

User Group Meeting I2ES, 18 March 2016, VIC, Vienna

Swiss experience in using I2ES



Monika Joos, Head of Narcotics Division

Swissmedic – Narcotics Division

Strong need for an efficient process in line with the conventions

- In charge of: Narcotics, Psychotropics and Precursors
- 8 staff members (5.9 full time equivalents)
- Strong chemical and pharmaceutical industry:
 - 7500 to 8000 Import and Export authorizations / year
 - Processing time for new requests is at the most 10 working days
- Electronic systems used:
 - NDS, NDS-WEB, NDS-SPA
 - I2ES
 - PEN online
 - MESA (national trade)

Motivation for Switzerland to use I2ES

Electronic exchange of information with I2ES, why?

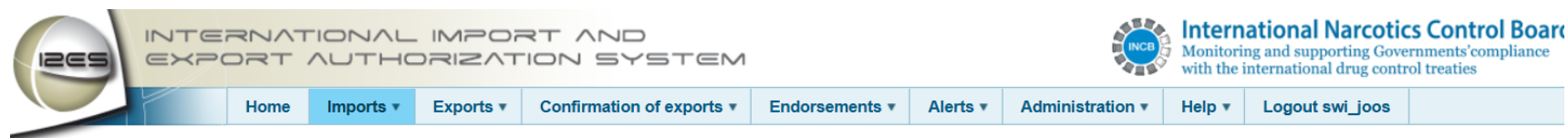
- More efficient
- Improvement of of Import / Export process
- Increasing need to use IT technology
- Need for verification of import authorizations

Current options to use I2ES













- Manual use: could be used as basic system
- XML upload of data (option to generate XML in NDS)
- **Automatic exchange of data between NDS (local system) and I2ES**

Manual use – experience from pilot phase







- Helpful IT-system to issue Import- and Export authorizations



List of authorized import authorizations

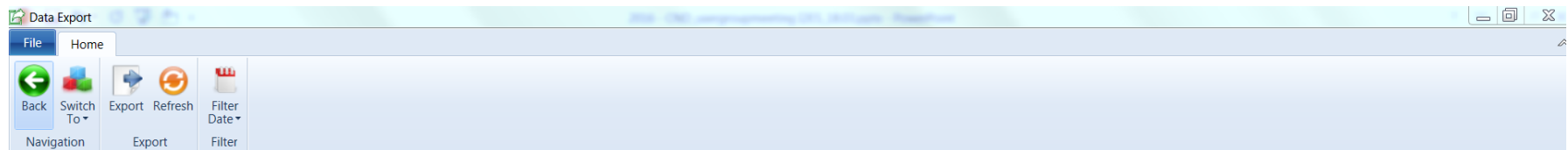
| Authorization type | Status | Creation method | Authorization number | Counterpart authorization number | Date of application | Date of issuance | Expiration date | Importer / exporter | Counterpart country | Counterpart importer / exporter | | | |
|--------------------|------------|--|----------------------|----------------------------------|---------------------|------------------|-----------------|---------------------|---------------------|---------------------------------|--|--|--|
| IMPORT | AUTHORIZED |  | IMP/1759/2015 | | 08/10/2015 | 14/10/2015 | 14/02/2016 | Konapharma... | Germany | Develco Phar... |  |  |  |
| IMPORT | AUTHORIZED |  | IMP/1757/2015 | | 08/10/2015 | 14/10/2015 | 14/02/2016 | Salmon Phar... | Germany | MEDICE Arzn... |  |  |  |
| IMPORT | AUTHORIZED |  | IMP/1691/2015 | | 30/09/2015 | 07/10/2015 | 07/02/2016 | Salmon Phar... | Germany | MEDICE Arzn... |  |  |  |

List of pre-drafts (for export authorizations)

| Authorization type | Status | Creation method | Authorization number | Counterpart authorization number | Date of application | Date of issuance | Expiration date | Importer / exporter | Counterpart country | Counterpart importer / exporter | | | |
|--------------------|-----------|---|----------------------|----------------------------------|---------------------|------------------|-----------------|---------------------|---------------------|---------------------------------|---|---|--|
| EXPORT | PRE-DRAFT |  | EXP/3492/2015 | CSH1512314 | 01/12/2015 | 31/12/2015 | 30/06/2016 | Novartis Phar... | Australia | Novartis Phar... |  |  | |
| EXPORT | PRE-DRAFT |  | EXP/3492/2015 | CSH1512314 | 01/12/2015 | 31/12/2015 | 30/06/2016 | Novartis Phar... | Australia | Novartis Phar... |  |  | |

XML-generation since April 2015

- Generation of XML files (option available in NDS)
- XML generation for authorizations and endorsements



Authorizations

Drag a column header and drop it here to group by that column

| | Authorizati | Exported | Reference Number | Authorization Number | Establishment Code | Establ | Trading Country | Trading Establishn | Tr | Trading Approval Date | Request Date | Approval Date | Valid From | Valid To | Reexport |
|-------------------------------------|-------------|----------|------------------|----------------------|--------------------|-----------|-----------------|--------------------|-------|-----------------------|--------------|---------------|------------|------------|----------|
| <input checked="" type="checkbox"/> | Export | No | REF/100033/2015 | EXP/1276/2015 | ESTB-2517 | Sigma-AI | FRA | ESTB-6057 | Sigma | 17/03/2015 | 25/03/2015 | 01/04/2015 | 01/04/2015 | 01/08/2015 | No |
| <input type="checkbox"/> | Export | No | REF/100034/2015 | EXP/1277/2015 | ESTB-559 | Selectche | HUN | ESTB-131 | Hung | 13/03/2015 | 25/03/2015 | 01/04/2015 | 01/04/2015 | 14/06/2015 | No |
| <input type="checkbox"/> | Export | Yes | REF/100035/2015 | EXP/1278/2015 | ESTB-4375 | Acino Ph | GER | ESTB-3350 | PS Ph | 19/03/2015 | 25/03/2015 | 01/04/2015 | 01/04/2015 | 20/06/2015 | No |
| <input type="checkbox"/> | Export | Yes | REF/100036/2015 | EXP/1279/2015 | ESTB-4375 | Acino Ph | GER | ESTB-3350 | PS Ph | 17/03/2015 | 25/03/2015 | 01/04/2015 | 01/04/2015 | 20/06/2015 | No |
| <input type="checkbox"/> | Export | Yes | REF/100037/2015 | EXP/1280/2015 | ESTB-4375 | Acino Ph | GER | ESTB-3350 | PS Ph | 23/03/2015 | 25/03/2015 | 01/04/2015 | 01/04/2015 | 30/06/2015 | No |
| <input type="checkbox"/> | Export | Yes | REF/100038/2015 | EXP/1281/2015 | ESTB-4375 | Acino Ph | GER | ESTB-3350 | PS Ph | 23/03/2015 | 25/03/2015 | 01/04/2015 | 01/04/2015 | 30/06/2015 | No |

