



Austrian  
Federal Office for  
Safety in Health Care  
**BASG**

Austrian Federal Office for Safety in Health Care  
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# Integration Concept OMS -> PHAROS

Georg Neuwirther, VET webinar 20th of February 2018

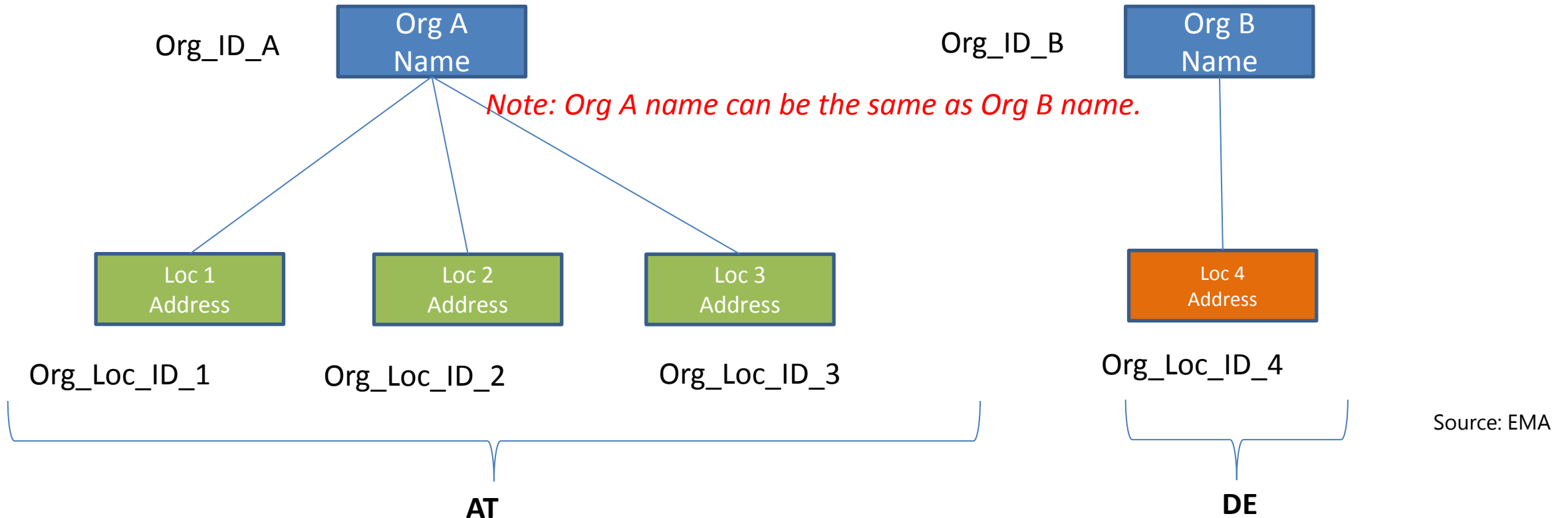
# OMS – Organisation Management Service

## Scope



**“Only” Names and Addresses – not like “yellow pages”**  
**OMS organisation have no context information like “I’m a manufacturer”**

# OMS - Basic concept



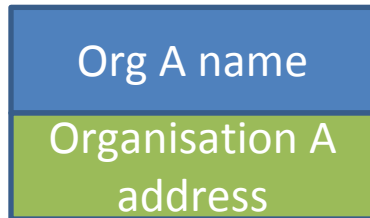
## Rules for unique organisations:

- All location addresses in the same country
- Organisation name is unique for all organisations in the same country.

We have a very different concept of storing organisations!

