eHealth Network

ePrescription & eIDAS integrated vision

2022-07-13

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth. The Joint Action supporting the eHealth Network (JAseHN) provides scientific and technical support to the Network.

Adopted by the eHealth Network on 13 July 2022

Introduction

Peoples' access and control over their health data is currently limited, even though it is recognised as an EU right. According to the Commission's 2030 Digital Compass[1], by 2030, all citizens should have access to their electronic medical records; and 80% citizens should use an eID solution. As an important concrete step towards achieving this goal, on 3 May 2022 the European Commission adopted the European Health Data Space regulation proposal[2].

One of the enablers for realising the goal of enabling people to access, share and control their electronic health data would be use of the EU Digital Identity Wallet. It could become a key element in not just accessing but also sharing health data in a citizen-controlled manner. To this end, health is defined as one of the priority use cases for the EUDI Wallet enabling people to easily access - and potentially securely store - a number of health-related documents (patient summaries, ePrescriptions, vaccination card, laboratory results etc.). People would also be able to decide when, with whom, and for which purpose they share their health data.

The purpose of this document is to help reach a common understanding of the eHealth requirements for the EUDI Wallet, thereby describing one concrete health-related use case feeding into the technical development of the Wallet so that it delivers effectively and seamlessly on its functionalities in all Member States. The document presents one concrete and complete use case that is representative and at the same time impactful for the citizen.

ePrescription was chosen as this first use case to be supported through eIDAS features, paving the way for other use cases to be supported and enhanced in the near future.

This document:

- determines the business requirements;
- proposes an outline of the architectural approach to the possible solution;
- identifies the actors of the wallet ecosystem for the use case;
- defines a concrete user journey for the ePrescription use case;
- identifies key functional requirements for the wallet on the basis of the user journey.

The document has been developed by the eHN Technical IOP Topic Group on the Integrated Vision for eHealth/ePrescription and eIDAS, following the mandate provided by the eHN to the Technical IOP Subgroup on 30 March 2022.

It uses input from the current ePrescription/eDispensation use case implemented in MyHealth@EU (referred to as the eP/eD Use Case[3]) and the eHealth user stories developed by the eIDAS working group on eHealth.

It further includes collaborative input from the eIDAS Expert Group that develops the EUDI Wallet Toolbox (for more information on the policy context and eIDAS working group, see Annex I).

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[1] 2030 Digital Compass: the European Way for the Digital Decade. Communication from the Commission COM(2021) 118 final
[2] Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space COM/2022/197 final
[3] https://webgate.ec.europa.eu/fpfis/wikis/x/iuHzN

Problems and needs

Challenges

Many Member States (MS) have introduced national e-Prescription systems. And many of these use (1D or 2D) barcodes (printed on paper or shown through mobile apps) to support the processing of a prescription.

However:

- The (2D-)barcodes of different Member States **are not interoperable**. A barcode issued by one MS is not understood by a pharmacy system in another Member State.
- There is an operational cross-border ePrescription system in MyHealth@EU. This does not support barcodes, but instead, person's identification data needs to be **entered manually** by a pharmacy.
- Having the ePrescription on the smartphone provides ease for the citizen.

Basic business requirements

- Citizens need to get their prescriptions accepted in any Member State of the EU, in a secure and privacy-preserving manner.
- The pharmacist needs to validate the authenticity of the prescription.
- In applicable situations, an authorised person should be able to purchase medication on behalf of the patient.
- The pharmacist needs to report the dispensation details and update (invalidate or calculate the remaining amount) the prescription after dispensing it.
- A prescription may change after it has been issued/provided. Pharmacies should act on the latest version of the prescription and should not dispense invalidated or out-of-date prescriptions. There should be a way to invalidate (cancel) a prescription by the prescriber or by the pharmacy that has dispensed (part of) the prescription.
- The implementation should not require extensive new infrastructure (devices etc) in pharmacies.
- The use case refers to a face to face encounter between a citizen and a pharmacist, not to an online dispensation service.

