

Substitution component

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- ▶ IDMP standards provide the conditions for exact representation of medicinal products across countries.
- ▶ It allows to recognize any medicinal product from anywhere in the world.
 - ▷ It allows to identify precisely a medicinal product from Country A, so that a similar medicinal product can be identified in Country B.
 - ▷ Smart substitution provides an additional service, on top of IDMP, which provides, in a controlled and transparent way, similar pharmaceutical products, to allow more choices for replacement, while respecting the essence of the targeted medicinal product.



- ▶ Currently, Member States are in Routine Operation with some (sometimes all) the MyHealth@EU services.
- ▶ According to the number of exchanged documents until Q3/2022 (D7.1)
 - ▶ For eP, a significant number of them have been exchanged, but there is a gap between 90.000 ePrescriptions and “only” 35.000 eDispesations.
- ▶ Currently substitution in MyHealth@EU is limited to a “selection” of fully equivalent medicinal products. The potentialities of “substitution methodology”, proposed by UNICOM should be considered by the MyHealth@EU ePrescription Cluster to extend safe substitution.



Challenge: Difficult to have same brand product in all countries.

Need/Definition: Immediate identification of an equivalent (pharmaceutical) product for dispensation.

Country A → Country B

*Modified Substance or Product name (+ dose form + strength) → Different Product
(Generic Substitution)*

Patient should get his/her medication with doses needed for the treatment period.



- ▶ Rule based approach
 1. a set of rules based on substance,
 2. a set of rules based on dose form,
 3. a rule for those cases that we know should never be substituted.
 4. Future rules (Strength, package etc)

- ▶ Rules are local for each member state (Not global)
- ▶ Administrative (National) rules for substitution out of scope.
- ▶ Smart Substitution component does not cover therapeutic substitutions. Only generic substitution



Substitution approach 2/2

- ▶ The A-Country (origin) sends the chemical (or modified) substance (or Brand product and easily acquire the chemical substance) with the associated dose form and strength that exists in its products-drugs' database (eg. Amlodipine besilate 5mg tablet)
- ▶ In B-Country:
 - ▷ Initially we apply the local rules if substitution is allowed.
 - ▷ A rule transforms the “Amlodipine besilate” to “Amlodipine” and this is the reference substance we use for smart substitution with the same dose form and strength.
 - ▷ If we do not have a product with the same dose form the necessary rules are applied to identify equivalent.

LODIPIN

Medicinal Product

Medicinal Product Identifier	MPID_LODIPIN								
Pharmaceutical Product Identifier	PhPID_Identifier								
Active Ingredient	<table border="1"><thead><tr><th>Code System</th><th>Code</th><th>Name</th><th>Strength</th></tr></thead><tbody><tr><td>ATC</td><td>C08CA01</td><td>Amlodipine</td><td>10 mg</td></tr></tbody></table>	Code System	Code	Name	Strength	ATC	C08CA01	Amlodipine	10 mg
Code System	Code	Name	Strength						
ATC	C08CA01	Amlodipine	10 mg						
Brand Name	LODIPIN								
Dose Form	Capsule Hard								
Route of Administration	Oral Use								

Prescription Details

Duration of treatment	From 2023-02-01 Until 2023-02-28
Units per intake	1 caps hard
Frequency of Intakes	Once a day
Instructions to patient	One capsule once a day
Advise to the dispenser	Co-Administration with PPIs
Is substitution of brand name allowed?	Yes

Packaging Details

Package Identifier	PCID_LODIPIN
Number of packages	1
Package Size	<ul style="list-style-type: none">• Box<ul style="list-style-type: none">◦ 3 Blisters<ul style="list-style-type: none">▪ 10 capsules