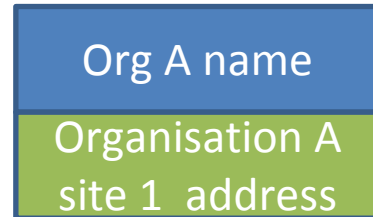
# PHAROS - Basic concept

## Organisations A



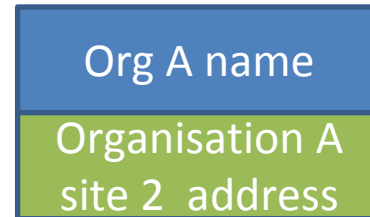
ID 1

## Organisations A site 1



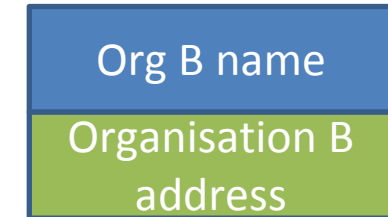
ID 2

## Organisations A site 2



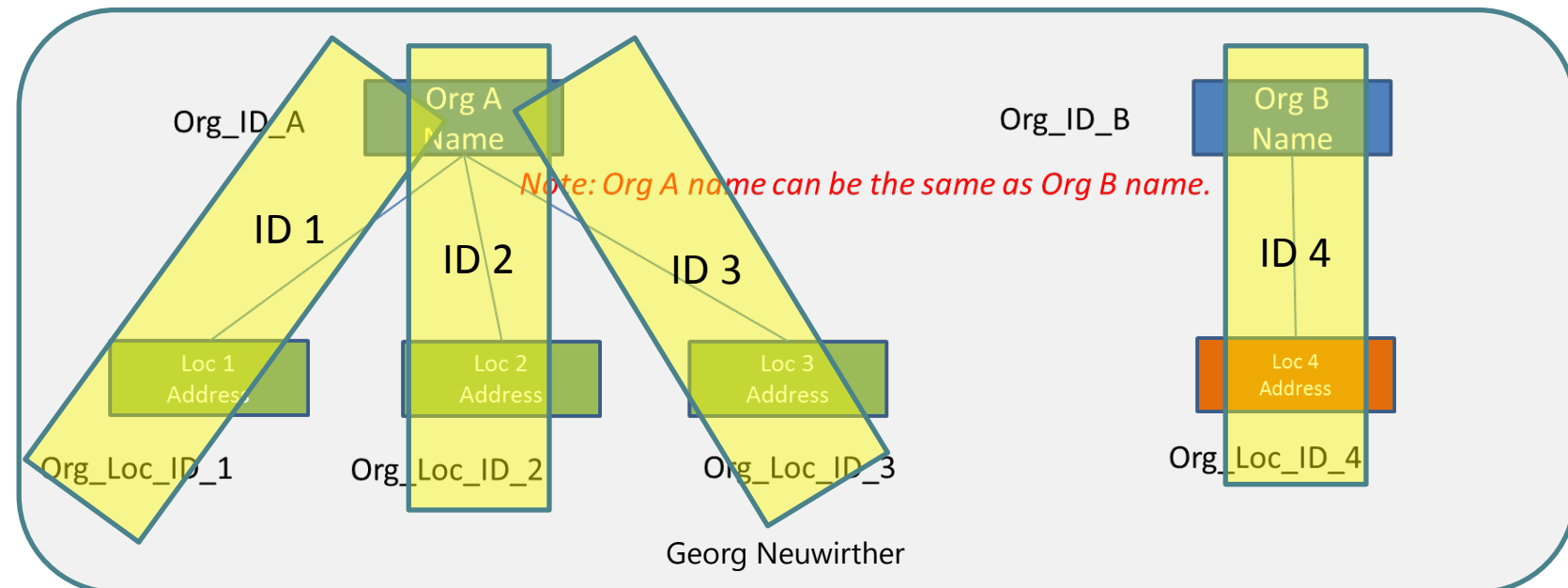
ID 3

## Organisations B



ID 4

Compared to  
OMS

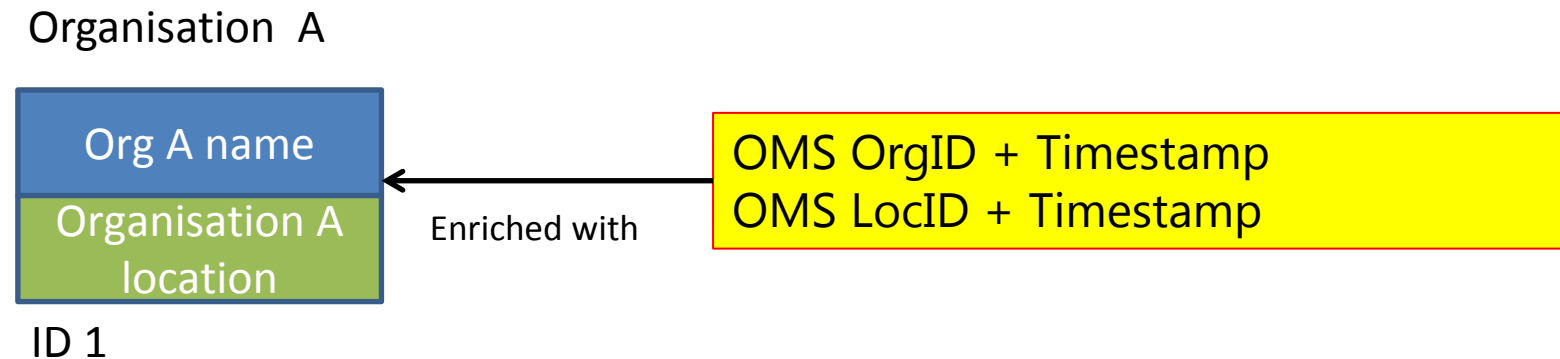


# Principles

- **AGES implements a phased approach for OMS integration**
  - PHASE 1 - Mapping
  - PHASE 2 - Automated data synchronisation
  
