

# Danish Medicine Verification Organisation

Virtual Meeting 30.04.2020

Overview of next release R6.2. of the verification system.



# Danish Medicines Verification Organisation



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- Patient safety in collaboration with other national stakeholders and the NCA.
- Ensure an operational and well-functioning verification system in Denmark in full compliance with the Falsified Medicines Directive(FMD).
- Focal point of Contact for questionnaires regarding the FMD.

# Virtual meetings

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- **Why:**
  - Survey
  - Transparency
  - Direct communication /dialogue with stakeholders
- **What:**
  - Different topics/themes based on needs/questionnaires
  - English
  - Open for suggestions
- **When:**
  - Monthly meeting
  - Morning - same time 8.30 - 9.15.
- **Where:**
  - Virtually
- **How to join:**
  - Sign up by sending an email to [info@dmvo.dk](mailto:info@dmvo.dk) - everyone is welcome to join

# New release 6.2 DMVS

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## What's new in 6.2

- OBP reports
- NCA reports

# Reports

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- R.3 - Specific product packs decommissioned as supplied by a local organisation.
- R.5 - Product code to National code
- S.1.2 - Decommissioned/Reverted Packs Report for an OBP
- S.2.6 - Designated Wholesaler Report
- S.4.1 - No Activity Report for an OBP
- S.4.2 - No Activity Report for Wholesalers
- S.4.3 - No Activity Report for Local Organisations
- S.5.1 - Linking Report of a Re-packaged Batch
- S.5.2 - Linking Report of Batches
- Ph.1 - Number of products decommissioned in a specific market
- Ph.2 - Batch Destination Report
- Ph.3 - Active Packs Available Report
- S.5.1 - Linking Report of a Re-Packaged Batch
- S.5.2 - Linking Report of Batches

# New reports for OBP/Parallel Distributer?

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- S.5.1 - Linking Report of a Re-Packaged Batch
- S.5.2 - Linking Report of Batches

# OBP Report / Parallel Distributer

## S.5.1 - Linking Report of a Re-Packaged Batch

<b>Date Requested:</b>	28/04/2020 11:11:32
<b>Parallel Distributor Name:</b>	EMVO_OBP_IOT_PD1
<b>Parallel Distributor Address:</b>	Rue du Commerce, 123, , Brussels, 1080, Belgium

<b>Name Medicinal Product (Repackaged):</b>	EMVO IOT PC0082
<b>Product Code (Repackaged):</b>	GTIN:05430001877830
<b>Batch Number (Repackaged):</b>	BATCH-BC
<b>Expiry Date (Repackaged):</b>	09/05/2021 00:00:00

<b>UIs (Repackaged)</b>	<b>Date/Time Uploaded</b>
BC001	28/04/2020 09:27:00
BC002	28/04/2020 09:27:00

<b>Name Medicinal Product (Original):</b>	EMVO IOT PC0083
<b>Product Code (Original):</b>	GTIN:05430001877847
<b>Batch Number (Original):</b>	BATCH-NA
<b>Expiry Date (Original):</b>	09/05/2021 00:00:00

<b>UIs (Original)</b>	<b>Date/Time Decommissioned (Checked Out)</b>
NA001	28/04/2020 09:15:58
NA002	28/04/2020 09:15:58



# OBP Report / Parallel Distributer

## S.5.2 - Linking Report of Batches

Date Requested: 28/04/2020 12:04:00

Parallel Distributor Id: 2323

Parallel Distributor Name: EMVO\_OBP\_IOT\_PD1

Parallel Distributor Address Line 1: Rue du Commerce, 123

Parallel Distributor Address Line 2:

Parallel Distributor City: Brussels

Parallel Distributor Postcode: 1080

Parallel Distributor Country: Belgium

Name medicinal product (Re-packaged): EMVO IOT PC0082

Product Code Scheme (Re-packaged): GTIN

Product Code (Re-packaged): 05430001877830

Batch Number (Repackaged)	Expiry Date (Repackaged)	Name medicinal product (Original)	Product Code (Original)	Batch Number (Original)	Expiry Date (Original)
BATCH-BC	09/05/2021 00:00:00	EMVO IOT PC0083	GTIN:05430001877847	BATCH-NA	09/05/2021 00:00:00
BATCH-BD	09/05/2021 00:00:00	EMVO IOT PC0083	GTIN:05430001877847	BATCH-NB	09/05/2021 00:00:00

