

7th NDS Usergroup Meeting (Mexico City, September 2009)

National Drug Control

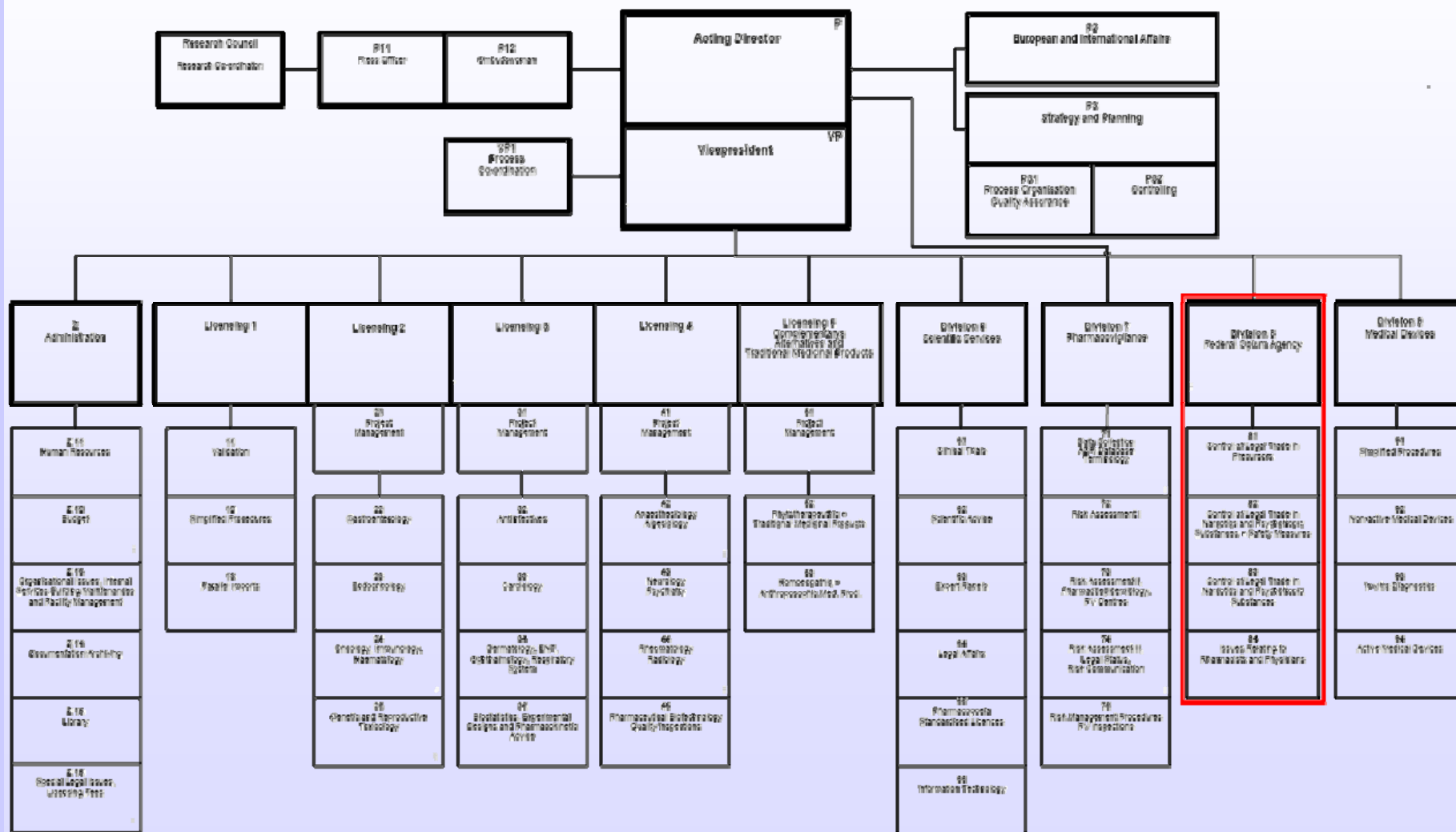


Dirk Ohlenforst

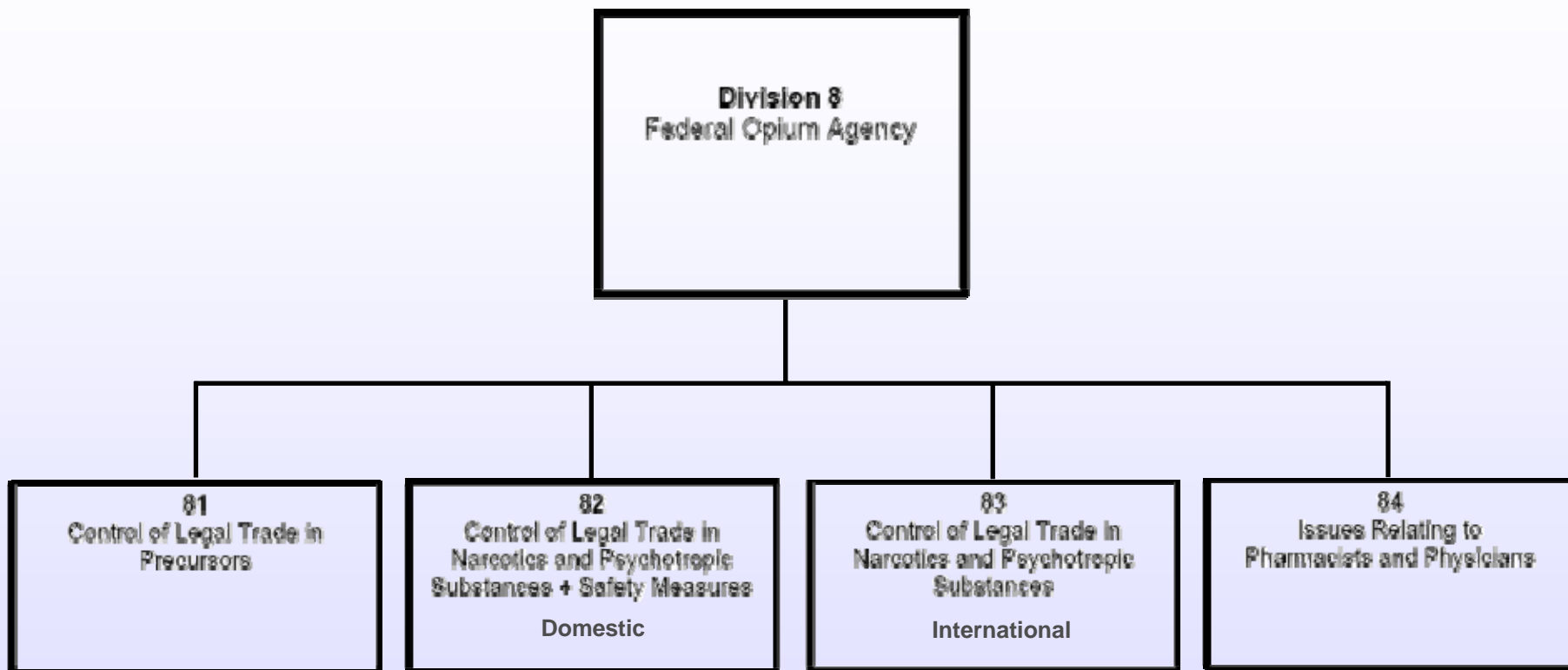
Federal Institute for Drugs and Medical Devices
Federal Opium Agency
(Germany)



The BfArM



The Federal Opium Agency



Scope of national control (I)