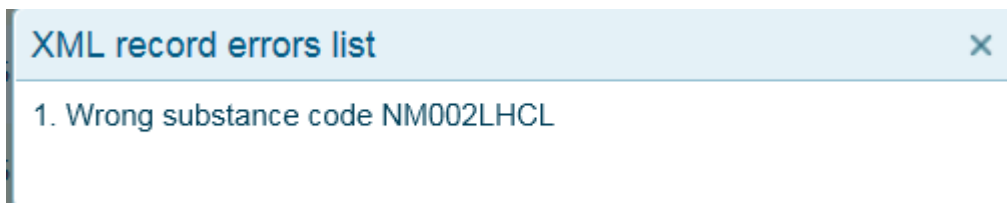
- Filter functions available
- Option to tick more then one transaction

XML-upload to I2ES since April 2015

- Upload in I2ES



- Error message in case of issue



Experience: XML upload using NDS

- Switzerland used XML upload as an interim solution to get experience for the automatic data exchange
- XML upload works efficient:
 - Batch upload to I2ES possible
 - Filter functions allow to select a period (like one week) and country
- Learning: Substance codes used in national system have to be the same as in I2ES (e.g. Levo-methadone)
- To get data from I2ES, login in I2ES is required, two separate systems
- Import and export authorizations not linked in case of XML upload

Automatic data exchange NDS and I2ES

Goals:

- More efficient process
- Improved Import / Export process

Improvements due to automatic data exchange

- Automatic data exchange between authorities could replace paper
- Approval of export requests is based on I2ES data
- Management of discrepancies in endorsements / confirmation of export is based on individual transactions
- Improved management of Estimates / Assessments