Commercial Name

Package Size

Quantity

AGEN 10 mg Tablet ▼

AGEN 10 mg Tablet

Hipres 10mg Tablet

AGEN 5 mg Tablet

Hipres 5 mg Tablet

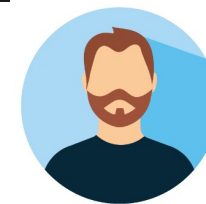


Use Case scenario: Patient Facing App

The following use case was presented live in IHE Connectathon in Rennes 2023



- A. **Patient from Greece:** in need for a medication refill in Italy. Able to use his Patient-Facing Application (PFA)
- B. **Healthcare provider (HCP) in Italy:** a dispenser (pharmacist) able to hand over the information of the equivalent medication to the patient and possibly dispense an OTC medication or a prescriber (physician) who can prescribe an equivalent medication, according to the local rules (Country Italy local rules)



Use Case scenario: Patient Facing App – IHE Connectathon

During an unexpectedly extended stay in a foreign country, the patient is in need of a **refill** of **amlodipine**. He shows the HCP the **QR code** for the drug needed.

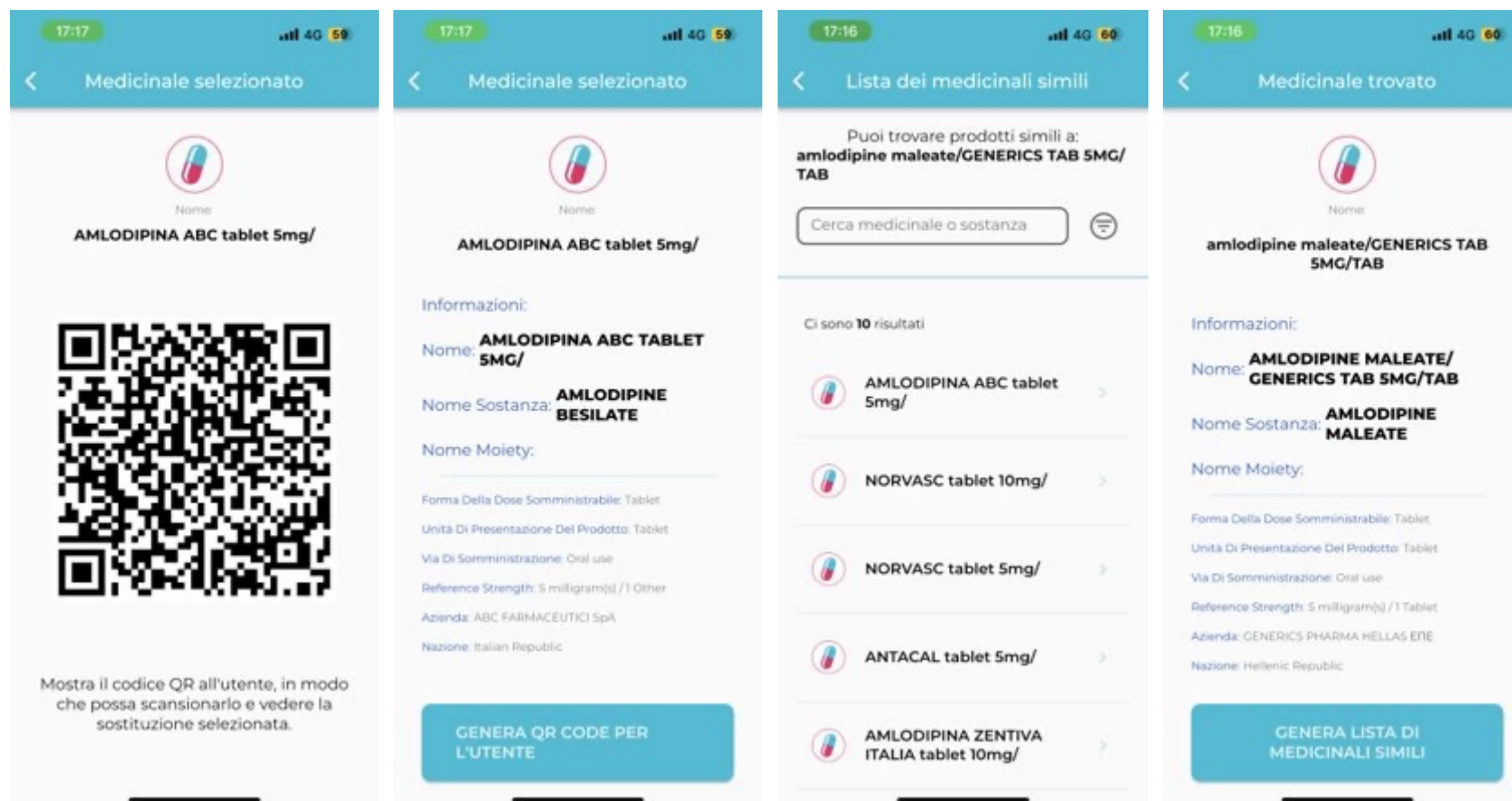


The screenshot displays the eHealthPass app interface. On the left, there is a sign-in/register section with the text: "The logging information is credentialed and recorded in a safe environment." Below this are "SIGN IN" and "REGISTER NOW" buttons, and an "Instructions" link. The main content area is divided into three