1961 / 1971 Convention

- General licences (August 2009)
 - Approx. 13.000
 - Plus approx. 23.000 pharmacy shops
- Domestic trade
 - Approx. 25.000 records per day
 - Approx. 6.000.000 records in 2008
- International trade
 - Approx. 5.000 import authorizations per year
 - Approx. 5.000 export authorizations per year

Scope of national control (II)

1961 / 1971 Convention

- paper reports by permission holder (on a 6-month basis) per substance (on salt-basis) of
 - Inventory
 - Quantities
 - Manufactured
 - Traded Domestically
 - Traded International (Imports / Exports)
 - Losses
 - Destructions
 - Balances
- Subsequent assessment of these reports
 - to ensure control according to conventions & national §§

Scope of national control (III)

1961 / 1971 Convention

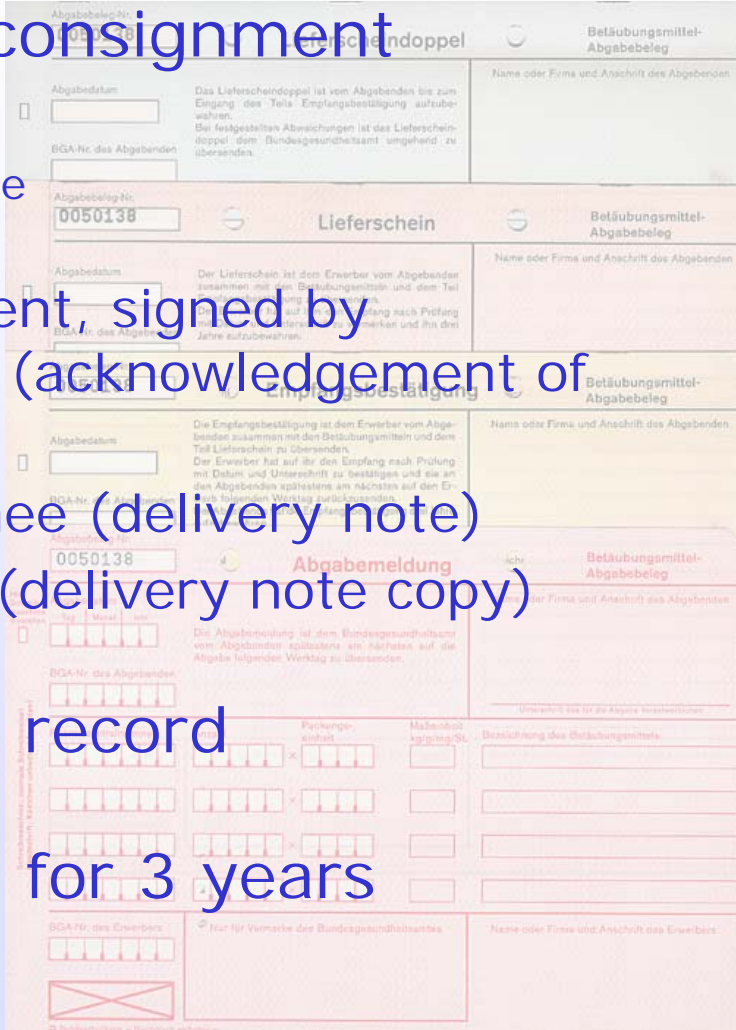
- Inspections
 - conducted at all general permission holders
 - conducted every two-years according to national §§

BUGIS

- National Drug Control Software since 2000
 - Replaced a previous software
- To support (inter-)national control of
 - Substances/preparations according to 1961 Convention
 - Substances/preparations according to 1971 Convention
 - Substances according to 1988 Convention
- To generate reports for the INCB
 - Since 2008 generation of NDS-compatible .xml reports (1961, 1971 Convention)

Domestic trade (I)

- Quadruplicate record for each consignment
 - original to be sent to BfArM
 - BfArM: Scan record → OCR → Database
 - Remember: 25.000 records per day
 - 1st copy to be sent with consignment, signed by consignee and returned to sender (acknowledgement of receipt)
 - 2nd copy to be retained by consignee (delivery note)
 - 3rd copy to be retained by sender (delivery note copy)
- Consignment of 4 products per record
- Records to be archived at least for 3 years by sender / consignee