Proposed solution

Basic principles

The solution should utilize the following building blocks and elements:

- Upcoming EUDI Wallet, based on the eIDAS toolbox
- MyHealth@EU infrastructure and services
- EU DCC trust framework, either directly or as a separate implementation
- QR code technology (signing, encryption, compression et cetera)

The solution may be based on online communication, i.e. as a difference with the EU DCC framework it does not need to exclusively rely on offline verification. However, an offline approach may be part of the solution in case needed in exceptional situations or as a fallback solution for business continuity.

The proposed solution should not replace the currently established MyHealth@EU processes, but rather provide an additional way of sharing ePrescription details, at the same time improving usability and security. The standard MyHealth@EU procedures should remain as a fallback solution. At the same time, the translation functionality of MyHealth@EU should be relied upon and used. The coded payload data should be shown in the target language at the dispensing pharmacy.

An outline of the proposed architectural approach is depicted in the figure below:
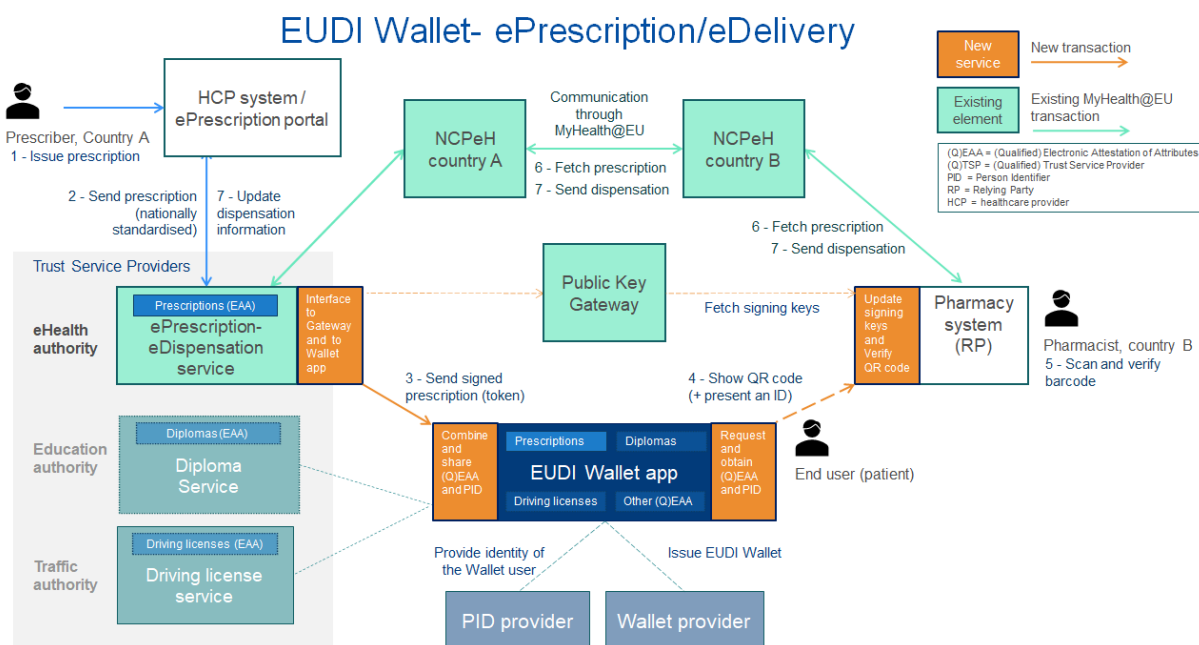
User journey and related functionalities

Preconditions for the user journey:

- National health authorities in country A (country of prescription) need to have deployed an ePrescription service interoperable with the Wallet and have enabled doctors in that country to create (authentic) ePrescriptions.
- The patient is in possession of an activated, valid Wallet and has connected it to the ePrescription service in country A.

