User Group Meeting I2ES, 18 March 2016, VIC, Vienna
Swiss experience in using I2ES

swissmedic

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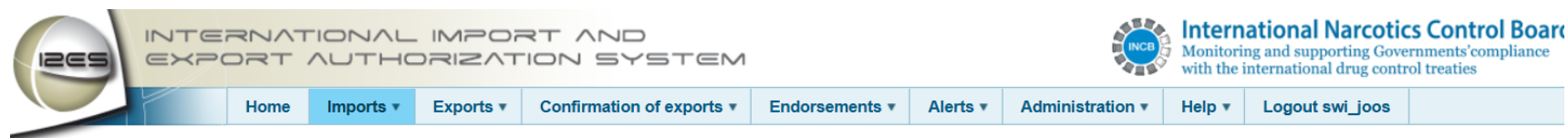
- More efficient
- Improvement of of Import / Export process
- Increasing need to use IT technology
- Need for verification of import authorizations

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

XML-generation since April 2015

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

- 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
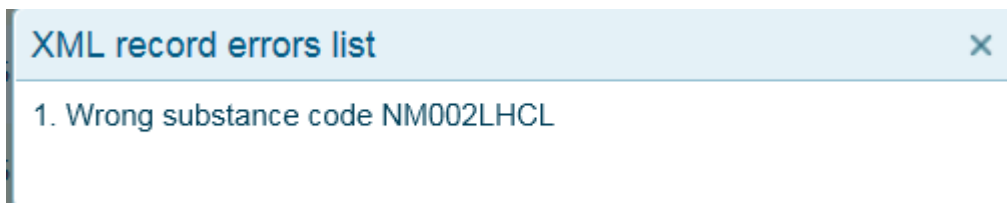
Experience: XML upload using NDS

- 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 selecte 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

Request from company

Counterpart data

Approval of Export

EXPORT
REQUESTED

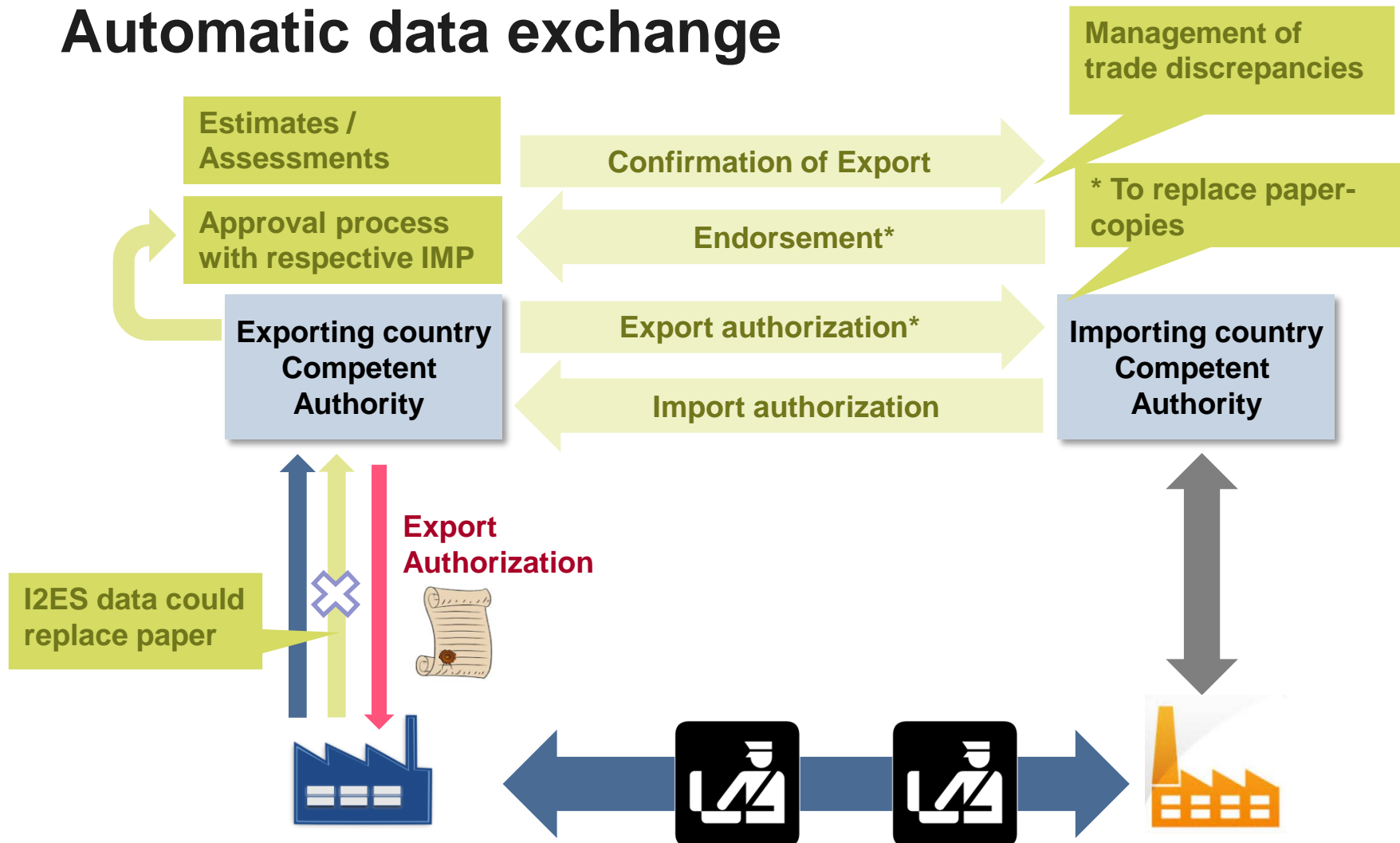| Web Request Id: 23819				
Authorization Number	Enter number		**Reference Number**	Enter number
Request Date	07.03.2016		**Approval Date**	Enter date
Valid From	07.03.2016		**Valid To**	07.07.2016
Endorse Date	Enter date		**Cancel Date**	Enter date