panels. The top panel shows the user's name "Mary Karena" and a notification for "1 εκκρεμής δραστηριότητες από 1". Below this are two cards: "Η Υγεία μου" and "Φαρμακευτική αγωγή". The middle panel, titled "Φαρμακευτική αγωγή", shows a list of medications with status buttons (Ενεργό, Άκυρο, Ολοκληρωμένο) and a "ΠΕΡΙΣΣΟΤΕΡΑ" link for each. The bottom panel, titled "Φάρμακο στη λίστα φαρμάκων", shows a detailed view for "LODIPIN 10 mg καψάκια, σκληρά". It includes a QR code, the name "LODIPIN 10 mg καψάκια, σκληρά", and detailed information: "Πληροφορίες: -", "Όνομα: LODIPIN 10 MG ΚΑΨΑΚΙΑ, ΣΚΛΗΡΑ", "Όνομα Ουσίας: AMLODIPINE BESILATE", "Δραστικό Τμήμα: -", "Μορφή Χαρτηγίσιμης Δόσης: Capsule, hard", "Μονάδα Παρουσίασης Προϊόντος: Capsule", "Τρόπος Χορήγησης: Oral use", "Ισχύς: 10 mg", "Ετικέτα Κατόχου Άδειας Κυκλοφορίας: Iasis Pharmaceutical S.A.", and "Χώρα: Hellenic Republic". At the bottom of this panel, there are buttons for "ΣΧΕΤΙΚΑ ΦΑΡΜΑΚΑ" and "ΔΗΜΙΟΥΡΓΙΑ QR CODE". A note at the bottom right states: "*ΣΑΡΩΣΗ QR CODE ΤΗΣ ΕΦΑΡΜΟΓΗΣ ΠΑΡΟΧΟΥ ΥΓΕΙΟΝΟΜΙΚΗΣ ΠΕΡΙΘΑΛΨΗΣ".



Use Case scenario: Patient Facing App – IHE Connectathon

The HCP recognizes that the medicine comes from a foreign country. Thanks to his/her App, can identify the similar medicine marketed in his/her country. He/she shows the patient the new drug.