# NCA

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*The following NCA reports are no longer part of the URS and have been removed:*

- Suspicious Pack Activity Summary report
- Suspicious Pack Activity Detail Report
- Supplied Packs by Product Report

# NCA

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*The following NCA reports are added:*

- R.3 - Specific product packs decommissioned as supplied by a local organisation.
- R.5 - Product code to National code
- S.1.2 - Decommissioned/Reverted Packs Report for an OBP
- S.2.6 - Designated Wholesaler Report
- S.4.1 - No Activity Report for an OBP
- S.4.2 - No Activity Report for Wholesalers
- S.4.3 - No Activity Report for Local Organisations
- S.5.1 - Linking Report of a Re-packaged Batch
- S.5.2 - Linking Report of Batches
- Ph.1 - Number of products decommissioned in a specific market
- Ph.2 - Batch Destination Report
- Ph.3 - Active Packs Available Report

# R.3 - Specific Product Packs Decommissioned As Supplied By A Local Organization

## Input parameters:

- Local Organisation's Location ID
- Product Code Scheme (Optional)
- Product Code (Optional)
- Start Date
- End Date

## Report Content:

The report lists successful pack state change transactions to SUPPLIED state, carried out at the Local Organisation's Location ID between the supplied 'Start Date' and 'End Date' inclusive, where the related product is in the product specified or all products.

For each product code in the selected transactions:

- Record Product Code
- Record full Product Name
- Record Pack Serial Number
- Record the date of the state change.

Report Header	
Report Type	R.3 - Specific product packs decommissioned as supplied by a local organisation.
Report Name	R.3
Location ID	d437f3f8-e9c0-47bd-852d-14b061d28b85
Location Name	R6.2 Pharmacy Location A
Sequence Number	6
Date Requested (UTC)	09/04/2020 13:30:24
From Date (UTC)	06/04/2020
To Date (UTC)	09/04/2020
Product Code	-

Report Details			
Product Code	Name Of Medicinal Product	Unique Identifier Supplied	Date of Decommissioning
GTIN:34790271380006	SSR - Test Product 1	pack1	2020-04-07
GTIN:34790271380006	SSR - Test Product 1	pack2	2020-04-07
GTIN:34790271380006	SSR - Test Product 1	pack11	2020-04-07
GTIN:34790271380006	SSR - Test Product 1	pack12	2020-04-07
GTIN:34790271380013	SSR - Test Product 2	pack1	2020-04-07
GTIN:34790271380013	SSR - Test Product 2	pack2	2020-04-07

# R.5 - Product Code To National Code/S.2.6 - Designated Wholesaler Report

## Input parameters:

- Product Code Scheme (Optional)
- Product Code (Optional)

Report Header	
Report Type	R.5 - Product code to National code
Report Name	R.5
Sequence Number	12
Date Requested (UTC)	08/04/2020 11:10:33
Product Code	-

## Report Content:

For each product code in the scope:

- Record Product Code
- Record full Product Name
- Record the ID, name and address of the MAH.
- For each designated wholesaler record the wholesaler ID, name and address.
- Record the National Reimbursement Number (if any)

Report Details				
Product Code	Product Name	MAH (ID, name and address)	Designated wholesaler/s (ID, name and address)	National Code
GTIN:00000000000055	Lojuxta 150mg EN/DE/NL	Amryt Pharmaceuticals DAC, 90 Harcourt Street, Dublin 2, D02 CR98, IE	50304, A second Wholesaler, Wholesaler Street 2, Wholesaler City 2, 12345, IE 50305, Wholesaler, Wholesaler Street 1, Wholesaler City, 12345, IE	-
GTIN:00000050000029	a	MAHIE465, PCO Manufacturing, Unit 10 Ashbourne Business Park, Rath, Ashbourne, Co Meath, A84 WR60, IE	635, PCO Manufacturing, Unit 10 Ashbourne Business Park, Rath, Ashbourne, Co Meath, A84 WR60, IE 636, NIP Pharma Limited, Unit 8C Loughway Business Park, Newry, Co Down, BT342TH, GB	-