Exporter				Importer		
Country	SWITZERLAND			**Country**	GERMANY	
CA Name				**CA Name**		
Name	Swissmedic, Labor (OMCL)			**Name**	Abbott GmbH & Co. KG	
Code	ESTB-684	**City**	Bern	**Code**	ESTB-1393	**City** 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:	
CA Endorse Date:	04/04/2016	Share Endorsement:	✓				**Single Permit**

Automatic data exchange

Management of trade discrepancies

Estimates / Assessments

Confirmation of Export

* To replace paper-copies

Approval process with respective IMP

Endorsement*

Exporting country Competent Authority

Export authorization*

Importing country Competent Authority

Import authorization

Export Authorization

I2ES data could replace paper

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**
> +	10000	Synchronize active countries from I2ES to NDS		☑	🟢	Succeeded
+	10001	Synchronize trading authorizations from I2ES to NDS		☑	🟢	Succeeded
+	10002	Synchronize trading endorsements from I2ES to NDS		☑	🟢	Succeeded
+	10003	Synchronize estimates from I2ES to NDS		☑	🟢	Succeeded
+	10004	Synchronize authorizations from NDS to I2ES		☑	🟢	Succeeded
+	10005	Synchronize endorsements from NDS to I2ES		☑	🟢	Succeeded
+	10006	Create trading import authorization pdf		☑	🟢	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

