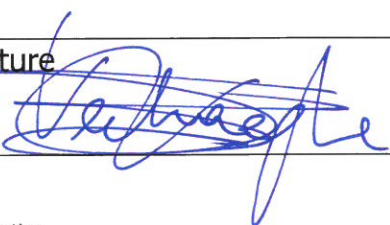
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European Medicines Verification System: Roadmap to NMVO and NMVS Implementation

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1 Introduction

The European Medicines Verification Organisation (EMVO) has taken responsibility for advancing the formation of the European Medicines Verifications System (EMVS) in accordance with the EU's Falsified Medicines Directive (FMD) and Delegated Regulation (DR). In order to achieve the implementation of a functioning, secure, interoperable and cost effective system across Europe, the EMVO pushes for minimum requirements that meet the FMD and the DR for the establishment of a repositories system, i.e. a European Hub with national or supranational verification systems.

The European Hub was implemented in full compliance with the EMVO requirements and is currently in start-up phase under the supervision of the EMVO.

The next step towards the Europe-wide establishment of the EMVS is the implementation of National Medicines Verification Systems (NMVS) and the national legal entity governing it (National Medicines Verification Organisation - NMVO) in each member state.

The EMVO provides guidance and support for this establishment process on behalf of the European Stakeholders. This paper is part of this guidance and sets out the necessary steps required for the efficient implementation of an NMVS as an essential part of the EMVS. It is meant to create awareness and to support the national stakeholders with their national communication, decision making and implementation effort. All recommendations are based on the experiences that were gathered while setting up the European Hub as well as the EMVO.

1.1 General context

Patient health and safety is of the utmost importance to the pharmaceutical industry (EFPIA and EGA), parallel distributors (EAEPC), wholesalers (GIRP) and pharmacists (PGEU). The infiltration of falsified medicines in the European supply chain is a real concern.

In order to counter this threat, the European Parliament and Council have released a Directive on Falsified Medicines (2011/62/EU amending Directive 2001/83/EC), which aims at improving patient safety by mandating the Marketing Authorisation Holders and manufacturers to put in place a system to prevent falsified medicines from entering the legal supply chain. Medicine authenticity should be guaranteed by an end-to-end verification system supplemented by risk-based verifications by wholesalers. Products that are in scope of the FMD are generally all prescription products with a few exceptions as specified in the Delegated Regulation (DR). While non-prescription products are largely not in scope, there are a few exceptions and more may be defined per market by national competent authorities. The directive also specifies that the cost of the system will be funded by the manufacturers and the operation should be supported by a non-profit organisation managed jointly by the stakeholders.

In essence, manufacturers will be required to print a Data Matrix code, which incorporates a unique identifier (UI) and apply an anti-tampering device on the outer packaging of all medicines for each individual sales package. At the point of dispense the medicine will be scanned, checked and verified for authenticity against a national (or supranational) repository. If the UI on the pack matches the information in the repository, the pack is decommissioned and supplied to the patient. Otherwise, if there is a warning related to this pack, then the system will highlight this as an exceptional event and the package will not be supplied to the patient. An investigation needs to determine whether the pack has been falsified or not.

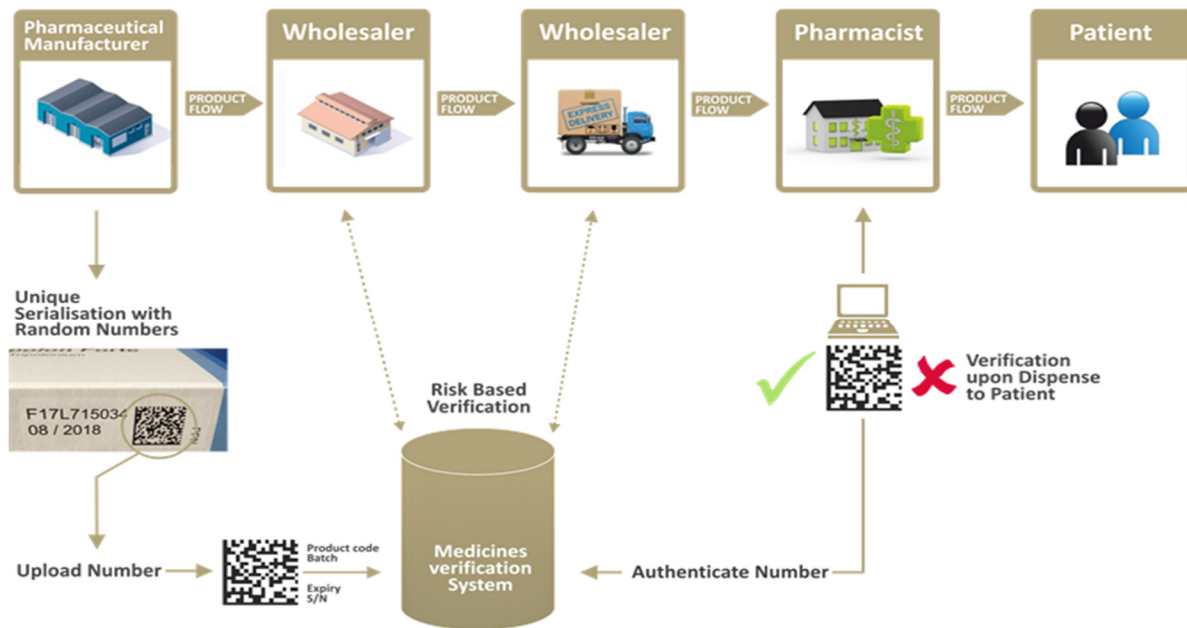


Figure 1: Point of dispense medicines verification

In a joint initiative, EU stakeholders representing manufacturers (EGA, EFPIA, EAEP), wholesalers (GIRP) and community pharmacists (PGEU) have defined a cost-effective approach to the repositories system according to the requirements of the FMD. Manufacturers can upload the unique identifiers via the **European Hub** and verification of medicines will take place in the **National Medicines Verification Systems**. The overall technical and quality standards, such as system interoperability, data ownership and access have been agreed by the stakeholders based on mutually endorsed principles that are compatible with the FMD requirements.