Concept: Data available in the national system



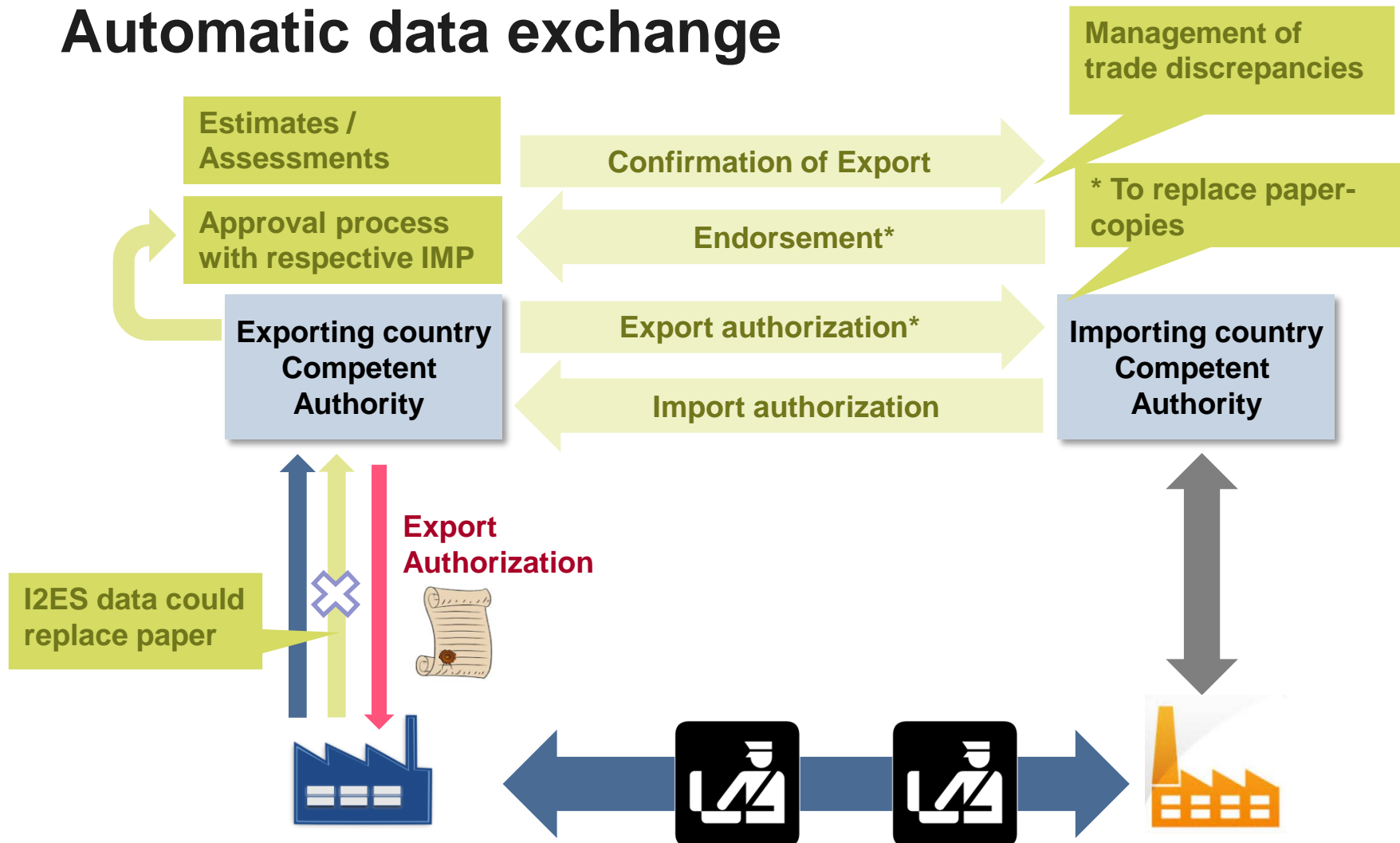
Approval of
Export

| EXPORT REQUESTED | | | |
|---|---|--|---|
| Web Request Id: 23819 | | | |
| Authorization Number | <input type="text" value="Enter number"/> | Reference Number | <input type="text" value="Enter number"/> |
| Request Date | <input type="text" value="07.03.2016"/> | Approval Date | <input type="text" value="Enter date"/> |
| Valid From | <input type="text" value="07.03.2016"/> | Valid To | <input type="text" value="07.07.2016"/> |
| Endorse Date | <input type="text" value="Enter date"/> | Cancel Date | <input type="text" value="Enter date"/> |
| Exporter Country: <input type="text" value="SWITZERLAND"/> CA Name: <input type="text"/> Name: <input type="text" value="Swissmedic, Labor (OMCL)"/> Code: <input type="text" value="ESTB-684"/> City: <input type="text" value="Bern"/> | | Importer Country: <input type="text" value="GERMANY"/> CA Name: <input type="text"/> Name: <input type="text" value="Abbott GmbH & Co. KG"/> Code: <input type="text" value="ESTB-1393"/> City: <input type="text" value="Ludwigshafen"/> | |

Endorsement /
Conf. of export

| Accept Web Request Endorsement | | | | | |
|--|--|--------------------------------------|--------------------------------------|--|--|
| Authorisation No.: EXP/437/2016 | Web Request ID: 23815 | Certificate No.: EXP/437/2016 | Status: ENDORSEMENT SUBMIT... | | |
| Establishment: Swissmedic, Abt. Laboratorien OMCL | Entity Endorse Date: 04/04/2016 | | | | |
| Entity Endorsed: ESTABLISHMENT | Entity endorsed by: Joos Monika | I2ES Endorse Date: 03/03/2016 | | | |
| Approval Date: 03/03/2016 | Valid From: 03/03/2016 | Valid To: 02/05/2016 | I2ES Endorse Disc: [Red Box] | | |
| CA Endorse Date: 04/04/2016 | Share Endorsement: <input checked="" type="checkbox"/> | Single Permit | | | |

Automatic data exchange



Automatic data exchange once per night

- Authorizations / Endorsements from NDS to I2ES
- Authorizations / Endorsements from I2ES to NDS
- Import Authorization counterpart from I2ES as pdf
- Estimates from I2ES


I2ES Jobs ×

| Jobs | | | | | | |
|------|---|----------------------|---|-------------------------------------|---|----------------------|
| | | Job Id | Name | Active | | Status |
| | | <input type="text"/> | <input type="text"/> | <input type="text"/> | | <input type="text"/> |
| > | + | 10000 | Synchronize active countries from I2ES to NDS | <input checked="" type="checkbox"/> | ● | Succeeded |
| | + | 10001 | Synchronize trading authorizations from I2ES to NDS | <input checked="" type="checkbox"/> | ● | Succeeded |
| | + | 10002 | Synchronize trading endorsements from I2ES to NDS | <input checked="" type="checkbox"/> | ● | Succeeded |
| | + | 10003 | Synchronize estimates from I2ES to NDS | <input checked="" type="checkbox"/> | ● | Succeeded |
| | + | 10004 | Synchronize authorizations from NDS to I2ES | <input checked="" type="checkbox"/> | ● | Succeeded |
| | + | 10005 | Synchronize endorsements from NDS to I2ES | <input checked="" type="checkbox"/> | ● | Succeeded |
| | + | 10006 | Create trading import authorization pdf | <input checked="" type="checkbox"/> | ● | Succeeded |

Matching of Export-Auth. with respective IMP

- Criteria for matching
Country code + Import-Authorization number
- Automatic matching
- Option for manual matching
- Authorizations are flagged according to matching status

NDS 7


| I2ES Match  |
|--|
| MATCH |
| NO MATCH |
| PENDING MATCH |
| |


NDS-WEB

| Paper Required |
|----------------|
| Yes |
| Pending |
| No |

- Non controlled + precursors + countries not active = flag **no match**


NDS-WEB





TEST 


[Home](#)
[Masters](#)
[Import/Export](#)
[Statistic Upload](#)
[User Settings](#)
[Important Informations](#)


Import/Export Requests Status ?