Import/Export Requests Status

Create Imp/Exp Request   Filter   Export General   Export Detailed   Cover Shee
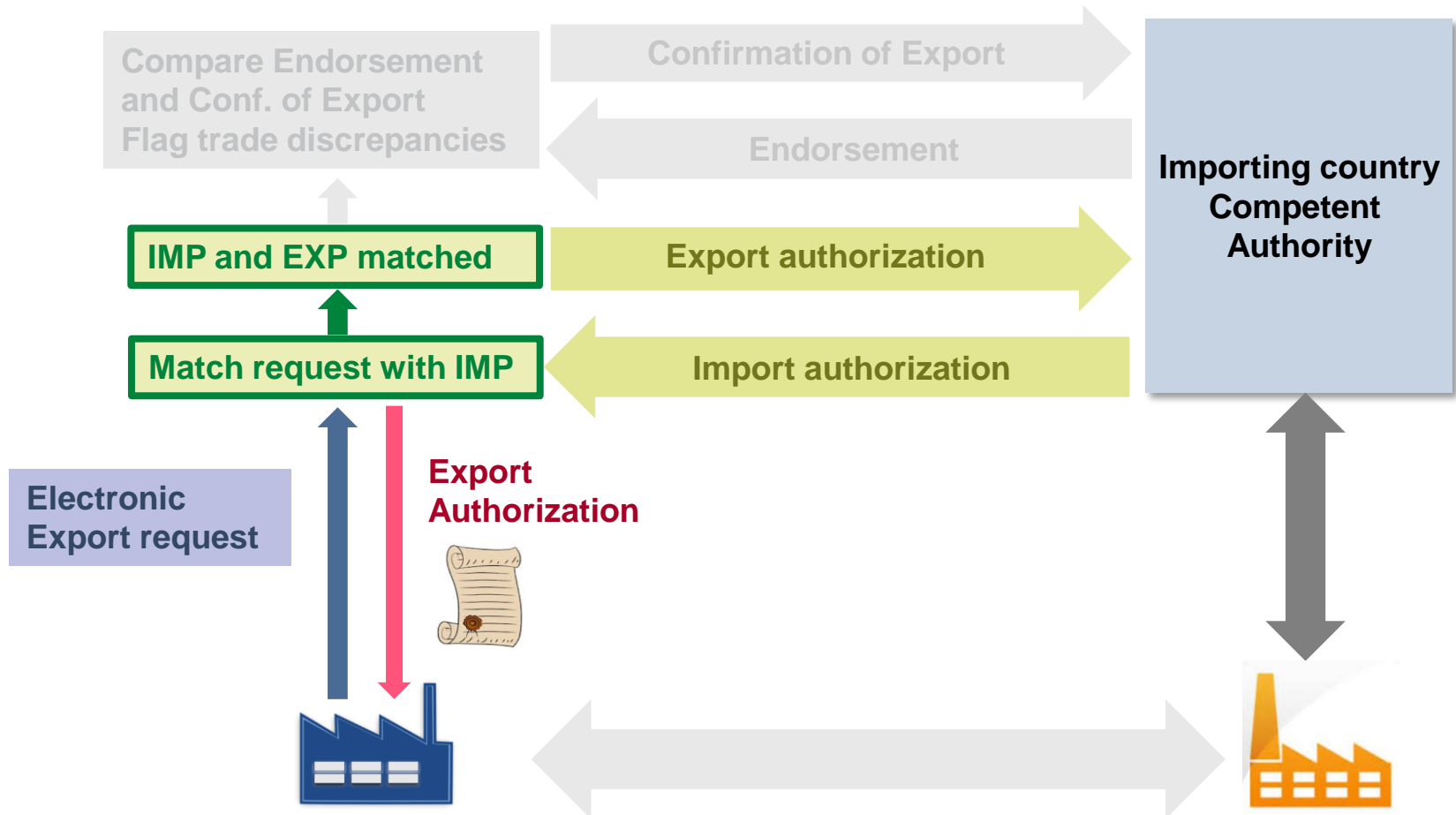
		Cover Sheet	Paper Required	Request ID	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Trading Country
>	☐		Yes	23811		REQUESTED	Export Precursors	23/02/2016			ITALY
>	☐		Pending	23810		REQUESTED	Export Controlled Drugs	23/02/2016			GERMANY
>	☐	🚩	No	23809		REQUESTED	Export Controlled Drugs	23/02/2016			GERMANY
>	☐	🚩	No	23808		REQUESTED	Export Controlled Drugs	23/02/2016			GERMANY
>	☐			23807		IN REVIEW	Import Controlled Drugs	22/02/2016		22/06/2016	GERMANY
>	☐			23806		IN REVIEW	Import Controlled Drugs	22/02/2016		22/06/2016	GERMANY
>	☐			23805	IMP/276/2016	APPROVED	Import Controlled Drugs	22/02/2016	22/02/2016	22/06/2016	GERMANY
>	☐			23804	EXP/429/2016	ENDORSED	Export Controlled Drugs	22/02/2016	22/02/2016	21/04/2016	GERMANY