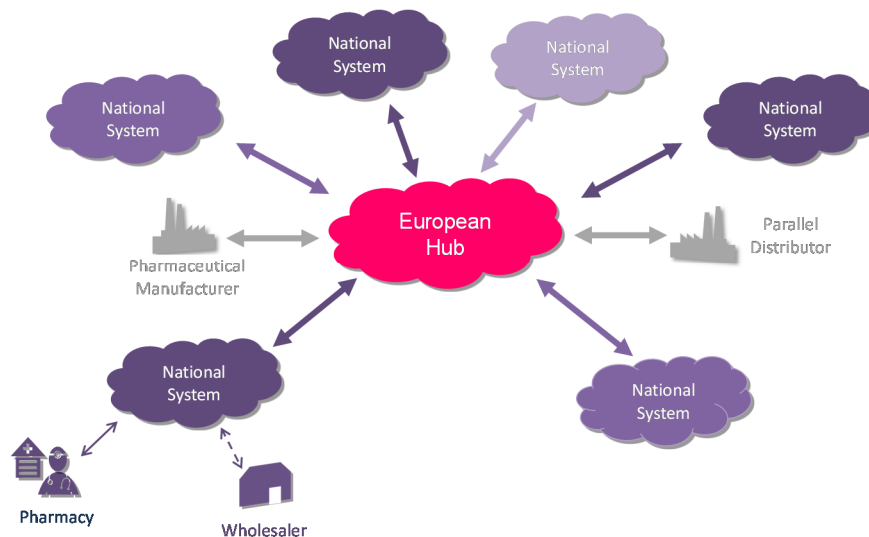


Figure 2: European Medicines Verification System

1.2 Time line and legal situation

The European Commission defines in a DR in detail the technical specifications of the “unique identifier” and how the EMVS will operate.

The FMD requires full implementation of the system no later than 36 months after the publication of the DR in the official journal of the European Union on the 9th of February 2016. This means that all countries in scope must have their national systems up and running by Q1 2019. This includes the connection to the European Hub and to all national users (pharmacies, wholesalers etc.). The countries in scope are all 28 EU Member States as well as the 3 EEA countries (Norway, Iceland, Liechtenstein). EU Member States which have a system in place that verifies individual medicines, (currently only 3 EU Member States fall into this category: Belgium, Italy, Greece) have an additional 6 years to implement.

EMVO has set itself the goal to support the roll-out of the system design and to motivate national stakeholders to further intensify their efforts with respect to the national systems as soon as possible.

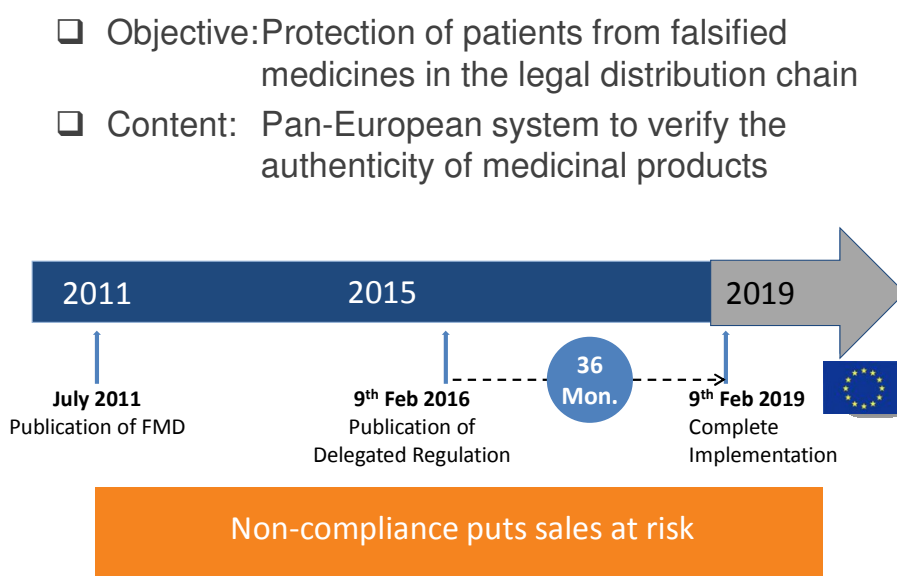


Figure 3: Implementation of Falsified Medicines Directive (FMD) is required by Q1 2019

1.3 National Medicines Verification Organisation (NMVO)

Article 31 of the DR requests that the national repository system shall be set up and managed by a non-profit legal entity which is established by manufacturers and marketing authorisation holders. Wholesalers and pharmacists are entitled to participate in the NMVO on a voluntary basis.

The main task of the NMVO is setting up and running a National Medicines Verification System (NMVS) for their market. The practical reason to establish a governance organisation is the need for, amongst others: political and legal representation within the activities to set up and run this NMVS.

1.4 National Medicines Verification System (NMVS)

The main purpose of the national system is to serve as the verification platform to which pharmacies, other persons authorised to supply medicines to the public and wholesalers connect in order to verify the authenticity of an individual pack. The national perspective on the EMVS is shown in figure 4.

The NMVS fulfils the requirements of a national repository as stipulated by the European legislation. The key tasks of the NMVS are:

- Receiving revised/new product serialisation data from the European Hub.
- Serving as the verification platform for pharmacies or other registered parties such as wholesalers to check a pack's authenticity.
- Serving as the platform for registered parties such as pharmacies, wholesalers, manufacturers, and parallel distributors to mark a product pack as 'decommissioned' (when product is sold, recalled, taken out of the supply chain, exported out of EU, ...).