- **AGES will keep the internal organisation database**
  - Essential due to the IT design of PHAROS
  - PHAROS covers additional - not EMA-related business - processes (like Medical Devices)
  - Essential for linkages to financial accounting systems
  - Essential for statistics, reporting

# PHASE 1 - Mapping

## Mapping PHAROS organisation records to OMS organisations



### Objectives

1. To create an initial mapping between OMS and PHAROS
2. To evaluate future benefits
3. To be able to design phase 2 – “automated data synchronisation”

# PHASE 1 - Mapping

## Example

**Pfizer Polska Sp. z o.o.**  
Q1-System Grundakttyp Organisation GRZ 9261750 Status GA - aktiv

**Organisationsdaten** Berechtigungen Verfahren

**Organisation**

Firmenname Pfizer Polska Sp. z o.o.  
Straße Ul. Postępu 17 B  
Hausnr. - Gebäudekürzel  
Stockwerk Raum  
PLZ 02-676 Ort Warszawa  
Bundesland  
Staat Polen

Zusatzinfo  
Gruppierung  
Portalzugang

**OMS**

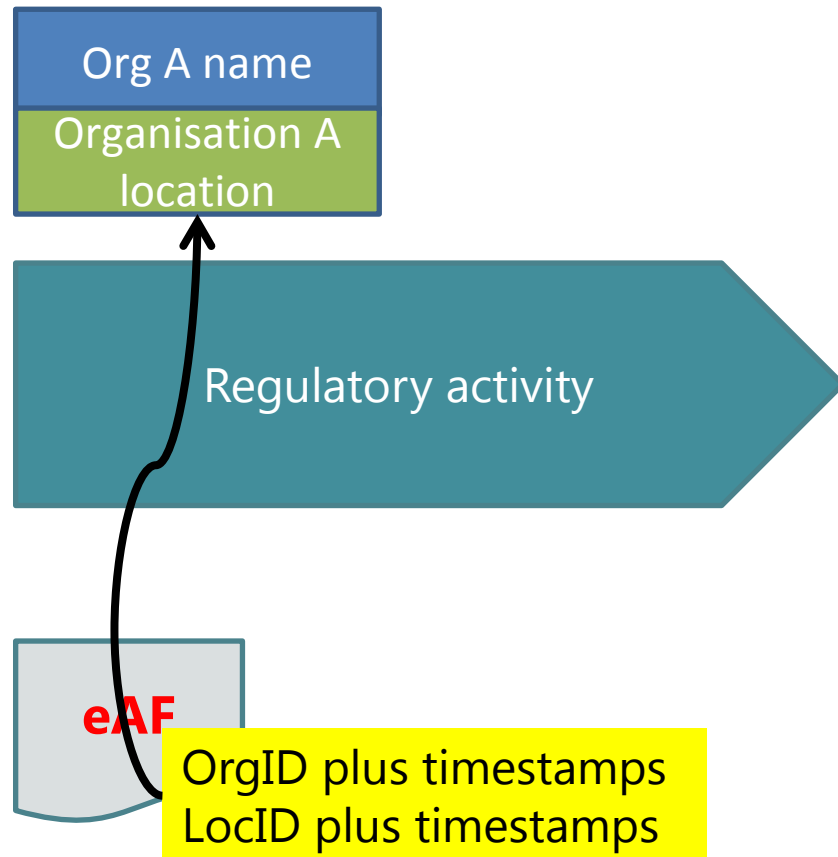
OrgId	ORG-100005724	OrgTimestamp	07-Dez-2017 15:27:48
LocId	LOC-100002415	LocTimestamp	07-Dez-2017 15:27:48

[Link zu SPOR - OMS](#)

**Identifikationsnummern**

# PHASE 1 – Data feed

## Triggered by regulatory activities




1. We start the mapping with relevant regulatory activities!
2. OMS data will be **automatically extracted** from the **eAF**
3. The PHAROS organisation database will be searched
4. Follow-up action
  - a. a new organisation record will be created
  - b. Or OMS data will be added to an identified record
  - c. Or organisation data will be semi-manual updated

# PHASE 1 – creation during regulatory activity

## Procedure

Q1-System Verfahren - 9261757 - Abgeschlossen/ - Lesemodus Speichern Tab Schließen Aktivität durchfüh