# S.1.2 - Decommissioned/Reverted Packs Report For An OBP

### Input parameters:

- OBP ID
- Product Code Scheme (Optional)
- Product Code (Optional)
- Start Date
- End Date

Report Header	
Report Type	S.1.2 - Decommissioned/Reverted Packs Report for an OBP
Report Name	S.1.2
OBP ID	1076
OBP Name	Test MAH Solidsoft
Sequence Number	2
Date Requested (UTC)	08/04/2020 11:23:19
From Date (UTC)	06/04/2020
To Date (UTC)	09/04/2020
Product Code	GTIN:34790271380006

# S.1.2 - Decommissioned/Reverted Packs Report For An OBP

## Report Content:

For each successful decommissioning transaction performed in the time frame specified by the specified OBP, on the products in scope:

- record the full product name
- record the product code
- record the batch number
- record the pack serial number
- record the decommissioned pack state
- record the date of decommissioning
- If the pack was subsequently reactivated during the period of the report then record the date of the reactivation.

*(Note: where a pack is decommissioned and reactivated multiple times then each line for a decommission shall be matched with the matching reactivation date.)*

Report Details						
Product Name	Product Code	Batch Number	Serial Number	Decommissioning Reason / Status	Date of Decommissioning	Date of Reactivation (if applicable)
SSR - Test Product 1	GTIN:34790271380006	batch1	pack4	LOCKED	07/04/2020	07/04/2020
SSR - Test Product 1	GTIN:34790271380006	batch1	pack3	LOCKED	07/04/2020	
SSR - Test Product 1	GTIN:34790271380006	batch1	pack5	LOCKED	07/04/2020	07/04/2020

# S.4.1 - No Activity Report For OBP

## Input parameters:

- Start Date
- End Date

## Report Content:

Select all OBPs that have not performed any transaction in the time frame specified.

- Record the OBP ID
- Record the OBP name
- Record the OBP address
- Record the OBP postal code

Report Header	
Report Type	S.4.1 - No Activity Report for an OBP
Report Name	S.4.1
Sequence Number	2
Date Requested (UTC)	08/04/2020 11:27:26
From Date (UTC)	06/04/2020
To Date (UTC)	09/04/2020

Report Details			
ID	Name	Address	Postcode
1084	Janssen Pharmaceutica NV	Turnhoutseweg, 30, Beerse, B-2340 , Belgium	B-2340
1090	Amgen Europe B.V.	7061 Minervum, Breda, 4817ZK, The Netherlands	4817ZK
1092	Gilead Sciences Ireland UC	NA IDA Business and Technology Park, Carrigtohill, Co. Cork, 0000, IRELAND	0000
1094	Grünenthal GmbH	6 Zieglerstrasse , Aachen, 52078, Germany	52078
1158	GlaxoSmithKline services unlimited	980 Great West Road, London, TW8 9GS, United Kingdom	TW8 9GS
1161	Bial-Portela & C <sup>ª</sup> , S. A.	A Av da Siderurgia Nacional, N/A, Trofa, 4745-457 Coronado, Portugal	4745-457 Coronado



# S.4.2, S.4.3 - No Activity Report For Wholesaler/Local Organisation

## Input parameters:

- Start Date
- End Date

Report Header	
Report Type	S.4.2 - No Activity Report for Wholesalers
Report Name	S.4.2
Sequence Number	1
Date Requested (UTC)	08/04/2020 11:32:51
From Date (UTC)	06/04/2020
To Date (UTC)	09/04/2020

## Report Content:

Select all locations that have not performed any pack state changes or verifications in the time frame specified.

- Record the local organisation's location ID
- Record the local organisation name
- Record the local organisation location name
- Record the local organisation location address
- Record the local organisation location postal code