The image shows a vertical stack of four German regulatory forms related to drug consignment. From top to bottom:

- Lieferscheindoppel**: A double-copy form for the delivery note, with fields for 'Abgabedatum' and 'BfArM-Nr. des Abgebenden'.
- Lieferschein**: The original delivery note, featuring a prominent BfArM number '0050138' and a 'Name oder Firma und Anschrift des Abgebenden' field.
- Empfangsbestätigung**: A receipt form for the consignee, with a 'Name oder Firma und Anschrift des Abgebenden' field.
- Abgabemeldung**: A reporting form for the sender, containing a table for product details (Packungseinheit, Maßinhalt) and a 'Name oder Firma und Anschrift des Erwerbers' field.

Domestic trade (II)

Information on trade record

- (Unique) record number
- Day of consignment
- Permission number / printed name / signature of sender
- Permission number / printed name of consignee
- Identification number of product
- Quantity (of packaging units)
- Packaging unit
- Dosage form unit
- name of product
- Signature of consignee on 2nd copy



Abgabemeldung **Betäubungsmittel-Abgabebeleg**

8408626

Abgabedatum: 07.07.09

Name oder Firma und Anschrift des Abgebenden: [Redacted]

Unterschrift des Abgebenden: [Signature]

Pharmazentralnummer: 7363295

Anzahl: 13

Packungseinheit: 5

Maßeinheit kg/g/mg/St.: ST

Bezeichnung des Betäubungsmittels: MSI 100 INJ LOE, 5ML MUNDI AMP

MSR 10 MUNDIPHARMA SUP

BIM-Nr. des Erwerbers: [Redacted]

Nur für Vermerke der Bundesopiumstelle


Name oder Firma und Anschrift des Erwerbers: [Redacted]

