Agenda

• E-Verification
• Pack Identifiers
• Use Cases
• Connection and Certification
• Integrating using the API
• Additional Considerations
European Medicines Verification System

Distribution of product and pack data to markets
Verification at the point of dispense
Additional Verification in the supply chain

Product and pack data upload from MAHs and PDs
Repacking
Multi-market packs
Notifications, alerts and reports
Verification, and decommissioning by pharmacies and wholesalers
Supply to public (dispense) by pharmacies

ESM European Stakeholders Model

Point-of-Dispense Verification Process

Verification upon Dispense to Patient
EMVS Components
National Blueprint System Scope

- Precisely meets the Delegated Regulation requirements
- Integrated on-boarding portal for Pharmacies and Wholesalers
- Web-based emergency Verification Portal
- NMVO Administration and Reporting Portal
- NCA Portal

Pharmacies
Wholesalers
Hospitals
IT Suppliers
Pilot Scope

POTI

Processes

- Speed, Quality and Efficiency
- Registration and Onboarding
- Manufacturing and Re-Packing
- Verification, Dispense and Decommission
- Investigation

Organisation

- NMVO and NCA Structure
- Capability
- Leadership
- Goals
- Workload

Technology

- European Hub and National System
- Client Systems
- Effectiveness
- Efficiency
- Capability
- Scalability and Availability

Information

- Reports and insight
- Requirements
- Format and Storage
- Audit and Measurement

Activities

- Onboarding manufacturers to the European Hub
- Distributing product and pack data to the National System
- Registering pharmacies, hospitals and wholesalers
- Implementing local operating procedures and processes
- Monitoring and supervision
Supporting IT Providers

• NBS scoped to EMVO requirements
• Focus on software providers
  Exploit existing commercial relationships
• Support mainstream standards
  • REST
  • Open ID Connect
  • OAuth 2.0
• Design simple, minimal interfaces
• Provide rich supporting information and guidance
• Implement self-service
Pack Identifiers

Product Code Scheme: Product Code Coding scheme: GS1 (GTIN/NTIN) or IFA (PPN)

<table>
<thead>
<tr>
<th>Field</th>
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<tr>
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</tbody>
</table>
Client System Use Cases

- Verify
- Dispense
- Decommission
- Reactivate
- Bulk-of-Packs
- Reports
- Product Data

- Active
- Supplied
- Sample
- Destroyed
- Stolen
- Free Sample
- Locked
- Exported
- Expired
- Withdrawn
- Recalled
- Checked-out
Environments

Integrated Test Environment
- Sandbox for interface / connectivity testing

Integrated Quality Environment
- Self certification

Production Environment
Integrated Test Environment

Identity Server

Authentication & Authorisation

API

No state changes

Pack Repository

IT Providers

Continuous Integration

Development Cycle

Test

Development

Replay solidsoft
These tests represent various scenarios where the pack cannot be found in the ITE repository or the request cannot be processed. In each case, the ITE returns a 404 Not Found or a 422 Unprocessable Entity response. Some tests contain incorrectly encoded barcodes. It is good practice to design client systems to detect missing data or other barcode issues before making a request to the NBS. Client systems should minimise the load on the NBS wherever possible.

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Serial Number</th>
<th>Batch (Lot)</th>
<th>Expiry Date</th>
<th>HTTP Response</th>
<th>Warning</th>
<th>Alert ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>(01) 200000608627252</td>
<td>(21) 0085530921</td>
<td>(10) AB123C4</td>
<td>(17) 210319</td>
<td>404 Not found</td>
<td>The product code is unknown.</td>
<td></td>
</tr>
<tr>
<td>(01) 15000436574634</td>
<td>(21) 0009556207</td>
<td>(10) 00001</td>
<td>(17) 201200</td>
<td>404 Not found</td>
<td>The serial number is unknown.</td>
<td>&lt;GUID&gt;</td>
</tr>
<tr>
<td>(01) 15000436574634</td>
<td>(21) 0000000001</td>
<td>(10) 00002</td>
<td>(17) 201200</td>
<td>404 Not found</td>
<td>The batch identifier mismatches the recorded batch identifier.</td>
<td>&lt;GUID&gt;</td>
</tr>
<tr>
<td>(01) 15000436574634</td>
<td>(21) 0000000001</td>
<td>(10) 00001</td>
<td>(17) 211200</td>
<td>404 Not found</td>
<td>The expiry date mismatches the recorded expiry date.</td>
<td>&lt;GUID&gt;</td>
</tr>
<tr>
<td>(21) 0000000001</td>
<td>(10) 00001</td>
<td>(17) 201200</td>
<td></td>
<td>422 Unprocessable Entity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(01) 0000000001</td>
<td>(21) 0000000001</td>
<td>(10) 00001</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Supporting Development