 Create Imp/Exp Request

 Filter






















 Export General

 Export Detailed

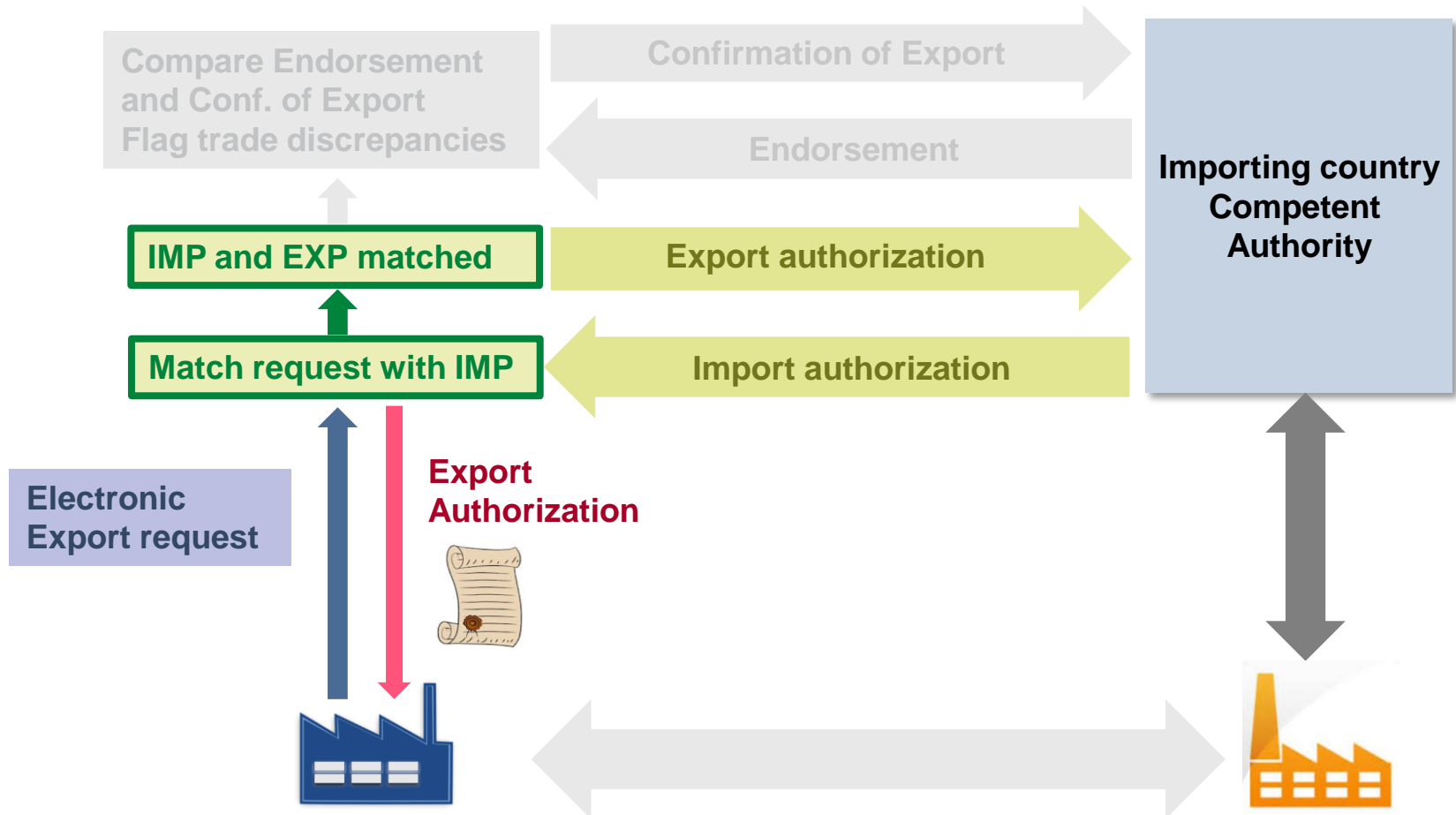
 Cover Sheet

| | Cover Sheet | Paper Required | Request ID | Auth. Number | Status | Request Type | Request Date | Approval Date | Valid To Date | Trading Country |
|---|--|----------------|------------|--------------|-----------|-------------------------|--------------|---------------|---------------|-----------------|
| > | <input type="checkbox"/> | Yes | 23811 | | REQUESTED | Export Precursors | 23/02/2016 | | | ITALY |
| > | <input type="checkbox"/> | Pending | 23810 | | REQUESTED | Export Controlled Drugs | 23/02/2016 | | | GERMANY |
| > | <input type="checkbox"/>  | No | 23809 | | REQUESTED | Export Controlled Drugs | 23/02/2016 | | | GERMANY |
| > | <input type="checkbox"/>  | No | 23808 | | REQUESTED | Export Controlled Drugs | 23/02/2016 | | | GERMANY |
| > | <input type="checkbox"/> | | 23807 | | IN REVIEW | Import Controlled Drugs | 22/02/2016 | | 22/06/2016 | GERMANY |
| > | <input type="checkbox"/> | | 23806 | | IN REVIEW | Import Controlled Drugs | 22/02/2016 | | 22/06/2016 | GERMANY |
| > | <input type="checkbox"/> | | 23805 | IMP/276/2016 | APPROVED | Import Controlled Drugs | 22/02/2016 | 22/02/2016 | 22/06/2016 | GERMANY |
| > | <input type="checkbox"/> | | 23804 | EXP/429/2016 | ENDORSED | Export Controlled Drugs | 22/02/2016 | 22/02/2016 | 21/04/2016 | GERMANY |

Flag in NDS 7

| File Home Masters Import/Export Licenses INCB Reports Synchronization | | | | | | | | | | | | |
|---|--------|---------|-------------|-----------|-------------|-----------|---------------|---|-----------|---------------|-------------|-------------|
|  Authorizations  Report  Refresh  Import  Export | | | | | | | | | | | | |
| General | | | | | | | | | | | | |
| I2ES Jobs x Authorization List x | | | | | | | | | | | | |
| I2ES Match | Source | Web Req | Authoriza | Status | Authoriza | Estab. Co | Estab. Na | Trading C | Trading E | Trading E | Request Dat | Approval Da |
| MATCH | WEB | 23809 | EXPORT | REQUESTED | | ESTB-684 | Swissmedic, L |  Germany | ESTB-1393 | Abbott GmbH | 23.02.2016 | |
| MATCH | WEB | 23808 | EXPORT | REQUESTED | | ESTB-684 | Swissmedic, L |  Germany | ESTB-1393 | Abbott GmbH | 23.02.2016 | |
| | WEB | 23807 | IMPORT | APPROVED | IMP/278/201 | ESTB-684 | Swissmedic, L |  Germany | ESTB-6911 | ABCR Dr. Bra | 22.02.2016 | 22.02.2016 |
| | WEB | 23806 | IMPORT | APPROVED | IMP/277/201 | ESTB-684 | Swissmedic, L |  Germany | ESTB-6911 | ABCR Dr. Bra | 22.02.2016 | 22.02.2016 |
| MATCH | WEB | 23805 | IMPORT | APPROVED | IMP/276/201 | ESTB-684 | Swissmedic, L |  Germany | ESTB-1393 | Abbott GmbH | 22.02.2016 | 22.02.2016 |
| MATCH | WEB | 23804 | EXPORT | ENDORSED | EXP/429/201 | ESTB-684 | Swissmedic, L |  Germany | ESTB-1393 | Abbott GmbH | 22.02.2016 | 22.02.2016 |
| MATCH | WEB | 23803 | EXPORT | APPROVED | EXP/428/201 | ESTB-684 | Swissmedic, L |  Germany | ESTB-1393 | Abbott GmbH | 22.02.2016 | 22.02.2016 |
| MATCH | WEB | 23802 | EXPORT | ENDORSED | EXP/427/201 | ESTB-684 | Swissmedic, L |  Germany | ESTB-1393 | Abbott GmbH | 22.02.2016 | 22.02.2016 |
| MATCH | WEB | 23801 | EXPORT | ENDORSED | EXP/426/201 | ESTB-684 | Swissmedic, L |  Germany | ESTB-1393 | Abbott GmbH | 19.02.2016 | 19.02.2016 |
| NO MATCH | WEB | 23800 | EXPORT | APPROVED | EXP/425/201 | ESTB-4503 | Swissmedic, L |  Australia | ESTB-1902 | Firmenich Lin | 19.02.2016 | 19.02.2016 |
| PENDING MATCH | WEB | 23798 | EXPORT | REQUESTED | | ESTB-4503 | Swissmedic, L |  Austria | ESTB-1133 | G.L. Pharma C | 19.02.2016 | |
| | MANUAL | | IMPORT | APPROVED | IMP/272/201 | ESTB-684 | Swissmedic, L |  Brazil | ESTB-4433 | Alpha Br Proc | 18.02.2016 | 18.02.2016 |
| | MANUAL | | EXPORT | APPROVED | EXP/422/201 | ESTB-4375 | Acino Pharmi |  Germany | ESTB-6873 | BTC Europe C | 18.02.2016 | 18.02.2016 |
| MATCH | WEB | 23796 | IMPORT | ENDORSED | IMP/271/201 | ESTB-684 | Swissmedic, L |  Germany | ESTB-6911 | ABCR Dr. Bra | 17.02.2016 | 17.02.2016 |
| NO MATCH | WEB | 23793 | EXPORT | APPROVED | EXP/421/201 | ESTB-684 | Swissmedic, L |  Afghanistan | ESTB-7486 | ICRC, Kabul C | 17.02.2016 | 17.02.2016 |
| NO MATCH | WEB | 23792 | EXPORT PREC | CANCELLED | | ESTB-684 | Swissmedic, L |  Italy | ESTB-2249 | A. F. O. M. M | 17.02.2016 | |