Bundesdruckerei - Nachdruck verboten -

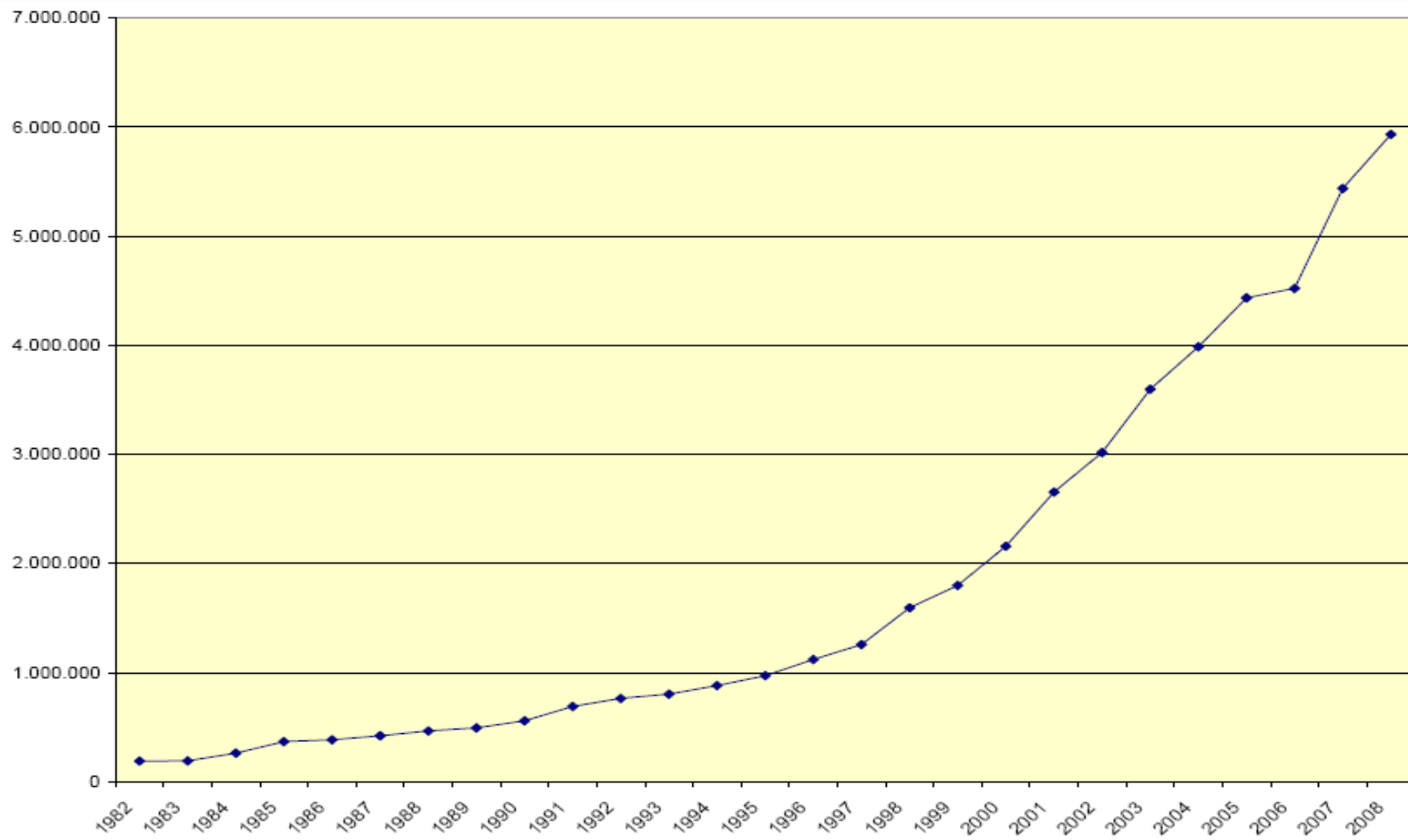
Domestic trade (III)

Development(s) planned to be realised

- Replace quadruplicate (by federal print-office) pre-printed record with quadruplicate self-printed record
- Change format to DIN A4
- Increase products per record from 4 to 6
- Electronic submission to BfArM
- Old records remain valid