Step	Description	Wallet Functionalities
0	A patient receives a prescription from an authorised prescriber in Country A. The wallet of the patient or their authorised representative is made aware of the prescription.	Connection to the ePrescription service in Country A, display of ePrescriptions (as per pre-requisites)
1	A patient or their representative from Country A visits a pharmacy in Country B to get the medicine(s) prescribed in Country A	

2	*(optional)* The patient or their representative identifies himself/herself in the pharmacy. The case of representation (by an authorised third party, e.g. by Next of Kin) needs to be covered.	User identification (also: representation)
3	The health professional (pharmacist) informs the patient or their representative about their data protection rights and asks for the patient's consent (where applicable).	
4 Option A Prescription list	The patient or their representative presents a QR code containing • Member State code • Set of prescription holder's identifiers • Set of the wallet holder identifiers (if different from prescription holder) • Timestamp and digital signature	Wallet generates QR code containing identifiers and instructions on how to fetch the prescription list Wallet could show a prescription list to the patient
4 Option B Specific prescription	The patient or their representative presents a QR code containing • Member State code • Set of prescription holder's identifiers • Set of the wallet holder identifiers (if different from prescription holder) • Prescription ID, dispensation PIN or other similar details • ATC code of the prescription, IDMP attributes (such as EDQM dose form), prescribed amount or other critical data • Timestamp and digital signature	Wallet generates QR code containing identifiers and instructions on how to fetch a specific prescription, and including limited prescription details (for offline use in exceptional situations)
5	The dispensation provider (pharmacy) scans the QR code, verifies the digital signature and generates a request to be sent to country A based on the information included.	

6A Default option	[Typical steps following the MyHealth@EU workflow leading to a possible dispensation]	
6B exceptional situations (internet disruption or other similar case)	*(If supported by both Country A and Country B)* In case of disruption or other exceptional situation preventing communication via MyHealth@EU, the dispenser evaluates the possibility of dispensing medicine based on the information included in the QR code. If dispensation can be performed, its details will be stored in the pharmacy system. Steps under 6A Default option will need to be performed once connectivity is restored.	
7	The dispenser provides the medicine to the patient. In case of 6B, the dispenser manually invalidates the prescription in the Wallet app.	
8	Wallet receives updated prescription status from country A with the invalidated or updated (in case dispensed partially) dispensed prescription	Updated prescription status in Wallet, possibly received through a push notification.
9	The workflow is terminated. No more access to patient data from Country A is possible.	

In the description above, instead of QR codes other alternatives may be used where supported both by the wallet and by the pharmacy system, such as NFC or other device-to-device communication means.

Use of QR code would be the preferred method; it is currently understood as the technically easiest and most economical solution having the lowest impact on pharmacies in terms of additional infrastructure.

For reading the QR codes, either a separate QR code reader or a mobile device linked to the pharmacy system would be sufficient. As a measure to limit use of falsified medicines, Regulation (EU) 2016/161 already foresees the use of 2-D barcodes on medicinal product packaging having DataMatrix structures, for providing product information via scanning in pharmacies. Some of these barcode readers currently used in pharmacies support QR code reading. Therefore, some of the infrastructure is already in use and certain changes in pharmacy software systems will be necessary.

In addition, QR codes allow printing on paper and scanning for business continuity for both the patient and pharmacy.

## User perspective of the ePrescription use case

As a patient:

- I can activate an ePrescription functionality of the wallet, so that I can be sure I have an access to my ePrescription data at any time.
- I can present my ePrescription to a pharmacist, so that s/he can deliver my medication without me bringing a printout of the prescription with me.
- I can prove my identity and the authenticity of the prescription.