Flag in NDS 7

Export – Approval process of Export request

Compare Endorsement and Conf. of Export Flag trade discrepancies

Confirmation of Export

Endorsement

Importing country Competent Authority

IMP and EXP matched

Export authorization

Match request with IMP

Import authorization

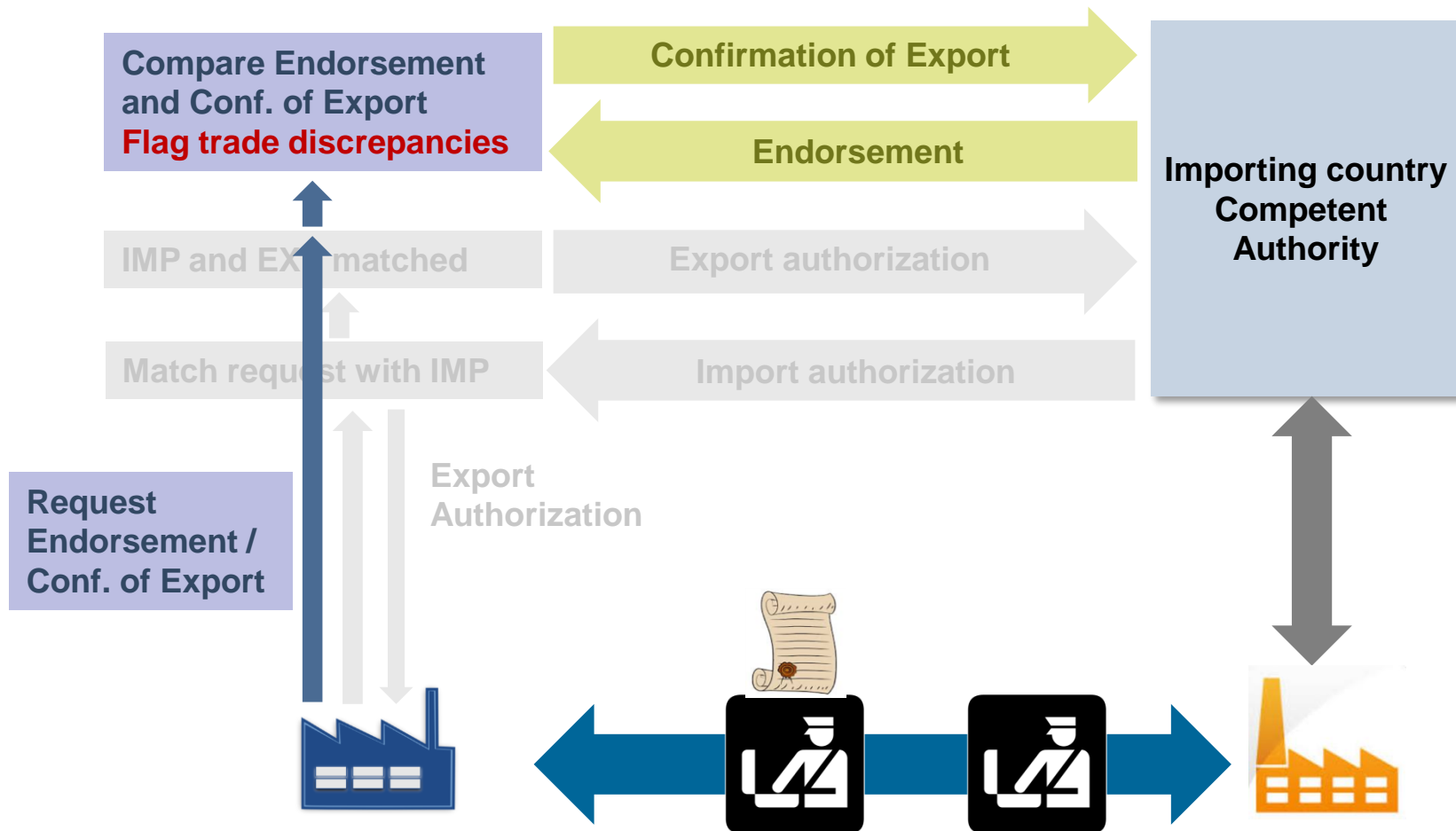Electronic Export request

Export Authorization

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 Requ	Authoriza	Status	Authoriza
MATCH	WEB	23817	EXPORT	REQUESTED	

Approval process of Export authorizations

Export and Import

Compare Endorsement and Conf. of Export
Flag trade discrepancies

Confirmation of Export

Endorsement

Importing country Competent Authority

IMP and EXP matched