Export – Approval process of Export request



Export request

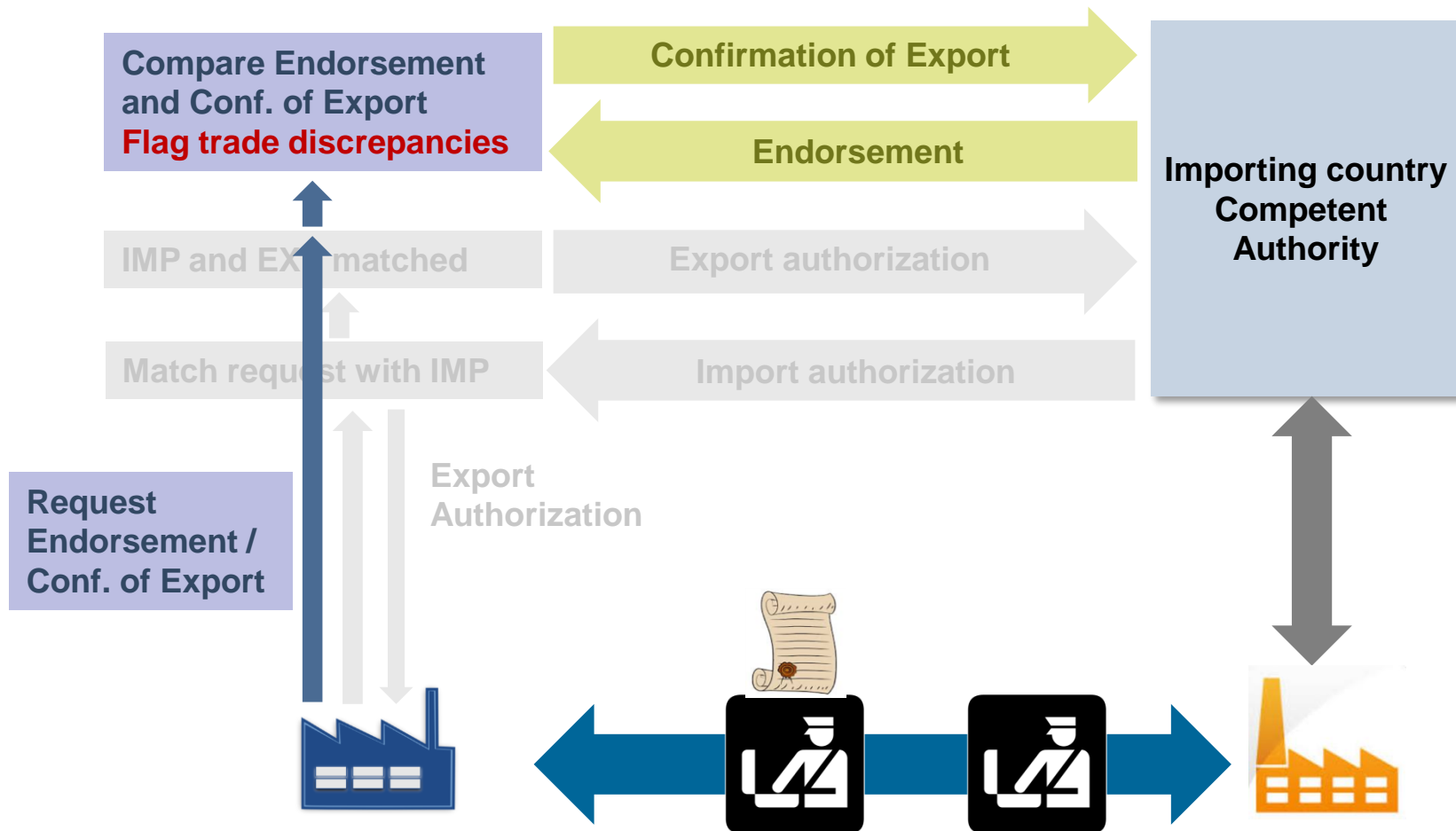
- Import authorization data from I2ES to NDS
- Automatic or manual matching EXP with resp. IMP in NDS
- Request in NDS-WEB: flag show to Exporter that paper is not required

| Paper Required | Request ID | Auth. Number | Status | Request Type | Req Date |
|----------------|------------|--------------|-----------|-------------------------|----------|
| No | 23817 | | REQUESTED | Export Controlled Drugs | 04/0 |

- Request in NDS 7: flag indicates that data from I2ES are available

| I2ES Matc ▼ | Source ▼ | Web Req ▼ | Authoriza ▼ | Status ▼ | Authoriza ▼ |
|-------------|----------|-----------|-------------|-----------|-------------|
| MATCH | WEB | 23817 | EXPORT | REQUESTED | |

Export and Import



Manage discrepancies – counterpart first

- Counterpart information available in national system
- Discrepancy is flagged (quantity, quarter of date)

Accept Web Request Endorsement

Authorisation No.: EXP/437/2016 Web Request ID: 23815 Certificate No.: EXP/437/2016 Status: ENDORSEMENT SUBMIT...