For illustration purposes, this could be done through a QR code generated, which may contain the following information:

- Member State code
- Set of prescription holder's identifiers
- Set of the wallet holder identifiers (if different from prescription holder)
- Prescription ID, dispensation PIN or other similar details
- ATC code of the prescription, IDMP identifier, EDQM dose form, prescribed amount or other critical data
- Timestamp and digital signature
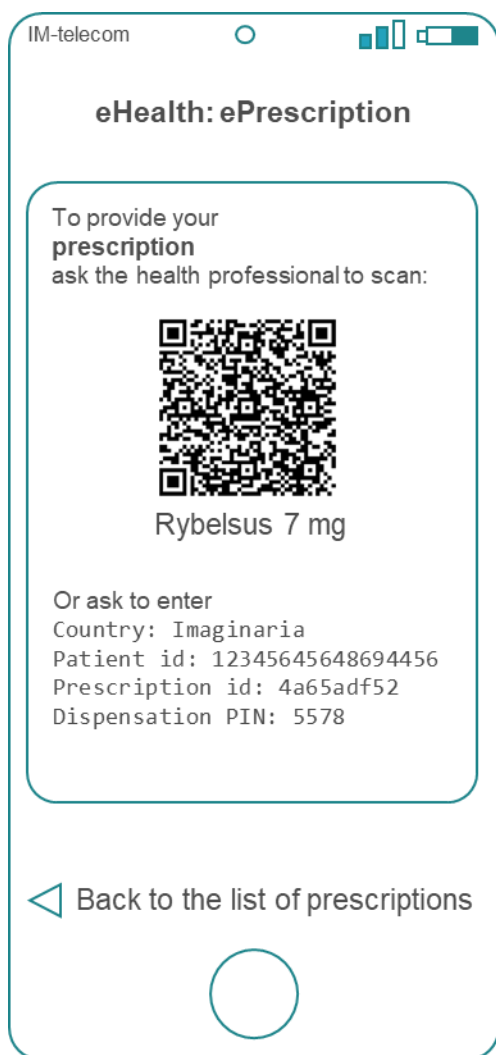
As a pharmacist:

- I can verify, identify and check the patient user's ePrescription (from another EU MS) by looking at his/her Wallet, so that I have an additional, quicker and more secure method for delivering medication when needed.
- I can check the patient user's ePrescription by scanning a QR code, so that I am certain I can deliver her/his medication.
- I can in an offline situation evaluate the possibility of dispensing medicine, and then manually invalidate the ePrescription in the Wallet (using Wallet functionality).

For illustration purposes, this may be done through the following steps:

- Pharmacist/health professional scans the QR code to retrieve or to verify the data.
- Manual entry of identity traits (including in some cases document identifiers) currently implemented in MyHealth@EU is supported as a fall-back solution.
- Verification of identity using a travel document or an eID Wallet based travel document.

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Health Professional's system/portal                          ● ● ●

  ┌────┐   My health @ EU
  │ ** │   eHealth Digital Service Infrastructure
  │ ** │   A service provided by the European Union
  └────┘

        Through MyHealth@EU services, you can access health data of a patient
        from another Member State.


  Select the country of affiliation of the patient:
  ⊙ Imaginaria
  ○ Anthracitia                                    Alternatively, scan the QR code
  ○ Pilimuta                                       shown to you by the citizen
  ○ ...

  To identify a patient from Imaginaria, please enter the
  following information:
  National identity card number:
  ┌──────────────────────────────────┐
  │                                  │
  └──────────────────────────────────┘

  Choose information to be requested:
  ⊙ Electronic  prescription
  ○ Patient Summary
  ○ Vaccination data
  ○ Laboratory  results  and  reports
  ○ Medical  images  and  reports

  To request a prescription from Imaginaria, please
  enter the following information:
  Prescription identifier:
  ┌──────────────────────────────────┐
  │                                  │
  └──────────────────────────────────┘
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Conclusions and recommendations

The EUDI Wallet may be seen as an element further improving the access by patients to their health data in a secure way. The proposed improvement of the ePrescription use case may provide additional usability and security to the patients and pharmacists.

As next steps, further technical specifications for the contents of the QR code (schema, datasets, etc) and transactions should be developed. This use case should be validated via a large scale pilot where expected impacts on usability, privacy, security should be further analysed and evaluated. The Large Scale Pilot should also consider possible future extensions to other health-related use cases (e.g. Patient Summary, vaccination card).