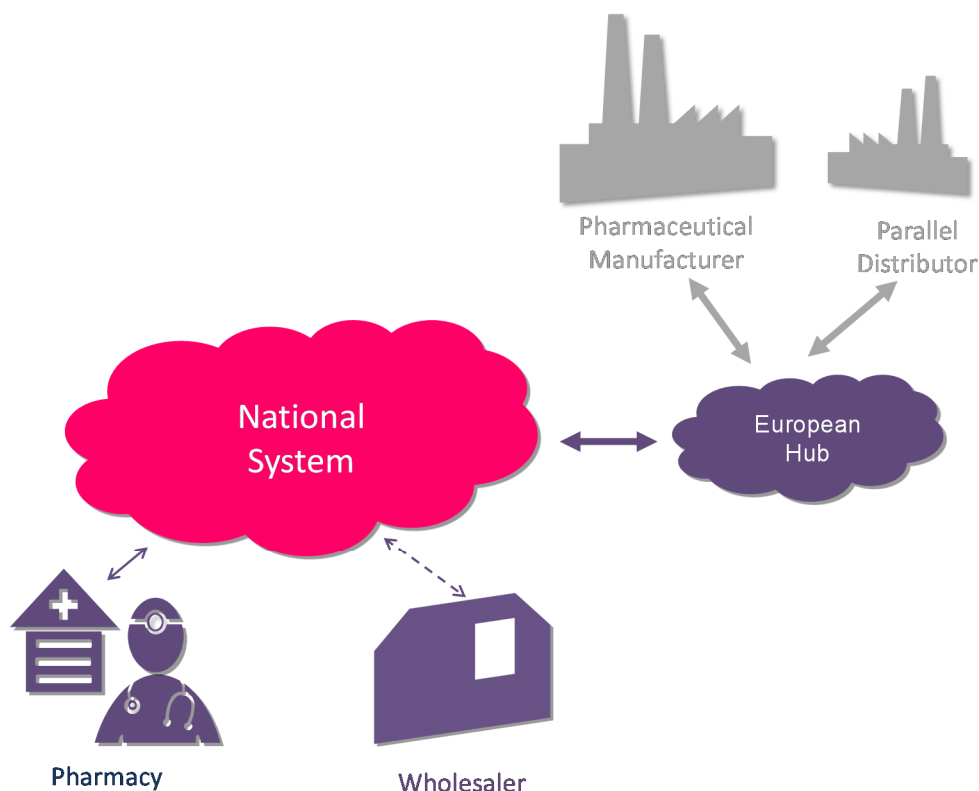


Figure 4: EMVS from the perspective of the national stakeholders

1.5 The Blueprint Approach for national systems

The implementation of the European Hub has shown that setting up and managing such a system is a complex task. A concerted approach should be taken for the implementation of national systems similar to the approach taken at European level where the Hub is supported by the EMVO. It is also clear that substantial synergies might be achieved by combining activities on national and European level at least to a certain extent. Therefore EMVO offers an approach called the Blueprint Approach in order to support the stakeholders in the Member States with the establishment of their national verification system.

The purpose of the Blueprint Approach is to minimize overall system costs and the risk to fail. At the same time it supports national stakeholders in implementing their National Medicines Verification System (NMVS) in the easiest way.

The most important elements of the Blueprint Approach are:

- National Systems are implemented and operated based on a “Blueprint standard” as defined in
 - the template of national Memorandum of Understanding
 - the template statutes of an NMVO
 - The EMVO User Requirement specifications (URS)
 - Requirements for the European Medicines Verification System (URS light), including the cost allocation model which set out the rules how Marketing Authorisation Holders and Parallel distributors will be invoiced for using the system.
- System operation is carried out by pre-qualified IT service providers.
- EMVO offers support to national stakeholders during the system deployment phase
- Management of National System operation can be partly outsourced to the EMVO to use synergies and for reducing management cost.

This Blueprint Approach will give national stakeholders the opportunity to bring into use a pre-designed system according to the agreed principles of the EU stakeholders with a possibility to extend the system functionality due to specific national requirements where necessary. The Blueprint approach enables national stakeholders to comply with the FMD and its DR. Additional features to the Blueprint, as chosen by national stakeholders, can lead to increased service fees.

Such systems are called “National Blueprint Systems” (NBPS) and are developed in accordance with the requirements as set forward by the European Commission in a most cost effective and efficient way.

Those systems that do not follow the Blueprint Approach are called Standalone Systems. They must connect to the European Hub according to its terms, but are otherwise not supported by EMVO.

While the national stakeholders might still opt to develop their own standalone NMVS, the Blueprint Approach offers the following advantages:

1. Configuration and adaption of pre-designed and existing systems that cover EU legislation instead of starting software development from scratch
2. Starting provider selection with already pre-designed contracts including pre-negotiated maximum thresholds for the pricing
3. Negotiations with pre-qualified and committed IT Service Providers (AEGATE, ARVATO, SOLIDSOFT) – without the need for further tendering procedures
4. Pre-designed cost allocation model for the NMVS and NMVO
5. Strong basis for communication management - use of consistent terminology
6. EMVO support for preparatory phase, e.g. by provision of an implementation package
7. EMVO support during implementation, e.g. providing guidance for the specification of additional requirements where necessary or during contract negotiations with Blueprint providers
8. EMVO support for system management

These substantial technical and process synergies across the National Blueprint Systems result in

- Low extra cost for system adaption instead of high cost for new system development
- Minimal maintenance and service costs
- Minimized duration of implementation projects

Based on earlier cost estimates and on gathered experiences NMVOs are expected to achieve effective and significant cost savings when choosing the NBPS compared to a Standalone system. In addition, time for implementation will be significantly longer with Standalone Systems (assuming they also will have to be designed from scratch) and the risk of failure is thus estimated substantially higher. Based on this argumentation EMVO recommends that national stakeholders join the Blueprint Approach.

If national stakeholders should nevertheless decide for a Standalone System, this should lead to a solution that does fulfill the EMVO User Requirement Specification (URS) to ensure interoperability between the systems. Any extra costs which might be incurred by EMVO adapting the EU hub to communicate appropriately with a Standalone system, will be borne by the national stakeholders opting for this Standalone system.

2 From initiation to full operation

The manufacturers and MAHs in each Member State are obligated to set up, fund and run the national repository system. Other national stakeholders, e.g. wholesalers and pharmacists associations should participate in setting up and running the national repository system where they choose to and have to take up responsibility for their relevant internal systems components and processes.

In order to meet these goals a governance organisation (the NMVO) and a technical system (the NMVS) have to be set up. The EMVO has set out the key steps for a phased approach in two work streams:

Governance organisation NMVO:

1. Start initiative to seek alignment
2. Agree on shared rules and goals and document these in a national Memorandum of Understanding (MoU)
3. Set up national stakeholder organisation

Technical system NMVS:

1. Specify country specific requirements based on URS for the Blueprint System
2. Refine cost estimation for the ramp-up and full-operations phase
3. Select IT service provider
4. Implement system
5. Test and qualify system
6. Go-live and ramp up to full operation with all users connected

EMVO can offer support to the national stakeholders within the Blueprint approach.

A more detailed look into the related activities is presented in the following chapter.

2.1 Creating the governance organisation

Starting with the already existing level of organisation between stakeholders within a Member State the manufacturers and marketing authorisation holders have to set up a non-profit legal entity that implements, manages and operates the national repository system. For this non-profit legal entity it is suggested to take over the approach of 'Constituencies' (Each of the following stakeholder communities representing material users of the EMVS are entitled to full membership of the NMVO as separate Constituencies: (1) the research based pharmaceutical companies, (2) generic pharmaceutical companies, (3) self-medication pharmaceutical companies, (4) full-line pharmaceutical wholesalers, (5) community pharmacies, (6) hospitals, and (7) pharmaceutical parallel distributors) as it has been agreed on a European level in order to obtain a fair and balanced division in the voting rights between associations (or constituencies where applicable).

In order to cover most of the potential needs for action, a start from "zero" is assumed in this chapter and is illustrated in figure 5. In any case it is essential to install or use an existing steering group that coordinates the stakeholders' interests and mentors the necessary activities.

2.1.1 Full Membership

The repository system should be set up and managed by a non-profit legal entity established by associations of manufacturers and marketing authorisation holders ("MAHs"), including parallel importers, wholesalers and persons authorised or entitled to supply medicinal products to the public (pharmacies and healthcare institutions).