Export authorization

Match request with IMP

Import authorization

Export Authorization

Request Endorsement / Conf. of Export

Manage discrepancies – counterpart first

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

Manage discrepancies – counterpart second

- Discrepancy report transaction based

Estimates / Assessments from I2ES

Data Estimates / Assessments from I2ES on a daily basis

Development

Require-ments I2ES

Pilot phase I2ES

Go live I2ES

XML upload to I2ES

Getting experience with I2ES
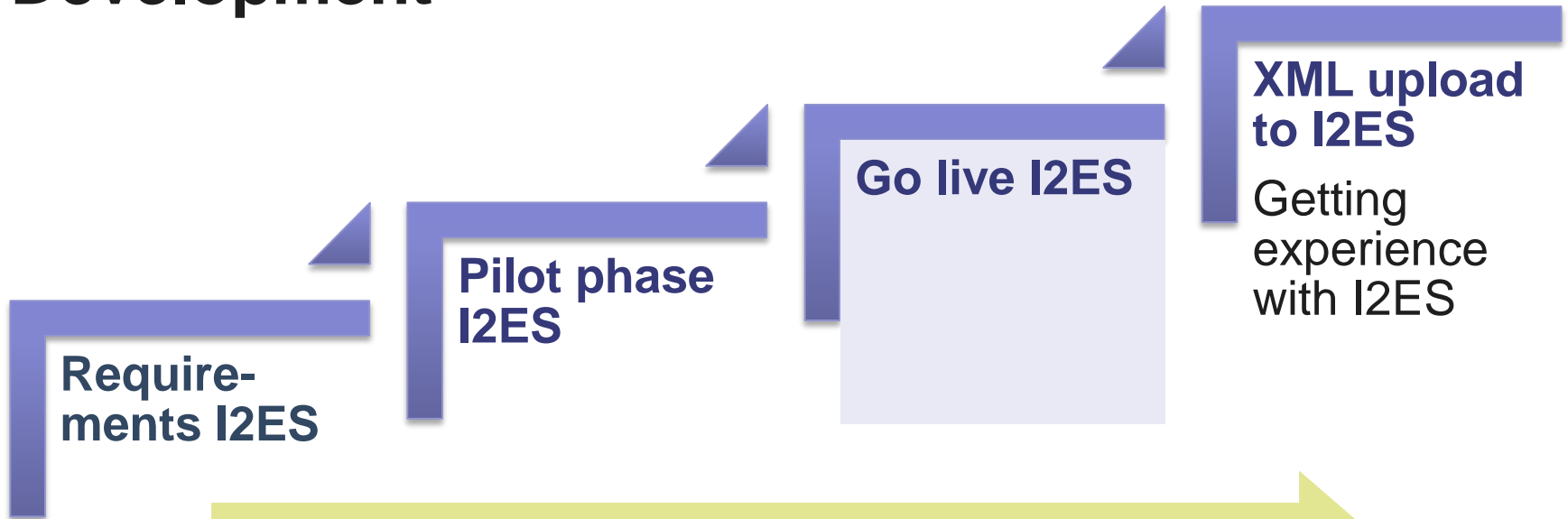
- Concept and goal
- Requirements for the automatic data exchange
- Analysis of benefit, quantitativ and qualitativ
- Internal approval process
- Analysis of major trading countries (export)