Report Details				
Location ID	Organisation Name	Location Name	Address	Postcode
0a0b3ce5-c95a-465f-ac67-b273f14b6b2d	Quick Pharm Test	QPS_PPD	-	-
206c57bc-48e4-44a7-bb12-e7369564272c	Quick Pharm Test	QPS_AD	-	-
2e93859b-8b3b-4605-8422-35f7afb7e151	Quick Pharm Test	QPS_IPU	-	-
430959fe-ba29-447b-9693-931fb5fa7c3d	SSR Wholesaler	R6.2 Wholesaler Location B	Via Castellanza 11, Milano, 20151	20151
55888e57-1612-45d6-beaa-507b4ee2e9ef	Antal Wholesalers	alntechnology	-	-
66eec7d2-9652-4062-885f-4db49fce40a0	Antal Wholesalers	FMC	-	-
b77fcbda-ed84-4d46-a062-b0c2c6bf49d5	Quick Pharm Test	QPS_PRL	-	-
c564feaa-a6ae-4fe8-92f7-967cff1f492d	Antal Wholesalers	United Drug	-	-
d8f379f9-f482-414a-9585-e6dfa1f1dd30	Antal Wholesalers	Becton Dickinson 01	-	-
e2990eaa-af85-449c-ae0b-4b32694346ef	IMVO Wholesaler.IQE2	IMVO IQE Location	IMVO Offices, Dublin	-
f1ebfea8-42f7-4c7b-8c5e-fd2aa9082b3b	Antal Wholesalers	Movilitas	Kasteelhoekstraat 1, 1820 Perk (Steenokkerzeel)	-
f2b6b3d0-6295-4035-bc47-7d57825d5b35	Antal Wholesalers	Navitas Life Science	-	-
fb9fe5f7-a658-4a1d-801c-51a34e7c2652	Quick Pharm Test	QPS_GM_Test	-	-

## S.5.1 - Linking Report of a Re-packaged Batch

### Input parameters:

- Product Code Scheme
- Product Code
- Batch Number

Report Header	
Report Type	S.5.1 - Linking Report of a Re-packaged Batch
Report Name	S.5.1
Sequence Number	1
Date Requested (UTC)	08/04/2020 11:43:23
Parallel Distributor Name	Test PD Solidsoft
Parallel Distributor Address	Grove House, Org Rd, Chineham, RG8 2RG, UK

### Report Content:

The first section of the report is populated with the data from the repackaged batch:

For each Serial number:

- Record the serial number.
- Record the date the serial number was uploaded as part of a new re-packed batch.

Re-packaged Packs	
<b>Name of medicinal product (re-packaged)</b>	SSR - Test Product 3
<b>Product Code (re-packaged)</b>	GTIN:34790271380020
<b>Batch number (re-packaged)</b>	batch6
<b>Expiry date (re-packaged)</b>	221200
<b>UIs (re-packaged)</b>	<b>Date/Time of Upload</b>
pack1	07/04/2020 16:57:42
pack2	07/04/2020 16:57:42
pack3	07/04/2020 16:57:42
pack4	07/04/2020 16:57:42
pack5	07/04/2020 16:57:42

# S.5.1 - Linking Report of a Re-packaged Batch

## Input parameters:

- Product Code Scheme
- Product Code
- Batch Number

Report Header	
Report Type	S.5.1 - Linking Report of a Re-packaged Batch
Report Name	S.5.1
Sequence Number	1
Date Requested (UTC)	08/04/2020 11:43:23
Parallel Distributor Name	Test PD Solidsoft
Parallel Distributor Address	Grove House, Org Rd, Chineham, RG8 2RG, UK

## Report Content:

The second section is populated with the checked-out packs of the original batch:

For each Serial number:

- Record the serial number
- Record the date the serial number was decommissioned.

Original Packs	
<b>Name of medicinal product (original)</b>	SSR - Test Product 1
<b>Product Code (original)</b>	GTIN:34790271380006
<b>Batch number (original)</b>	batch3
<b>Expiry date (original)</b>	221200
<b>Uls (original)</b>	<b>Date/Time Decommissioned (checked-out)</b>
pack21	07/04/2020 16:52:47
pack22	07/04/2020 16:52:47
pack23	07/04/2020 16:52:47
pack24	07/04/2020 16:52:47
pack25	07/04/2020 16:52:47
pack26	07/04/2020 16:52:47
pack27	07/04/2020 16:52:47
pack28	07/04/2020 16:52:47

# S.5.2 - Linking Report of Batches

### Input parameters:

- Product Code Scheme
- Product Code

### Report Content:

Details the list of batches that have been repackaged as part of the specified repackaged product.