2.1.1.2 Constituency or association membership

Full membership is open and should comprise associations of manufacturers and marketing authorisation holders (MAH), wholesalers and persons authorised or entitled to supply medicinal products to the public, i.e. community pharmacies and healthcare institutions which may be organised to the constituency principles. The membership fee structure should be laid down in the statutes. The membership fees cover the administrative and governing costs of the entity (technical and operational costs of the verification system are borne by the manufacturers). The membership fees should be determined by the General Assembly and should be the same for the full members (or constituencies where applicable).

2.1.1.3 Rights and obligations of full members

Each constituency or member association should have a vote and veto rights in relation to the General Assembly's decision-making powers after due consultation and debate and provided the exercise of such right results in an outcome that is compliant with applicable laws. The specifications of voting and veto rights should be specified in the foundation documents of the legal entity and should include:

- Changes to the contractual arrangements with the IT service providers that deviate from the EMVS Requirements (without prejudice to those mandated by the Directive or Delegated Regulation) including changes to the agreed principles on data access and management provided these latter changes concern the respective Member's own data;
- Changes to the agreed principles on the cost allocation model that serve as a guidance for charging Manufacturing and/or Marketing Authorisation Holders on an annual basis for the use of the System as set out in the EMVS Requirements;
- Increases in NMVO membership fees above e.g. 15% on a year on year basis;
- Each Constituency representing the Manufacturing Authorisation Holder stakeholders (those being (a) the research based pharmaceutical companies, (b) generic pharmaceutical companies, and (c) pharmaceutical parallel distributors) shall have a veto right in relation to increases in the NMVO annual budget e.g. above 20% on a year on year basis save where such increase is necessary to comply with the EMVS Requirements.

2.1.1.4 Balance in representation

Within EMVO there are three associations of manufacturers and marketing authorisation holders (EAEP, EFPIA and EGA), one association of wholesalers (GIRP) and one association of community pharmacists (PGEU), which each also represent a constituency.

In many countries the exact same constellation of national trade associations may not exist. However, it is recommended that national stakeholders aim for a fair and balanced division in the voting rights between associations (or constituencies where applicable) of manufacturers and marketing authorisation holders and associations (or constituencies where applicable) of wholesalers and pharmacies.

Since they all participate in the governance of the entity and financially contribute to its costs, associations of manufacturers, marketing authorisation holders, wholesalers and pharmacists should actively take in part in all decisions. Decisions should be taken on a consensus basis. Decisions based upon or according to majority of voting rights should be avoided by principle.

2.1.2 Access to the Repository System

Marketing Authorisation Holders and Parallel distributors should be able to use the European Medicines Verification System for the verification of medicinal products which they bear responsibility for in a certain market at a defined fee structure (see chapter “Fee structure for MAH”).

All holders of a wholesale distribution authorisation and all persons authorised or entitled to supply medicinal products to the public in the country should be able to verify individual medicinal products with the European Medicines Verification System free of charge.

The National Medicines Verification Organisation (NMVO) is responsible for the accreditation/validation of access by wholesale distribution authorisation holders and persons authorised or entitled to supply medicinal products to the public in the respective country. It is also responsible for invoicing Marketing Authorisation Holders and Parallel distributors that use the verification services offered by the NMVO.

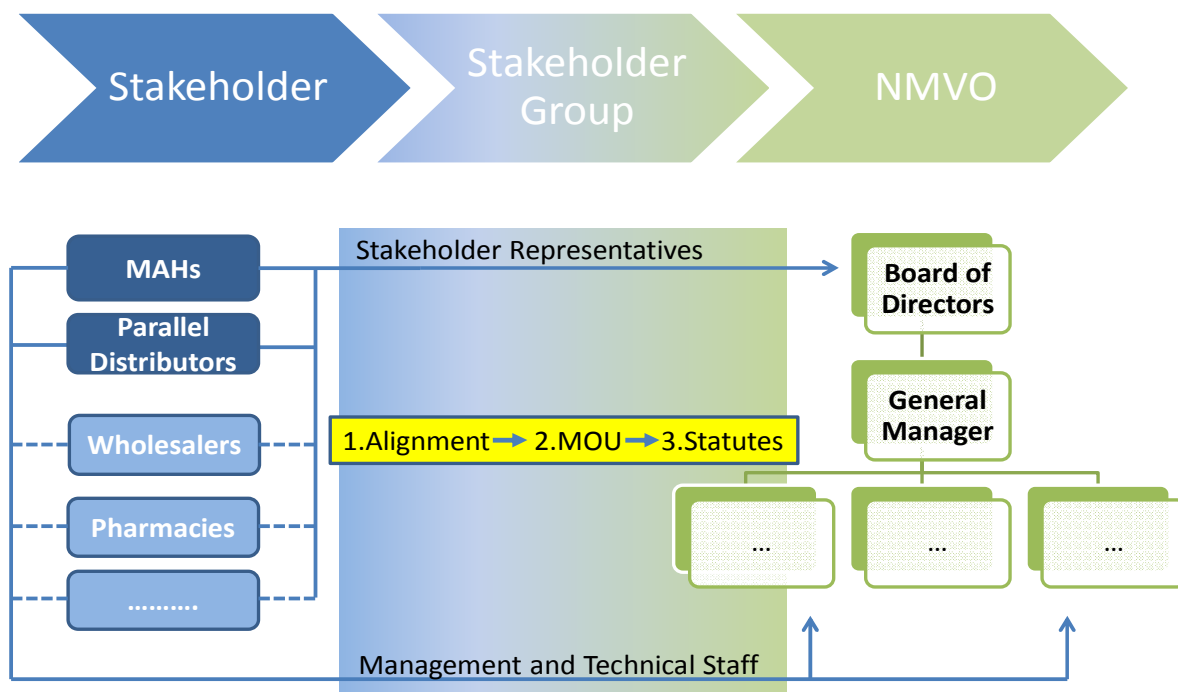


Figure 5: Development of the governance organisation

2.1.1 Three steps to the NMVO

Step 1: Start initiative to seek alignment

National stakeholders are required to seek alignment amongst each other to take a joint approach for the establishment of the national repository system.

If not already started the national manufacturer associations are responsible to initiate this process that should lead to a document, e.g. Power Point presentation or protocol that roughly covers a shared understanding on the following topics:

- Background and Overview: EU-FMD and DA, What is the scope? What does it mean for all Stakeholders?
- Who else is or needs to be involved in the project and how?
- Who will be impacted by the project and how?
- How will cooperation between the involved parties be organized?
- What are the specific needs of the member state if any?
- What are specific needs of any involved stakeholder?
- Is there a shared understanding with respect to the National Blueprint System and which are the other technical options?
- What are the expectations regarding timeline of the realization of the different phases?
- What are the success factors, constraints and risks (budget, resources...)?
- What will the funding mechanisms specifically for the early phases look like?