Implementation

Go live
22.03.2016

Internal use
Use of I2ES data in approval process

Pilot
with selected companies using NDS-WEB

Regular use
with all companies using NDS-WEB
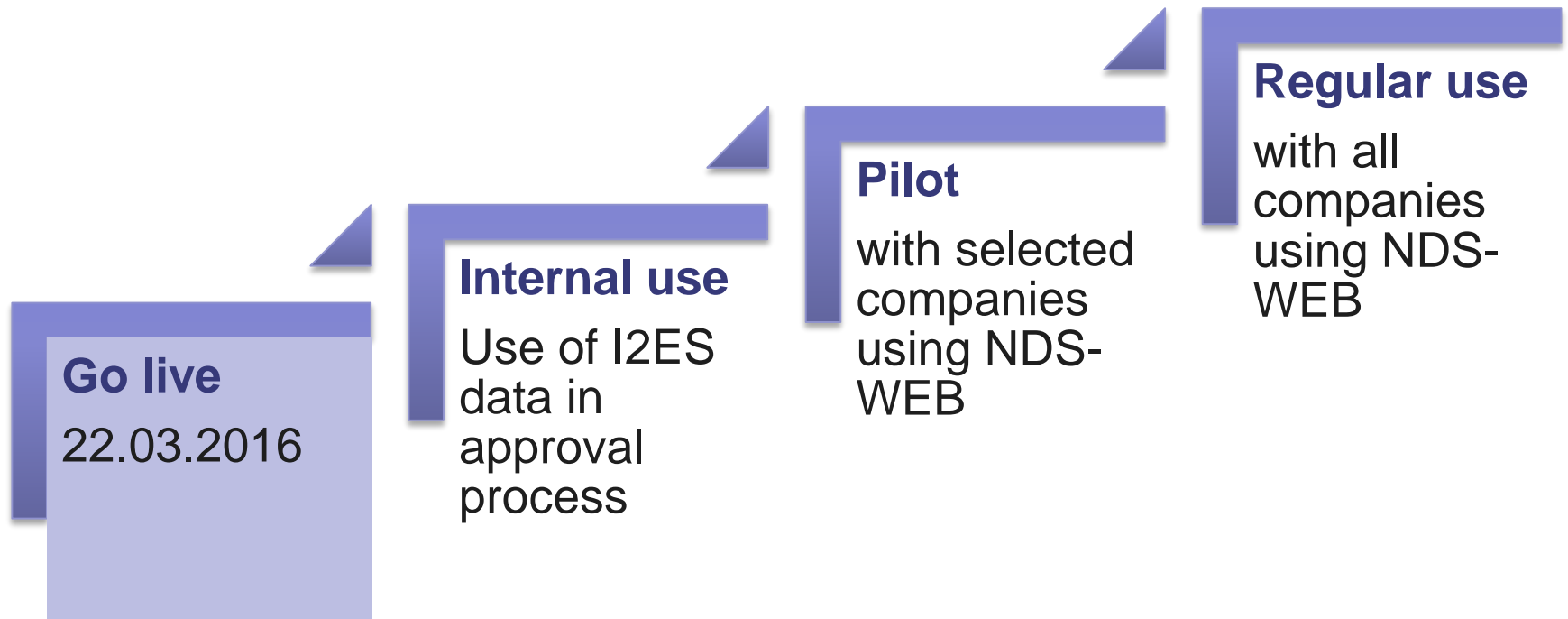
Improvements due to automatic data exchange