Establishment: Swissmedic, Abt. Laboratorien OMCL Entity Endorse Date: 04/04/2016

Entity Endorsed: ESTABLISHMENT Entity endorsed by: Joos Monika I2ES Endorse Date: 03/03/2016

Approval Date: 03/03/2016 Valid From: 03/03/2016 Valid To: 02/05/2016 I2ES Endorse Disc: [Redacted]

CA Endorse Date: 04/04/2016 Share Endorsement: ☒ Single Permit

Request details

| Subst./Prep. Code | Subst./Prep. Name | No. of Units | Requested Qty. | Approved Qty. |
|-------------------|-------------------|--------------|----------------|---------------|
| PD006--- | Diazepam | 0 | 1.50 | 1.50 |

Record 1 of 1

Endorsement details

| Auth. No. | Endorse ... | Item Name | Package ... | Package ... | Item UOM | Pharm. F... | Qty. Volu... | Substanc... | Substanc... | Substanc... | Is Exemp... |
|-------------|-------------|-----------|-------------|-------------|----------|-------------|--------------|-------------|-------------|-------------|--------------------------|
| T_IMP_20... | 1.80 | Diazepam | | | G | | | | | | <input type="checkbox"/> |

Endorsement details

| Subs./Prep. Co... | Subs./Prep. Na... | No. Units | UOM | Requested Qty. | Approved Qty. | Entity Endorse... | CA Endorsed Qu... |
|-------------------|-------------------|-----------|-----|----------------|---------------|-------------------|-------------------|
| PD006--- | Diazepam | 0 | G | 1.50 | 1.50 | 1.50 | 1.50 |

Flag discrepancy date

Flag discrepancy quantity

Manage discrepancies – counterpart second

- Discrepancy report transaction based

I2ES Discrepancy Endorsements

Parameters

Discrepancy Type : DISCREPANCY ON QUANTITY

☒ Search by Endorsement. Date : From: 01/02/2016 To: 06/07/2016
☐ Search by Auth. No. :

Discrepancies

| Web Request ... | Establish... | Estab... | City | Transaction Type | Permit Type | Auth. No. | Trading Auth. No. | Trading Country | I2ES Auth. No. | Va |
|-----------------|--------------|------------|------|------------------|----------------|--------------|-------------------|-----------------|----------------|----------|
| 23741 | Swissmedi... | Freibur... | Bern | EXPORT REQUEST | Single Permit | EXP/400/2016 | TE_IMP_2016_4 | GERMANY | T_IMP_2016_4 | 08/02/21 |
| 23801 | Swissmedi... | Freibur... | Bern | EXPORT REQUEST | Single Permit | EXP/426/2016 | T_IMP_2016_18 | GERMANY | T_IMP_2016_18 | 19/02/21 |
| 23802 | Swissmedi... | Freibur... | Bern | EXPORT REQUEST | Single Permit | EXP/427/2016 | T_IMP_2016_19 | GERMANY | T_IMP_2016_19 | 22/02/21 |
| 23771 | Swissmedi... | Freibur... | Bern | EXPORT REQUEST | Single Permit | EXP/411/2016 | t_imp_2016_12 | GERMANY | T_IMP_2016_12 | 10/02/21 |
| 23747 | Swissmedi... | Freibur... | Bern | IMPORT REQUEST | Single Permit | IMP/246/2016 | | GERMANY | T_EXP_2016_1 | 09/02/21 |
| 23779 | Swissmedi... | Freibur... | Bern | IMPORT REQUEST | General Permit | IMP/260/2016 | | GERMANY | T_EXP_2016_14 | 10/02/21 |
| 23795 | Swissmedi... | Freibur... | Bern | IMPORT REQUEST | Single Permit | IMP/270/2016 | | GERMANY | T_EXP_2016_21 | 03/02/21 |

Estimates / Assessments from I2ES

EXPORT (2016)

Transaction details

Substance/Preparation name

Buprenorphine

Package size

0

Quantity

1.800 g

Base substance details

Substance name

Buprenorphine

Substance code

PB006---

Base quantity

1.800 g

Estimate balance

| Country | Estimate/assessment quantity | Balance 1 | Balance 2 | UOM |
|-------------|------------------------------|---------------|-------------|-----|
| SWITZERLAND | 800'000.000 | 798'743.629 | 797'248.929 | g |
| GERMANY | 1'000'000.000 | 1'001'180.820 | 999'993.300 | g |

Import balance

| Country | Import approved | Endorsed | Pending endorsed | Import approved (Reexport) | Endorsed (Reexport) | Pending endorsed (Reexport) |
|-------------|-----------------|----------|------------------|----------------------------|---------------------|-----------------------------|
| SWITZERLAND | 2'362.751 | 388.320 | 1'974.431 | 0.000 | 0.000 | 0.000 |
| GERMANY | 6.900 | 6.700 | 0.200 | 0.000 | 0.000 | 0.000 |

Export balance

| Country | Export approved | Export confirmed | Export confirmed pending | Export approved (Reexport) | Export confirmed (Reexport) | Export confirmed pending (Reexport) |
|-------------|-----------------|------------------|--------------------------|----------------------------|-----------------------------|-------------------------------------|
| SWITZERLAND | 1'401.900 | 1'308.700 | 93.200 | 0.000 | 0.000 | 0.000 |
| GERMANY | 799.200 | 388.320 | 410.880 | 0.000 | 0.000 | 0.000 |