Software Development Kit
Documentation and Guidance
Code Examples (Java, C#)
Working example of store & forward
Tools and libraries
Development Portal
Development hub
Evolves to capture ‘lessons learned’, best practice, etc.
Sign NDA for access
Helpdesk
Technical support
API Principles

- REST philosophy
- Consistency
- Discoverability
- Affordance
- No dependency on pack state beliefs
- Constrained disclosure
Authentication & Authorisation

- OAuth 2.0 Client Credential Grants
- Client Credentials
  - Client ID
  - Client Secret

- Validated National System
  - Client Credentials obtained via portal

Client Credentials

- Organisation
- Location
- Equipment

Access Token
Requesting an Access Token

Request

POST http://nbs-preview.northeurope.cloudapp.azure.com:8080/identity/connect/token HTTP/1.1
Content-Type: application/x-www-form-urlencoded

grant_type=client_credentials
&client_id=5sRrbLTQCf8XiUROAPV0l9xO
&client_secret=jY2F0foZN6toz8YehWofI3ju

Response

{"access_token": "eyJhbGciOiJSUzI1NiIsImtp...",
"expires_in": 32767,
"token_type": "Bearer"}
# HTTP Status Codes - Semantics

<table>
<thead>
<tr>
<th>HTTP Response</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>200 OK - GET</strong></td>
<td>The system has found the pack within the EMVS and reports its current status.</td>
</tr>
<tr>
<td><strong>200 OK - PATCH</strong></td>
<td>The system agrees that the state change request is valid, changes its records accordingly and reports the same pack state. If the pack is already in the requested state, the request is treated as valid.</td>
</tr>
<tr>
<td><strong>403 Forbidden</strong></td>
<td>The request is rejected because the client system does not have permission to make the request.</td>
</tr>
<tr>
<td><strong>404 Not Found</strong></td>
<td>The pack cannot be reliably found in the repository. This includes scenarios where the pack exists, but the recorded batch identifier or expiry date do not match the values printed on the pack.</td>
</tr>
<tr>
<td><strong>409 Conflict</strong></td>
<td>The system does not agree that the state change is valid. It does not change its records and reports back the current state of the pack. In some cases, the reported state may actually apply to an entire batch or product.</td>
</tr>
<tr>
<td><strong>422 Unprocessable Entity</strong></td>
<td>The request is malformed or invalidly formatted.</td>
</tr>
<tr>
<td><strong>429 Too Many Requests</strong></td>
<td>The system is throttling.</td>
</tr>
</tbody>
</table>
Anatomy of Requests

All single pack requests use a common URL pattern:

```
/product/<scheme>/productCode/pack/<serialNumber>?batch=<batchId>&expiry=<expiry>
```

e.g.

```
/product/gs1/15000436574634/pack/09876543210?batch=B1A334&expiry=201200
```

• State Transition Requests
  ```
  {
    “state” : “Supplied”
  }
  ```

Responses (single pack)
```
{
  [“alertId” : “…”],
  “operationCode” : 11210000[,
  [“state” : “Supplied”[,]]
  [“information” : “…”] || [“warning” : “…”]
}
```
Verify Pack - Request

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/example/gs1/05060141900022/pack/96392630670?batch=DemoPack&expiry=210300

Token passed in HTTP header: Authorization: Bearer eyJhbGciOiJSUzI1NiIsImtp...

Data entry mode must be specified: emvs-data-entry-model manual / non-manual

Language selection (optional): accept_language en-GB
Verify Pack - Response

Status codes:

- Active
- Stolen
- Destroyed
- Sample
- Free Sample
- Supplied
- Checked-Out
- Locked
- Withdrawn
- Exported
- Recalled
- Expired

```
{
    "operationCode" : 11210200,
    "status" : "Supplied",
    "information" : "The pack has been dispensed."
}
```
Additional Considerations

• Local users – authorisation, user experience
• Support for GS1 and IFA standards
• Logging and auditing
• Alerting and notification
• Reporting
• Recovery Strategies