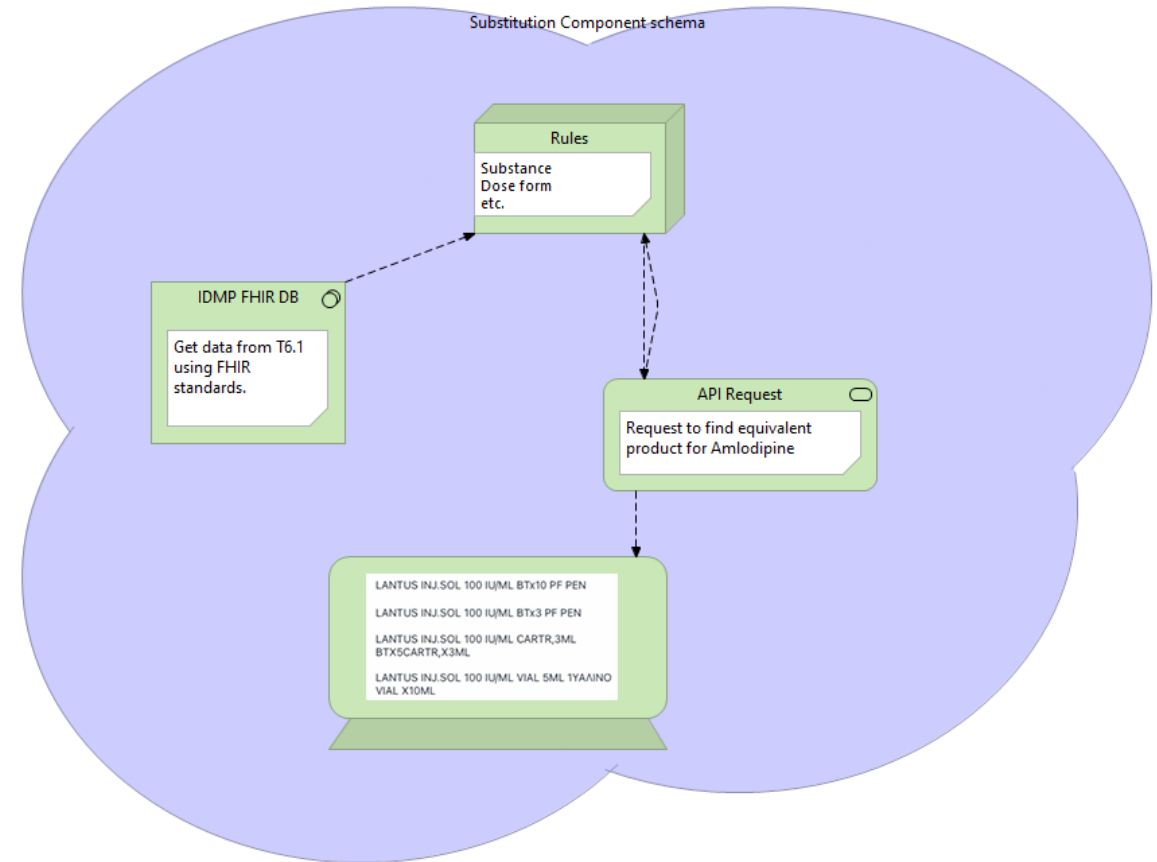
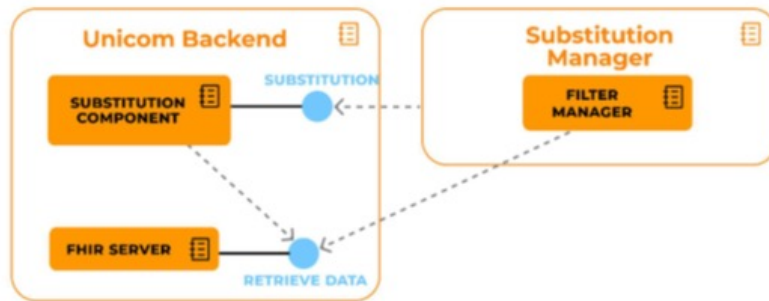


▶ Healthcare professional will choose the most appropriate of the given choices



Substitution component infrastructure

- ▶ FHIR API call to the Substitution Component to get the list of equivalent medications
- ▶ Substitution component interacts with the UNICOM FHIR server to retrieve data
- ▶ Processing through a rule's server
- ▶ API response to client request in FHIR R5



- ▶ In UNICOM substitution is not limited to select the exact same medicinal product.
- ▶ Following the methodology, we can have generic substitution
 - Use this process as a starting point for something new (continuous work in cooperation with beneficiaries)
 - Evolve in MyHealth@EU

Thank you ...

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