Some of these questions might be easy to answer but the resulting document which is supported by all involved stakeholders is a sound basis to start with the next step. The EMVO is willing to offer high-level support during this start-up phase by providing material, guidance and appropriate help for 'Blueprint countries'.

Step 2: Agree on shared rules and goals in MoU

National stakeholders will need to agree on shared rules and goals in some basic principles in order to become operative. These principles can best be documented in a Memorandum of Understanding (MoU) between the national stakeholders.

The MoU between the national parties should:

- Describe the conditions for the joint development of a national verification system to meet the requirements of the FMD and DR
- Support the internal processes and manage the NMVS
- Document further developed funding mechanisms and cost allocation for project phases
- Serve as a basis for decision making
- Support and facilitate communication on these issues.

The EMVO is able to offer a Blueprint MoU for the national stakeholders which is based on the MoU agreed between the European stakeholders and it is part of the Blueprint implementation package.

Step 3: Implement national stakeholder organisation

From the principles outlined in the MoU the NMVO statutes can be derived and the NMVO can be implemented.

After the foundation of the legal entity the possibilities to communicate and act as a national organisation for medicines verification will help to accelerate project progress significantly. The legal format builds the framework for

- Entering into contracts with IT service providers, users, EMVO
- Relationship to national competent authorities
- Meetings on regular basis
- Organisation and manpower
- Finalized routine funding mechanisms and cost allocation
- Internet presence

The EMVO can provide Blueprint template statutes for the foundation documents which will only require some adjustments in order to apply to national law.

The organigram below shows an example on how roles within the national organisation could be structured and defined. The management tasks in blue can be outsourced to the EMVO at cost in line with the Blueprint approach.

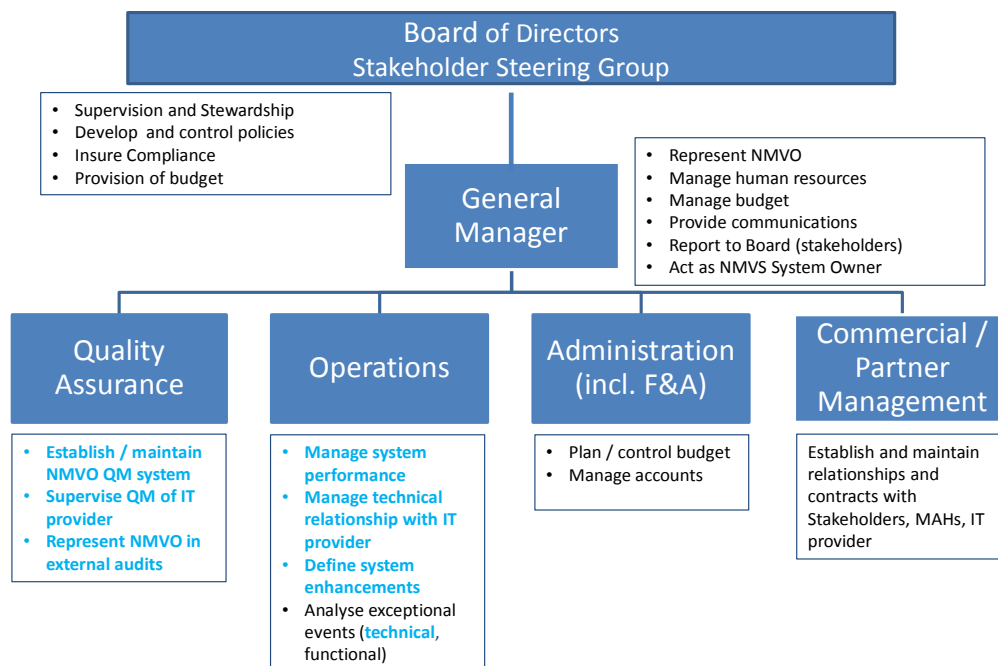


Figure 6: Proposed NMVOs organisational structure

2.1.2 Cooperation before and after NMVO incorporation

Parallel to the steps from the previous chapters there are also ongoing activities that have to be taken into account and that develop over the years. The benefit of setting up a cooperative relationship with important partners is highlighted here.

2.1.2.1 System Users

The DR requests that pharmacists, and in certain circumstances wholesalers, have to be able to verify and decommission packages of medicinal products. Therefore the wholesalers and the pharmacists have to connect to the NMVS with their IT systems (warehouse management system, inventory management

system, pharmacy system) in order to allow for an automated authentication process according to the provisions of the DR.

The DR stipulates that in some specific cases, if required by national legislation, a wholesaler also has to verify the safety features and decommission the unique identifier of a package instead of his customer that supplies medicinal products to the end-user. Examples are:

- Veterinarians and retailers of veterinary medical products
- Dental practitioners
- Prisons
- Schools

Since the system users will number thousands in most of the member states and because several different software solutions are in operation at the wholesalers and pharmacists, the planning and the management of that national on-boarding process is a challenge and has to be started early. The cooperation between system users and the NMVS needs to be governed by contracts that include technical and commercial rules for system integration and operation.

2.1.2.2 National Competent Authorities

The National Competent Authorities can be involved from the very beginning into the activities of the stakeholders in order to establish a good relationship and shared understanding on the EMVS and its national implications. If any, additional and country specific requirements for the national system will result from the related early phase discussions.

The DR requires authorities to supervise the functioning of verification systems in their territory and gives them a right to access data for pharmacovigilance, pharmacoepidemiology and reimbursement purposes. The national authority's position regarding these aspects, as well as their representation in the board of such legal entities, should be clarified early on.

The DR also requires the national authorities to inform the stakeholders of the additional products which will carry the unique identifier and/or the anti-tampering device in that member state.

2.1.2.3 EMVO

Besides the already mentioned interactions between an NMVO and EMVO with respect to the Blueprint Approach there are other early phase activities that might be beneficial for all countries participating in the EMVS. EMVO will support the national stakeholders to establish an implementation team and a project manager as single point of contact and to:

- Consolidate the national understanding of EMVO's general approach, expectations and the implementation package
- Articulate the preference for the Blueprint Approach
- Lead all discussions relating to the cooperation between national and European level, whether governance, administration, or technology related
- Consult the EMVO to help defining a rough-cut project plan
- Update national project status and provide feedback to the EMVO in order to support the overall progress monitoring process

Regardless of whether a Member State follows the Blueprint Approach or implements a standalone National System, the national stakeholders must enter into a cooperative contractual relationship with EMVO, in order to regulate topics like data protection, liability, etc. in relation to the connection to the European Hub and its associated processes. Within that cooperation agreement the details of collaboration are described and documented.