Annex I Digital health and identity policy context

In the 19th eHealth Network (eHN) plenary meeting on 03/06/2021, while the Commission announced the adoption of a proposal for a new European Digital Identity framework and the provisions it includes for a wallet approach, eHN adopted by consensus the deliverable of the eHAction D8.2.4 "Common eID approach for Health in the European Union"[4]. eHN then advised its Technical IOP Subgroup to further develop it in autumn 2021, also taking into account the new

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[4] http://ehaction.eu/wp-content/uploads/2021/06/eHAction-D8.2.4-Common-eID-Approach-for-Health-in-the-EU-_-for-adoption_19th-eHN.pdf

eID regulation[5]. Following the mandate to work on this eHealth use case further provided by the eHealth Network at the Coordinated Actions meeting of 30.03.2022, the eHN Technical IOP created a topic group to work on the Integrated Vision for eHealth/ePrescription and eIDAS.

Context:

Together with Proposal for a new European Digital Identify Framework, the Commission adopted a Recommendation calling on Member States to work together and develop a common Toolbox that can support the implementation of the European Digital Identity framework[6]. A key aspect of its development will be to have a number of priority use-cases, developed from the start of the Toolbox process. In this way, it can be confirmed and ensured that the European Digital Identity wallet will deliver effectively and seamlessly on its key functionalities in Member States. Given the recent success of the European Digital Covid-19 Certificate, use cases in healthcare are expected to be particularly important.

Under the new eIDAS Regulation, Member States would offer citizens and businesses digital "wallets" able to link their national digital identities with proof of other personal attributes: e.g. health documents, driving license, diplomas, bank accounts. The new European Digital Identity (EUDI) Wallets will enable all Europeans to access services online without having to use private identification methods or unnecessarily sharing personal data. With this solution they will have full control of the data they share.

To support implementation of the European Digital Identity Framework and Wallet, in the adopted Recommendation, the Commission called on Member States to work towards the development of a common Toolbox including a technical Architecture and Reference Framework (ARF), a set of common standards and technical specifications, common guidelines and best practices for the European Digital Identity (EUDI) Wallet. The Recommendation foresees that the Toolbox is developed by Member States' experts regrouped in the eIDAS expert group in close coordination with the Commission and, where relevant, other concerned parties. On 22 February 2022, the eIDAS expert group agreed on the first major milestone of the Toolbox, the technical architecture outline[7], and launched a consultation towards stakeholder feedback[8].

Furthermore, a call under the Digital Europe Programme shall support the piloting of the EUDI Wallets by Member States and relevant stakeholders in compliance with the common Union toolbox and the reference application of the Wallet, which will be made available to Member States[9]. For this purpose, it will promote the development and deployment of *use-cases* for the new EUDI ecosystem in different areas, involving both public and private sector stakeholders. It aims to test the interoperability and scalability of the developed solutions within their national and cross-border implementation contexts, trial user journeys, collect feedback as appropriate for iterative updates of the Wallet Toolbox and reference application, and promote the opportunities of the new infrastructure among public and private sector stakeholders and users. Overall this call should help

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[5] https://ec.europa.eu/health/system/files/2021-08/ev_20210603_sr_en_0.pdf
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021H0946&qid=1442476465850
[7] https://futurium.ec.europa.eu/en/digital-identity/toolbox/architecture-and-reference-framework-outline
(access needs registration to the Futurium platform)
[8] https://digital-strategy.ec.europa.eu/en/news/european-digital-identity-online-consultation-platform-european-digital-identity-wallets
[9] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/digital/wp-call/2022/call-fiche_digital-2022-deploy-02_en.pdf

Member States build the necessary expertise and infrastructure to facilitate the provision of Wallets following the relevant obligations which are to be set out in the future Regulation. Proposals should cover in particular eHealth, mobile driving license, payments, educational and qualifications (diploma) usage scenarios.