Report Header	
Report Type	S.5.2 - Linking Report of Batches
Report Name	S.5.2
Sequence Number	1
Date Requested (UTC)	08/04/2020 11:47:15
Parallel Distributor Name	Test PD Solidsoft
Parallel Distributor Address	Grove House, Org Rd, Chineham, RG8 2RG, UK
Name of medicinal product (re-packaged)	SSR - Test Product 3
Product Code (re-packaged)	GTIN:34790271380020

For each repackaged batch it shows:

- The re-packed batch number
- The re-packed batch expiry date
- The name of the original product
- The product code of the original product
- The batch number of the original product
- The expiry date of the original product

Report Details					
Batch number (re-packaged)	Expiry date (re-packaged)	Name of medicinal product (original)	Product Code (original)	Batch number (original)	Expiry date (original)
batch6	221200	SSR - Test Product 1	GTIN:34790271380006	batch3	221200
batch7	221200	SSR - Test Product 1	GTIN:34790271380006	batch3	221200

# Ph.1 - Number Of Products Decommissioned In A Specific Market

## Input parameters:

- Product Code Scheme (Optional)
- Product Code (Optional)
- Batch Number (Optional)
- Start Date
- End Date

## Report Content:

Breakdown at batch and post code level of the packs supplied by pharmacies and wholesalers during the specified time period.

For each line details:

- The product code.
- The full product name.
- The batch number.
- The number of packs decommissioned as supplied.
- The postal code of the initiating location ID.

NOTE: Intermarket initiating transactions are considered in this report

Report Header	
Report Type	Ph.1 - Number of products decommissioned in a specific market
Report Name	Ph.1
Sequence Number	4
Date Requested (UTC)	08/04/2020 13:38:48
From Date (UTC)	08/04/2020
To Date (UTC)	09/04/2020
Product Code	GTIN:34790271380008
Batch Number	-

Report Details				
Product Code	Name Of Medicinal Product	Batch Number	Number Of Packs Supplied	Postcode
GTIN:34790271380008	SSR - Test Product 1	batch1	2	SE1 8QS
GTIN:34790271380008	SSR - Test Product 1	batch2	2	SE1 8QS

# Ph.2 - Batch Destination Report

## Input parameters:

- Product Code Scheme (Optional)
- Product Code (Optional)
- Batch Number (Optional)
- Start Date
- End Date

## Report Content:

Select all batches in scope, where the batch was first uploaded between the specified 'Start Date' and 'End Date'.

## For each batch:

- Record the full product code.
- Record the product name.
- Record the batch number.
- Record the number of packs uploaded.
- Record the list of markets the batch is intended for.

Report Header	
Report Type	Ph.2 - Batch Destination Report
Report Name	Ph.2
Sequence Number	2
Date Requested (UTC)	08/04/2020 11:57:08
From Date (UTC)	06/04/2020
To Date (UTC)	09/04/2020
Product Code	GTIN:34790271380006
Batch Number	-

Report Details				
Product Code	Product Name	Batch Number	Number of Packs	Markets where product is intended to be placed
GTIN:34790271380006	SSR - Test Product 1	batch1	10	IE
GTIN:34790271380006	SSR - Test Product 1	batch2	10	IE, XS
GTIN:34790271380006	SSR - Test Product 1	batch3	10	IE

# Ph.3 - Active Packs Available Report

## Input parameters:

- Product Code Scheme (Optional)
- Product Code (Optional)
- Batch Number (Optional)
- Start Date
- End Date

## Report Content:

Select all batches in scope, where the batch was first uploaded between the specified 'Start Date' and the specified 'End Date'.

For each batch:

- Record the product code.
- Record the full product name.
- Record the batch number.
- Record the number of packs uploaded.
- Record the number of packs decommissioned as supplied.
- Record the number of active packs.
- Record the number of packs decommissioned as locked.

*NOTE: IMP pack state (Investigatory Medical Product) is not currently implemented, hence it will not appear in the report.*

### Report Header

Report Type	Ph.3 - Active Packs Available Report
Report Name	Ph.3
Sequence Number	3
Date Requested (UTC)	08/04/2020 12:05:29
From Date (UTC)	06/04/2020
To Date (UTC)	09/04/2020
Product Code	GTIN:34790271380006
Batch Number	batch1

### Report Details

Product Code	Product Name	Batch Number	Number Of Packs Uploaded	Number Of Packs Supplied	Number Of Packs Active	Number Of Packs Locked
GTIN:34790271380006	SSR - Test Product 1	batch1	10	2	1	2

# Question time !