2.2 Creating the technical system (NMVS)

Creating the national technical system is the core activity within the national project and technical and IT experts on behalf of every NMVO are needed.

Member States who choose the Blueprint Approach can profit from the work that already has been done.

Member States who do choose a Standalone System, need to ensure on their own that the integrity and credibility of the whole EMVS is not endangered by lack of compliance with any of the basic standards that are set forward by the EMVS URS:

- National System User Requirements Specification (that must be aligned with the European Hub)
- System Provider Selection (typically RFI, RFP followed by shortlisting vendor selection process, vendor audit and qualification)
- Commercial (contract negotiations)
- Implementation Phase (Vendor support during URS to Functional Specification / Design Specification Phase)
- Support during system development phase
- Computerized system validation
- Validation of security and interface standards mandated for connection to European Hub
- Go-live and post-go-live support

In order to protect the system against e.g. attacks from the internet, EMVO worked out standards for data handling and IT security and propagates these with the Blueprint Approach. These or equivalent standards are non-negotiable for all systems including Standalone systems that connect to the European Hub.

2.2.1 Six Steps to System Implementation

Based on the experiences that were made while implementing the European Hub and parts of the first national systems, a phased project structure, similar to the steps outlined in this chapter, is strongly recommended.

Step 1: Specify requirements

The EMVS URS describes all necessary functional and non-functional requirements to a national system and its interaction with the European Hub. It is in the process of being adapted to the content of the Delegated Regulation on safety features as currently known.

The most important elements needing compliance with this URS are:

- Coverage of necessary use cases (e.g. upload of pack data, pack verification, dispense, handling of cross-border trade),
- Employing an effective way of authenticating genuine system users and rejecting rogue players,
- Ensuring state-of-the-art IT security of the system,
- Using technology to avoid data loss,
- Having a Hub interface that is compliant with the existing technical specification.

These requirements have significant consequences for methods and technologies employed, e.g. the system's data model, encryption technology, or data center operation. Many of these consequences are described in more detail in the URS.

The respective members of the national team can get to work immediately and:

- Make the EMVS URS their own (read, understand and accept)
- Define additional country specific requirements due to
 - Requests of national authorities
 - Specific national IT Infrastructure and potential constraints
 - Specific national processes e.g. billing
- Attach additional requirements to the final URS for the NMVS
- Approve and sign the complete NMVS URS

Step 2: Refine cost estimation

Based on the learnings and results of step 1, the cost estimation for the technical part can be refined. The offerings of the Blueprint service providers are documented in the existing Blueprint agreements and can be used as a starting point although the current prices are only pre-negotiated, and the providers need to specify their best and final offers in the end. The strongest influence on costs, besides the size of the national repository system, can be expected from additional country specific requirements.

Step 3: Select IT service provider

The EMVO has identified 3 IT service providers (AEGATE, ARVATO, SOLIDSOFT) who were able to demonstrate their ability to develop and operate a National Blueprint System, including quality management according to relevant standards, e.g. GAMP 5 and ITIL, and to do this at reasonable cost. The IT service providers developed a software solution in due time that complies in full with the EMVO requirements.

The EMVO already negotiated the basic Blueprint agreement with these IT providers for the provision of National Blueprint Systems. This Blueprint agreement covers all technical, commercial and legal aspects of an IT service contract and can be used by the NMVO as a starting point for individual negotiations. The existing frame contract between EMVO and each of the IT service providers binds them to start discussions with the national stakeholders, or NMVOs as soon as these are incorporated, on the basis of this Blueprint agreement.

EMVO offers a comprehensive overview on the specific offerings of the 3 IT service providers in order to support early phase national evaluation process. This overview mirrors the specific features of the related National Blueprint contracts. Based on the country specific requirements and the gathered information the last activities before the conclusion of the contract can follow:

- Adapt contract to take local conditions into account
- Ask for best and final offer
- Clarify customer obligations, discuss and approve implementation plan

Key within this list is to approve the implementation plan from the provider. This implementation plan reflects the whole scope of work together with time schedules, resource planning and milestones during the implementation phase including the so-called "validation phase". This document will also be the legal basis for claims management in case of irregularities within the provider's performance. It comprises:

- Objectives
- Scope
- All implementation tasks to be performed
- Start and completion date for each implementation task
- Acceptance criteria to be applied by NMVO in evaluating implementation deliverables
- The allocation of responsibilities between the parties
- The specific resources to be provided by NMVO and its partners

Step 4: Implement system

During system implementation according to the provisions of the implementation plan, strong cooperation between the technical team and the IT service provider is mandatory to conduct the following permanent tasks:

1. Updating of shared understanding with respect to scope and progress
2. Updating of shared time line expectations
3. Evaluation of findings and decision on respective measures within the NMVO and the IT service provider organisation:
 - a. Technical relevance
 - b. Relevance for time line
 - c. Budget relevance

As part of the National Blueprint agreement cooperation between the partners is defined in detail. E.g. both parties have to name a contact person that acts as a technical project manager. Both technical project managers should define and set up standard procedures like weekly team and sub-team meetings, report mechanisms and weekly calls between technical project managers.

Step 5: Test and qualify system

All testing, with the exception of the User Acceptance Test (UAT), lies within the responsibility of the service provider. Testing and qualification for and after the UAT will be performed in the responsibility of the NMVO by the technical team and will be supported by the IT service provider along the provisions set forward in the contract. Testing and qualification cover all deliverables within the provided services. The final User Acceptance Test will include performance- and stress-testing, will be attended and supported by EMVO and marks the end of this step. Detected defects will be named by the technical team and repaired by the IT Service Provider until the system shows the required performance. It is very important to include at least some representatives of all connected parties, e.g. pharmacies and wholesalers, into the final phases of testing in order to make sure that the overall system is operable before the go live.

Step 6: Go Live and ramp up to full operation

The decision to go live with the open issues remaining on the punch list lies within the responsibility of the NMVO. An important precondition that has to be fulfilled, though, is the availability of a complete documentation set

- Of the NMVO covering its own quality assurance obligations, as well as
- Of the IT service provider describing processes and functions for the operation phase of the NMVS.

The content of the IT service provider's documentation as well as its respective obligations must be part of the service contract.

In order to support the decision a specific planning for the go live procedure should be elaborated between all involved parties. Since not all criteria from the acceptance test will be checked directly after go live, a set of criteria that is sufficient to decide whether the go live was successful or not may be selected up front.

The successful go live is followed by the hyper-care phase that is characterized by short response times of the IT Service Provider in case of defects or malfunctioning of the live system. All defects will be repaired and some operational experience will have to be gained before additional pharmacies or wholesalers are connected.