- **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

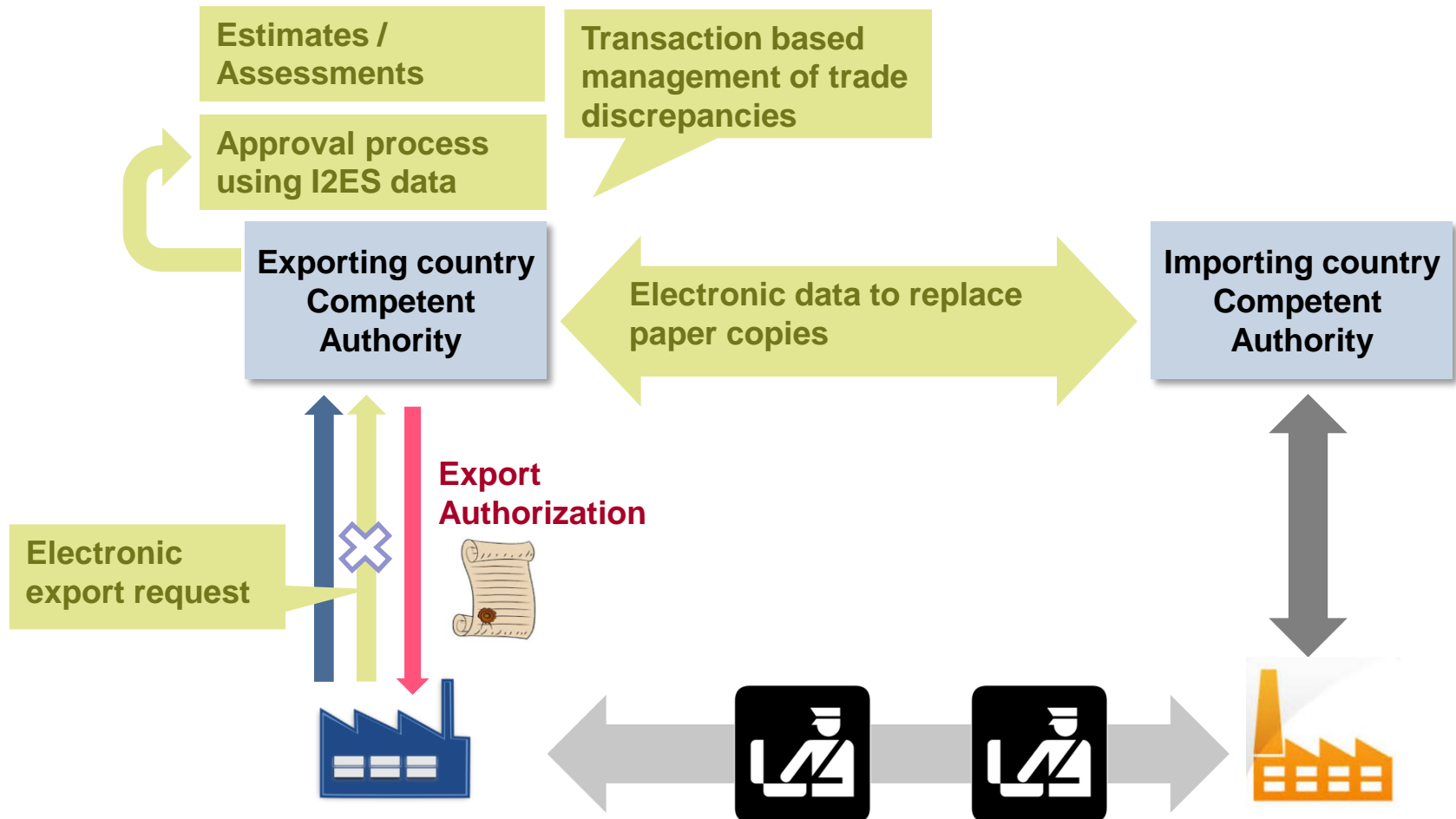Estimates / Assessments

Approval process using I2ES data

Transaction based management of trade discrepancies

Exporting country Competent Authority

Electronic data to replace paper copies

Importing country Competent Authority

Export Authorization

Electronic export request

Questions?

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