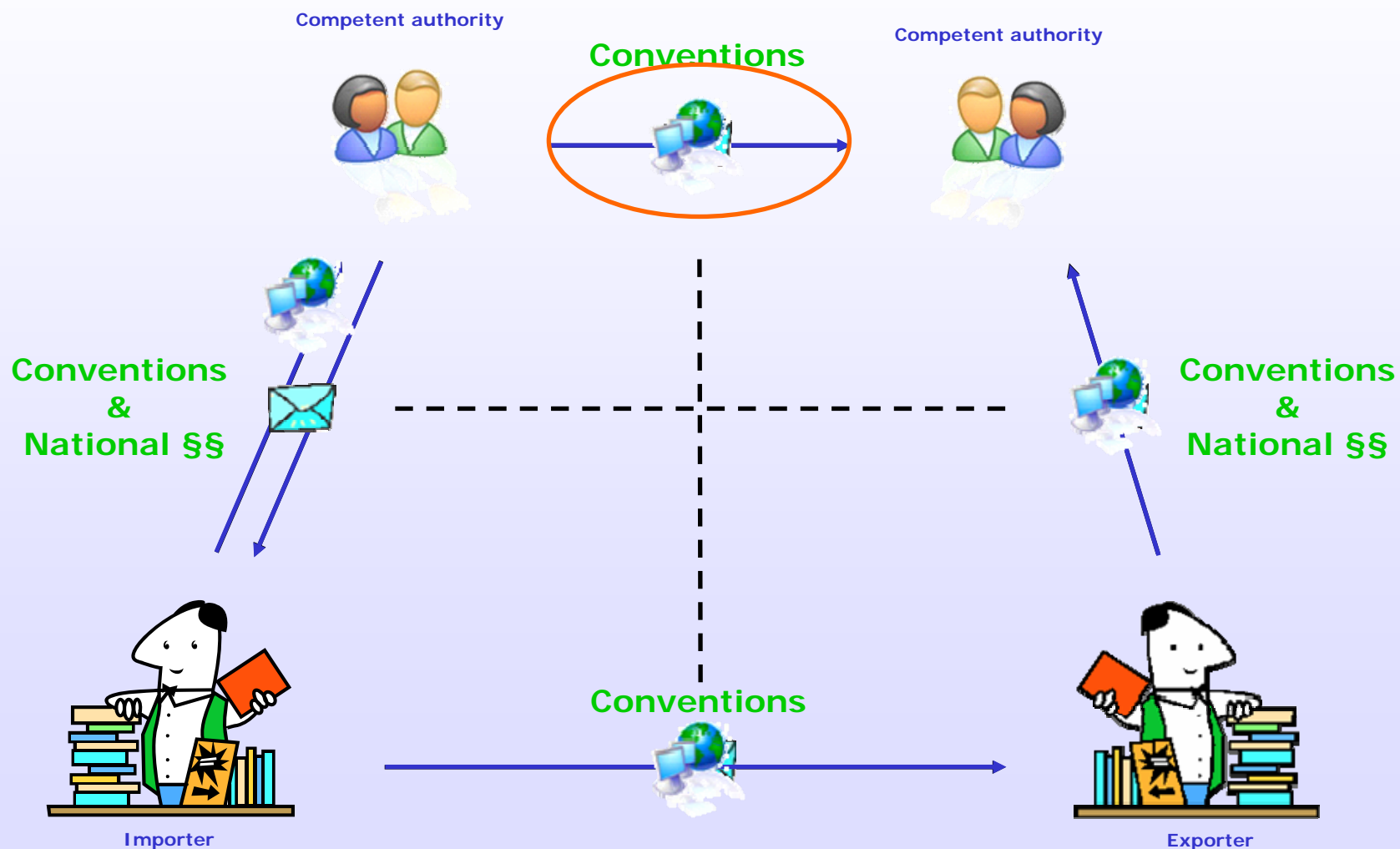
Abgabebeleg-Nummer 00006108	Abgabemeldung				Name oder Firma und Anschrift des Erwerbers Muster Abgeber Musterstr. 2 99998 Teststadt
Abgabemerkmal (Muster) 010108 BIM Nummer des Abgebers 9999999	Die Abgabe von Arzneimitteln und Medizinprodukten vom Abgebenden spätestens nach Ablauf einer Woche zu übermitteln.				Unterschrift des Abgebenden und Name Klartext  Willi Mustermann
Pharmazentralnummer (PZN) 9999998	Anzahl (max. 5 Stellen) 4	Packungseinheit gem. PZN x	Maßeinheit kg/g/l/ml/ST 50 ST	Bezeichnung des Betäubungsmittels Testmittel 20mg Tabletten Musterbezeichnung	Betäubungsmittel-Abgabebeleg
BIM Nummer des Erwerbers 9999998	Nur für Vermerke der Bundesopiumstelle		Name oder Firma und Anschrift des Erwerbers Testerwerber Name2 Teststr. 2 99998 Teststadt		

Domestic trade (IV)