License balance

License number

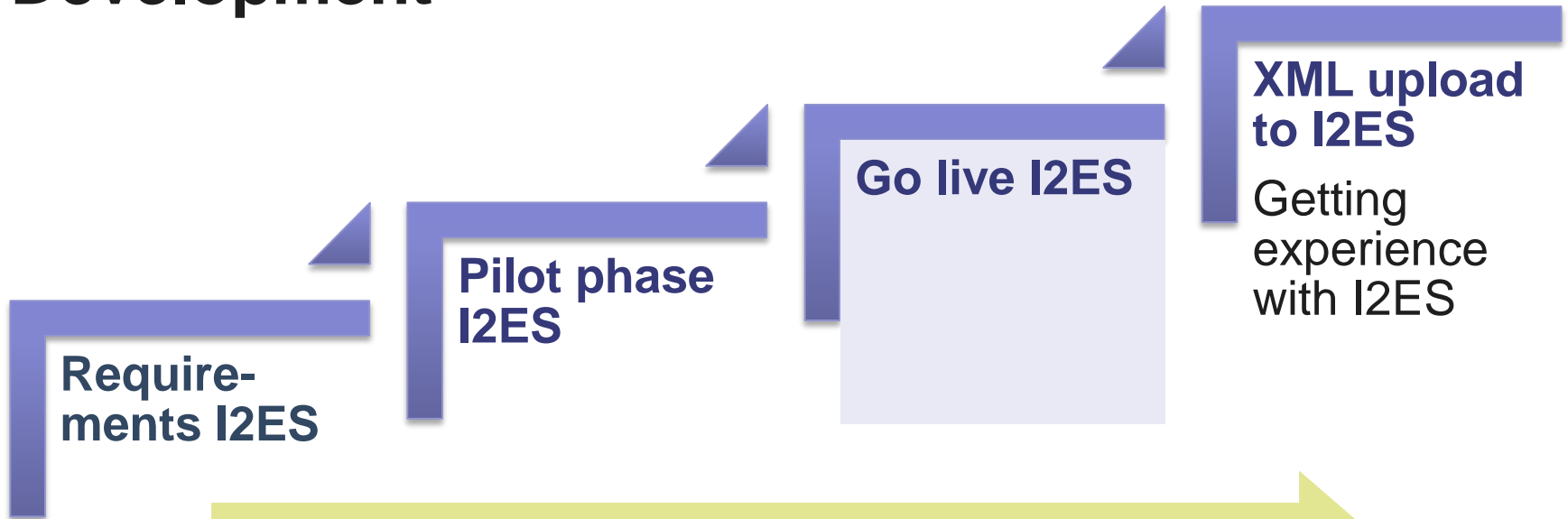
LIC-1798

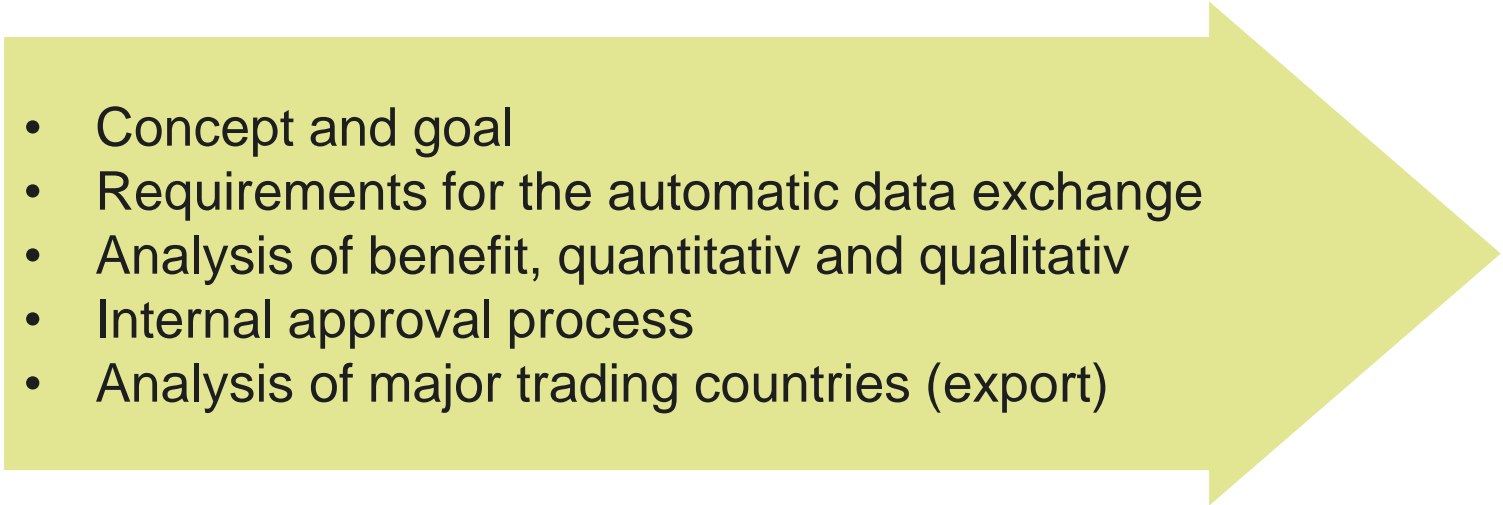
License status

License balance

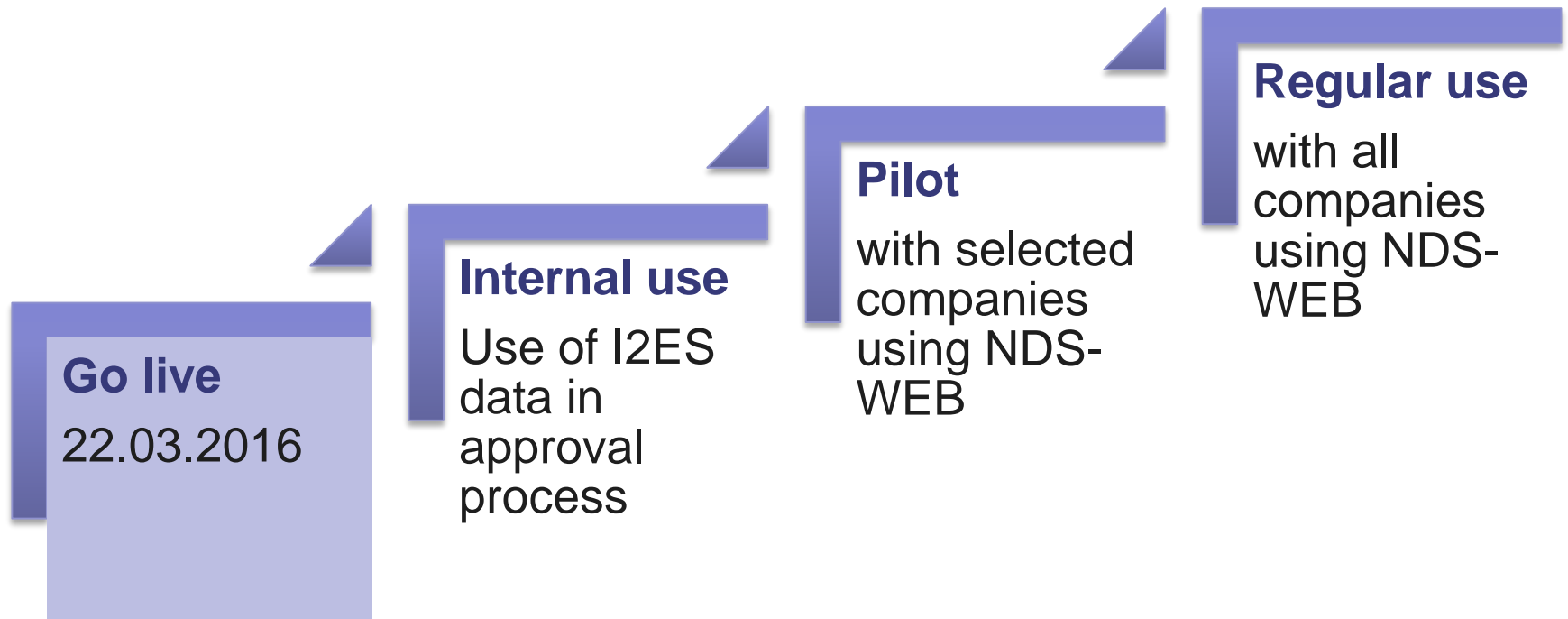
Data Estimates / Assessments from I2ES on a daily basis