As soon as the system runs in a stable and reliable mode the remaining participants shall get connected in order to achieve the goal of systematic medicines verification at the point of dispense.

2.3 System management and operation

2.3.1 Operational model for NMVS

As part of the implementation activities and the communication with EMVO the necessity to develop and decide on an operational model for the NMVS will come up: Who will do what when the system is running?

Every NMVO has the choice how to set up its organisation and can choose to outsource tasks to EMVO. This option has the advantage of overall synergies and could include:

- Establishing and maintaining NMVO Quality Management (QM) system
- Supervise QM of IT service provider
- Represent NMVO in external audits
- Manage system performance
- Manage technical relationship with IT service provider
- Define system enhancements
- Analyse exceptional technical events
- Invoice national marketing authorisation holders and parallel distributors on behalf of NMVO

2.3.2 Quality assurance system for the NMVS

Setting up the Quality Management system for the national system within the Quality Assurance (QA) organisation of the NMVO is an ongoing task requiring a significant level of effort if not outsourced to the EMVO.

At the latest before the go live of the system, the NMVO's own Quality Management system has to be in place in order to guide the IT service providers into the NMVO's QA requirements. The system should at least cover the following aspects:

- Quality Policy
- Document Management process
- Information Security Management process
- Change Management process
- Incident Management process
- Access Management process
- Test Management process
- Release and Deployment Management process
- Roles and responsibilities
- Training process

3 Project plan and timeline

The implementation of a National Blueprint System, including stakeholder alignment and the establishment of a governance organisation can be completed in 24 months. In order to achieve this, the stakeholders need:

- A steering group to take overall accountability, provide support, resources and budgets.
- A project manager who is in overall charge of the implementation process
- A project plan with clear milestones and work-packages
- A project team to carry out the activities organised in work streams

The starting point could be a workshop informing the national stakeholders about the implementation of the DR or any internal kick off organised by the national stakeholders. EMVO will happily support such a kick off and send a representative if asked. The key milestones are set out in the “Gantt chart” in figure 7. The chart shows one exemplary schedule that can be used as a starting point to set up the country-specific schedules. These will vary within certain limits.

It also shows that at least 2 budgeting rounds are necessary to facilitate the project before NMVO and NMVS reach a steady state operational mode. The first budgeting round supplies for the early phase and preparatory activities. The second round has to deal with the implementation activities. Details on costs and related budgeting requirements are described in chapter 4.

The NMVO has to be formally incorporated before the contract with the IT service provider can be signed. In order to make good use of the available time frame, the contract negotiations should be conducted in parallel to the preparation of the NMVO foundation. On the other hand the NMVO foundation should not delay the project kick off. As indicated with the yellow vertical bar in Figure 7 this is the point in time when the technical and the governance work stream should meet in the best case

Step	Year 01	Year 02	Year 03	Year 04	Year 05
Budget Provision					
Governance WS					
1 Initiative to seek Alignment		Start of Stakeholder Group and Shared Document			
2 Agreement between Stakeholders (MoU)		Stakeholder Group			
3 Preparation of NMVO foundation		NMVO Incorporated	Steering Group within Board of Directors		
Technical WS					
1 Requirement Specification		Complete URS			
2 Refinement of cost estimation		Sound Basis for Budget provision			
3 IT provider selection		Provider Contract Signed			
4 NMVS implementation			Implemented System		
5 Testing and Qualification			System Live		
6 Hypercare and Ramp up Phase			Plus /Minus half a Year	All Users Connected	

Figure 7: Gantt chart with project time line

4 Estimating the required budgets

Preparatory work, implementation, as well as the ramp-up and operation of medicines verification induce costs for all stakeholders arising from different activities. The EMVO has made a substantial effort to estimate the cost of medicines verification for each Member State (based on the Blueprint Approach) and proposes a simple mechanism for allocation to costs to the relevant payers in a certain market. This chapter provides the rationale used for both, cost estimation and cost allocation. The figures estimated for a specific market will be shared by the EMVO on a case-by-case basis.

As illustrated in figure 8 this chapter focuses on those costs that are directly associated with the NMVS and the European Hub. The most important and budget relevant aspects of cost estimation and allocation are described.

Out of scope are the costs for equipment and software that, e.g., pharmacists and wholesalers shall be required to upgrade in order to facilitate the verification process. The same applies for costs of manufacturers who have to upgrade their production lines with serialization equipment and software.

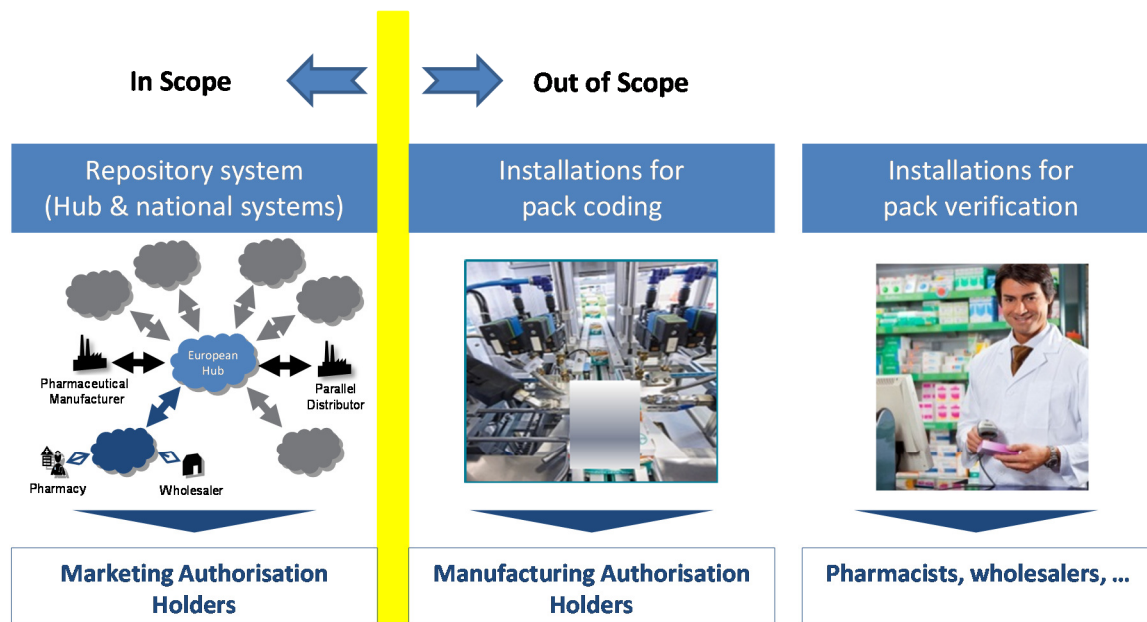



Figure 8: Costs within and out of the scope of consideration

In order to provide transparency the costs can be structured into 6 elements by differentiating between timely phases and sources of cost as shown in Fig. 9:



Cost Element		2016 to 2018	2019 onwards
		“top down” budget estimation: about 90 Mio € in total will be needed to build the EMVS in the 3 years from 2016 to 2018	Total costs for the operation of the EMVS are estimated around 90 Mio € per year
NMVS	IT service provider costs	covers all implementation services	covers all operation services / running costs
NMVO	Manpower costs	For establishing the organisation, commercial, legal and technical project resources	For operating the governance and management organisation
Hub share	IT service provider cost and EMVO		costs of developing and running the EMVO and the European Hub

Figure 9: Budget Elements for the Implementation of an NMVS

4.1 Building and operating the NMVS in the years 2016, 2017, 2018

A “top down” budget estimation from EMVO indicates that round about 90 Mio € in total will be needed to build the EMVS in the 3 years from 2016 to 2018, assuming every Member State chooses the Blueprint Approach. These costs have to be borne by the manufacturers and the parallel importers. The following paragraphs give a more detailed “bottom up” view of the cost components of an NMVO to support the stakeholders own calculations.

4.1.1 System costs for the NMVS

The highest percentage of costs results from the contract between the NMVO and the IT service provider for the NMVS. These costs cover all implementation services documented in the implementation plan.

The respective pricing is strictly confidential. It varies depending on country and IT service provider and will be made known and discussed during the contract negotiations.

4.1.2 Administration and Governance costs for the NMVO

The costs for an NMVO in this phase can be grasped by a rough estimation of the manpower requirements for the governance organisation as there are

- Steering group members representing stakeholders
 - 10% FTE for 18 months per stakeholder
- Project manager
 - 50% FTE for 18 months
- Work stream members representing stakeholders
 - Governance: 20% FTE for 12 months per stakeholder
 - Technical: 40% FTE for 18 months per stakeholder

- External consultancy depending on in-house capacity
 - Legal advice
 - Technical advice

Based on such a structure each member state can come to a cost estimation which is appropriate to define and allocate the respective budgets. These costs will have to be collected from the national stakeholders by the NMVO e.g. on loan basis, via NMVO membership fees or any other way chosen by the stakeholders.

4.1.3 Share of European Hub

All costs that come from developing and running the EMVO and its European Hub from 13 February 2015 (foundation date of EMVO) on, sum up to round about 4 Mio € per year and are pre-financed by the members of the European industry associations (EFPIA, EGA, EAEPC) on a loan basis. These loans have to be paid back by EMVO in the first three operational years of the EMVS and will be collected from the NMVOs in the same time span. According to the existing time lines this means from January 2019 until end of 2021. Since the share of costs coming from the European Hub is by far the smallest of the three cost components its impact on the budget planning process in general is minor.

4.2 Costs for operating the NMVS from January 2019

The overall costs for the operation of the EMVS are estimated around 90 Mio € per year, assuming all involved countries choose the National Blueprint System.

4.2.1 System costs for the NMVS

Expectations for operational annual costs vary widely depending on market size and country specific features within the delivered services. The realistic numbers per country result from the negotiations with the IT Service Provider and are fixed when the provider contract has been signed.

4.2.2 Administration and Governance costs for the NMVO

The annual cost induced by the NMVO during operation is expected to lie below the costs that are generated during system implementation and European ramp up. Therefore the structure outlined in chapter 4.1.2 can be used to calculate the upper limit for a potential budget. However, if an NMVO would opt for outsourcing these activities to EMVO, the costs can be significantly lower.

4.2.3 Share of European Hub

The running costs of the European Hub including EMVO organisation are expected around 4 Mio € per year. These costs together with the repayment costs from chapter 4.1.3 in the first 3 years will be shared between all NMVOs according to an allocation scheme that takes into account the market size as a main parameter based on the IMS figures for 2011.

The NMVO will refinance these costs, as it will with all its costs, with fees from its members and the national MAHs. While the regulation of the membership fees is free from restrictions, the participation of MAHs should best follow the “flat fee” approach as put forward in the Blueprint approach.

4.2.4 Flat fee cost allocation model

EMVO worked out a “flat fee” model that distributes all running costs directly connected to the EMVS in a fair manner on all MAHs in Europe. This cost sharing model is an essential element to the cost-effectiveness of the Blueprint approach. Figure 10 shows how the total cost of managing and operating a NMVS in connection with the European Hub is calculated and how it is allocated to the relevant MAHs in the respective market.

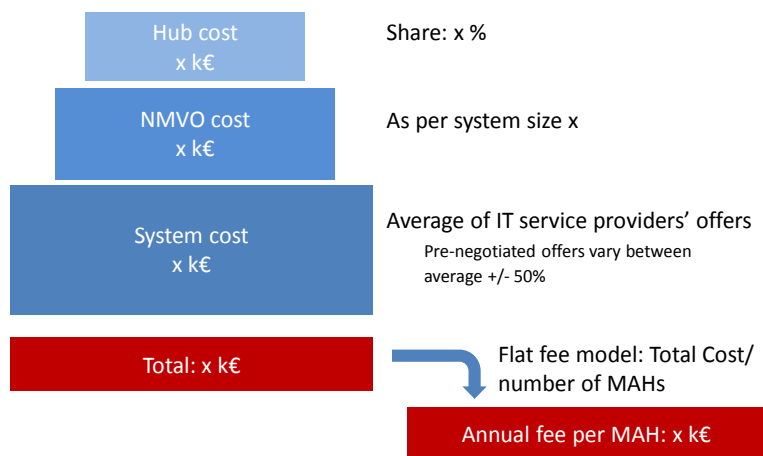


Figure 10: Elements of annual full operation cost for an NMVO and its MAHs

The level of the fees per MAH depend on the market size and the number of active MAH in that market. The fee level is comparable to the maintenance fee of one marketing authorization and can therefore be regarded as reasonable.

The principles of the cost allocation model are to charge a single fixed fee (flat fee) to all MAH requiring the verification services of the repository.

The costs of the performance of the repository systems are neither driven by the volume nor by the value of the products in the Blueprint approach.

The fee shall therefore be equal for all MAHs in one market. Operating a single flat fee has the following advantages:

- The entity charging the fees can easily calculate the fee level
- A single fee has a low level of complexity and can be re-calculated annually depending on the number of users. As such, the fee level will be very predictable and not sensitive to important variations. A lower level of complexity also brings a decrease in the costs of invoicing.
- There is a transparency to all who pay fees; the fees will be at the same level for all authorization holders. It also provides transparency in case of financial auditing.
- A single flat fee can be charged upfront to the authorization holders requiring the verification services. This prevents free use of the system and increases control and security.