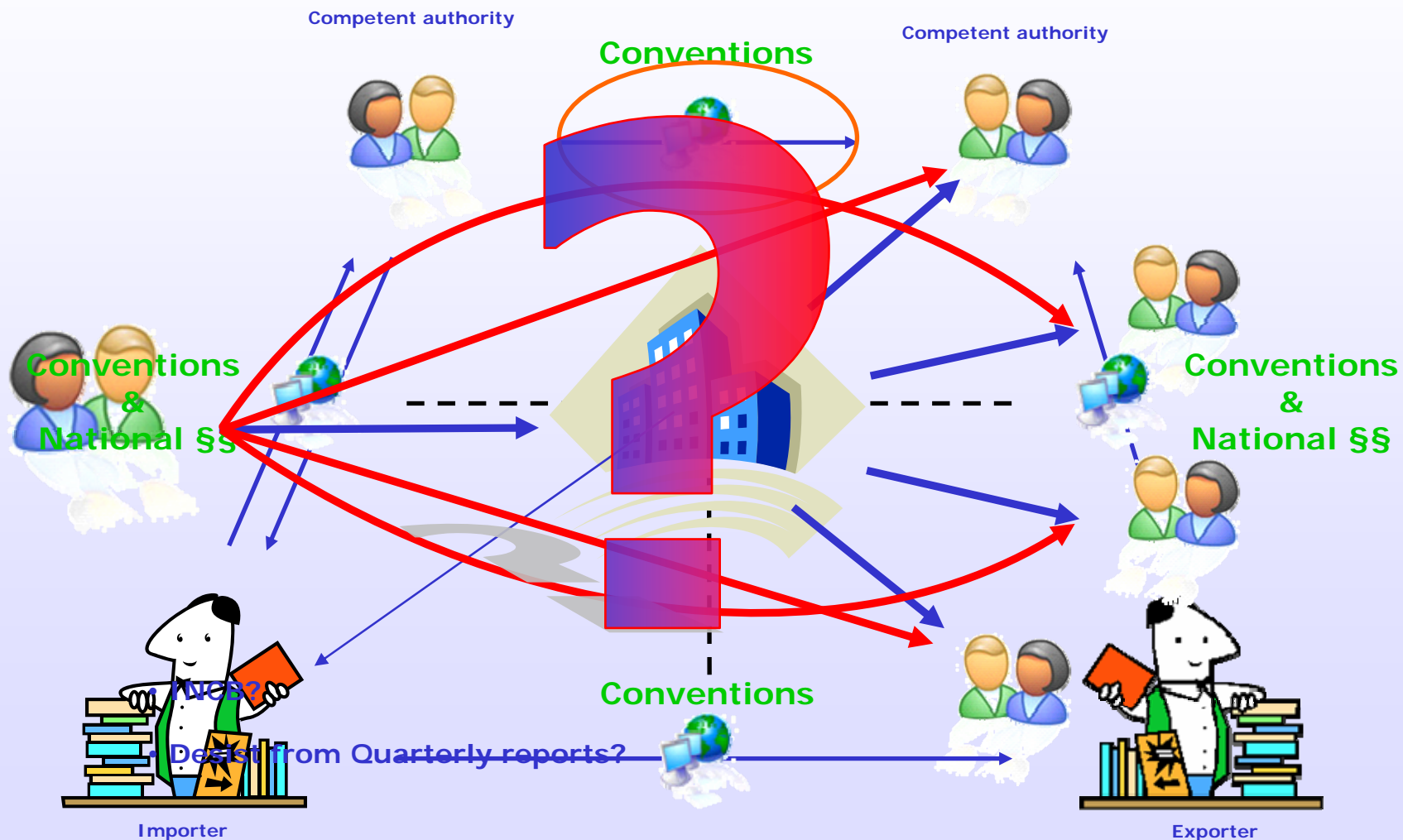
Imports / Exports (I)

1961 / 1971 convention



Imports / Exports (II)

1961 / 1971 convention
Electronic data exchange between Competent authorities



Conclusion

- Our Expectation is
 - to establish the electronic inter-competent authority data exchange
 - to be able to communicate with NDS software furthermore
- To do so
 - we would like to participate in the development of electronic data exchange principles
 - we have to make efforts to upgrade our BUGIS

Thank you very much



<http://www.marktkreisel.ch/fun/002/frames.htm>