**Verfahrensdaten** Termine & Fristen Anmerkung Verfahrenszeit Kommunikation Referenz Rolle Verrechnung

Verfahrenstyp  Adressprüfung Organisation

Europäische Verfahrensnummer

Bulking Nr

Verfahrensnummer Fremdsystem

Priorität  Zuteilungshinweis

Ansicht  Format

Name	Grundzahl	Status
Pfizer Polska Sp. z o.o.	9261750	GA - aktiv

**Adress- und Kontaktdaten** Aktenvermerk

**Organisation**

\* Firmenname  Dublettenprüfung ausführen

\* Straße

\* Hausnr.  Stockwerk

\* PLZ  Gebäudekürzel

Raum  \* Ort


Bundesland


\* Staat

Zusatzinfo

Gruppierung

**OMS**

OrgId  OrgTimestamp  

LocId  LocTimestamp  

[Link zu SPQR - OMS](#)

**Identifikationsnummern**

Imported data  
from eAF

# PHASE 1 - example future search result

Name	Nummer	Status	OrgID
Stada Arzneimittel AG	1171595	GA - aktiv	ORG-100000843
Baxter AG	1177838	GA - aktiv	ORG-100000816
Pfizer Polska Sp. z o.o.	9261750	GA - aktiv	ORG-100005724
Huvepharma N.V.	1179560	GA - aktiv	ORG-100005010
Bayer Pharma AG	1203098	GA - aktiv	ORG-100000124
Richter Pharma AG	1195196	GA - aktiv	ORG-100000500
Aristo Pharma GmbH	1203276	GA - aktiv	ORG-100000084
Le Vet. Beheer B.V.	7919455	GA - aktiv	ORG-100001413
Le Vet. Beheer B.V.	7919455	GA - aktiv	ORG-100001413
Le Vet. Beheer B.V.	1190137	GA - aktiv	ORG-100001413
Novartis Pharma Produktions GmbH	7392807	GA - aktiv	ORG-100004627
Synthon Hispania S.L.	1185455	GA - aktiv	ORG-100003270
Merz Consumer Care Austria GmbH	1180889	GA - aktiv	ORG-100001618
Mundipharma GmbH	1000550	GA - aktiv	ORG-100001578
Takeda Pharma Ges.m.b.H.	1237108	GA - aktiv	ORG-100003140
Servier Austria GmbH	1000176	GA - aktiv	ORG-100001127

# PHASE 2 – automated data synchronisation

## Objectives

- **Establish data updates outside regulatory activities – synchronise data**
  - **Via OMS interface (API)**

# Current challenges

**OR**

Organisation name

Country

Address Results

EN|Austrian Agency for Health and Food Safety Limited|Spargelfeldstrase 191|Donaust:

DE|Austrian Agency for Health and Food Safety Limited|Spargelfeldstraße 191|Donaust:

EN|Austrian Agency for Health and Food Safety Limited|03.Bez.:Geidorf|Beethovenstra:

DE|Austrian Agency for Health and Food Safety Limited|03.Bez.:Geidorf|Beethovenstral

Applicant	Austrian Agency for Health and Food Safety Limited
Address	Beethovenstrasse 6 03.Bez.:Geidorf
City/Locality/Town/Village	Graz
County	Steiermark
Postcode	8010
Country	Austria
OrgID	ORG-100003912
LocID	LOC-100000001

We are currently struggling with the 4 address lines provided by OMS.

They are unstructured and have no semantic description.

We understand the complexity “worldwide” but automated import would lead to confusing Content –especially for translations

# Current challenges

Organisation name

Country

Search

## Address Results

EN|Medicines and Healthcare Products Regulatory Agency|151 Buckingham Palace Roac  
EN|Medicines and Healthcare Products Regulatory Agency|Blanche Lane|South Mimms|I  
EN|Medicines and Healthcare Products Regulatory Agency|Medicines Inspectorate|1st F

Select

Select/Close

Applicant

Address

City/Locality/Town/Village

County

Postcode

Country

# Current challenges

Organisation name

Country

## Address Results

- EN|Pfizer Limited|Ramsgate Road||United Kingdom
- EN|Bristol-Myers Squibb / Pfizer EEIG|Bristol-Myers Squibb House|Uxbridge Business Park|United Kingdom
- EN|Pfizer Limited|Walton Oaks|Dorking Road|United Kingdom
- EN|Pfizer EU PFE MA EEIG|Ramsgate Road||United Kingdom
- EN|Pfizer Consumer Healthcare|United Kingdom|Ramsgate Road|Dorking|United Kingdom

Applicant	Bristol-Myers Squibb / Pfizer EEIG
Address	Bristol-Myers Squibb House  Uxbridge Business Park Sanderson Road
City/Locality/Town/Village	Uxbridge
County	Middlesex
Postcode	UB8 1DH
Country	United Kingdom



Thanks

Georg Neuwirther – Head of IT Austrian Medicines and Medical Devices Agency

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