Development



- 
- Concept and goal
 - Requirements for the automatic data exchange
 - Analysis of benefit, quantitativ and qualitativ
 - Internal approval process
 - Analysis of major trading countries (export)

Implementation



Improvements due to automatic data exchange

- **More efficient process**

- Electronic data to replace paper in communication between authorities

- **Use of I2ES data for approval of export requests**

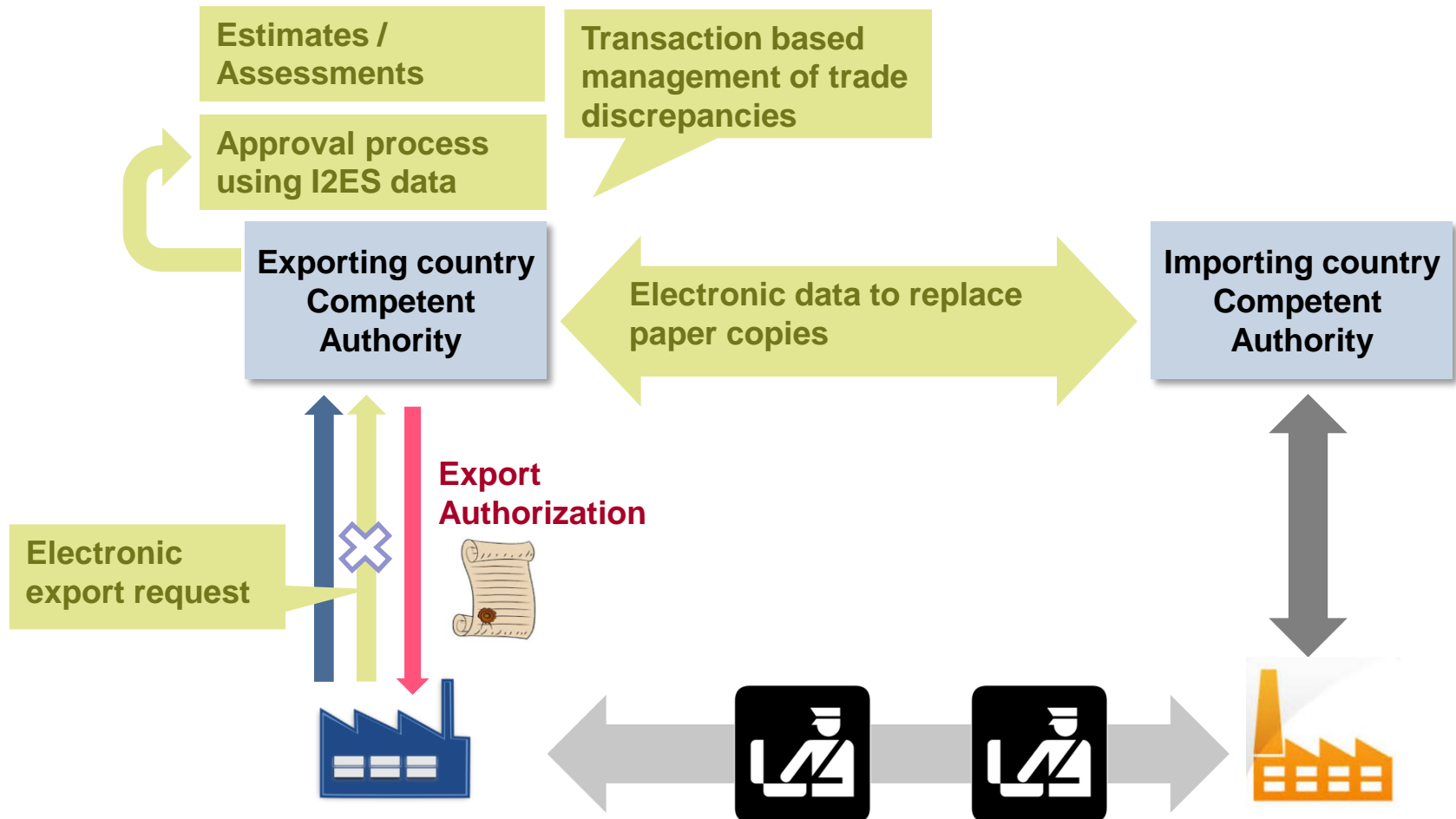
- I2ES data are more reliable, less risk to falsify
- I2ES data contain all mandatory data in a standardised format

- **Better management of trade discrepancies**

- Transaction based
- Realtime information

- **Estimate / Assessment on daily basis**

Improvements due to automatic data exchange





Questions?

Monika Joos

Head of Division Narcotics

e-mail: monika.joos@swissmedic.ch

Phone +41 58 464 91 87

www.swissmedic.ch