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Local versus Regional Approaches to Transparency Reporting

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- The Code – chance and challenge
- Local or regional approach
  - First approach
  - Pros & cons
- Looking beyond …..
- The IT challenge
- Local variations
- The data protection challenge
- Sum up

The Code – chance and challenge

EFPIA Disclosure Code

EFPIA

- Local transfer
- Cross border activities
- Local laws
  & regulations

The Code – chance and challenge
Disclosure code

How transactions occur locally and cross border ?

- Resources – manpower and budget needed
- In addition …?

Local or regional approach
First approach

a. Local approach
- Affiliates are responsible for their own activities
- All activities with HCPs/HCOs across EU are delegated to and managed by the respective affiliate (“home” of HCP/HCO)

b. Regional approach
- Affiliates manage their own activities (approved process)
- Activities with foreign HCPs/HCOs managed as well - but disclosed where recipients have their (main) business

Local or regional approach
First approach

a. Local approach

Pro	Con
Comply with local obligations and codes	Limited data & transparency from company perspective
No business processes to be changed	Re international projects: Comply with other codes ?
Limited data captures only	Legally correct ?
	Complex commu Affilate A with
	Budget pla transfer p
	„isolated

????
HQ / central activities:
Clinical trials
Congresses
Central medical education events

Local or regional approach
First approach

a. Regional approach

Pro	Con
Consistent transparency policies & procedures across region	Some complexity and …organisational challenges
Fulfills business needs: Flexible system	New processes, workflows to establish
Comply with „legal“ obligations & codes	New / modified IT systems needed…
Share & learning system	…investments
	Change management….
	Data privacy ……

Local or regional approach

a. Local Approach

- Small companies
- Low no. of cross border interactions

b. Regional Approach

- Mid size /global companies
- Regularly cross border interactions

Automatic system
generating reporting
Internal knowledge and transparency

The IT challenge

EFPIA template – Transfer of Value (ToV)

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CHANGES FOLLOWING CCSG "STRESS TEST TEAM" INCLUDED IN FUSHIA - for validation at the 11 December COMCOM TC

Date of publication: .....

	Full Name	HCPs: City of Principal Practice HCOs: city where registered	Country of Principal Practice	Principal Practice Address	Unique country identifier OPTIONAL	Donations and Grants to HCOs (Art. 3.01.1.a)	Contribution to costs of Events (Art. 3.01.1.b & 3.01.2.a)			Fee for service and consultancy (Art. 3.01.1.c & 3.01.2.c)			TOTAL OPTIONAL
	(Art. 1.01)	(Art. 3)	(Schedule 1)	(Art. 3)	(Art. 3)		Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract		
HCPs	INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)												
	Dr A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	Dr B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients - Art. 3.02					N/A	N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs		Optional
	Number of Recipients (named list, where appropriate) - Art. 3.02					N/A	N/A	number	number	number	number		Optional
	% of total number of Recipients - Art. 3.02					N/A	N/A	%	%	%	%		N/A
HCOs	INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)												
	HCO 1					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	HCO 2					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	etc.					Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount	Yearly amount		Optional
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients - Art. 3.02					Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs	Aggregate HCOs		Optional
	Number of Recipients (named list, where appropriate) - Art. 3.02					number	number	number	number	number	number		Optional
	% of total number of Recipients - Art. 3.02					%	%	%	%	%	%		N/A
R &D	AGGREGATE DISCLOSURE												
	Transfers of Value re Research & Development as defined - Article 3.04 and Schedule 1											TOTAL AMOUNT	OPTIONAL
	latest update: 10 December 2013												

The IT challenge

Transfer of Value (ToV) - Categories

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4 types of activities:

Donations & Grants	Events			Fee for service		R & D (Studies)

TRES AM" INCLUDED IN FUSHI idation at the 11 December COMCOM TC

Date of publicatio

Donations and Grants to HCOs *(Art. 3.01.1.a)*	Contribution to costs of Events *(Art. 3.01.1.b & 3.01.2.a)*			Fee for service and consultancy *(Art. 3.01.1.c & 3.01.2.c)*		Transfer of value re research and Development as defined (Art. 3.04)
	Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodati on	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract	

The IT challenge

Transfer of Value (ToV) - Recipients

Kind of interaction	HCP	HCO	3rd party
Grant/Donation	-	X	-
Event			
- Sponsorship	-	X	X
- Small group meeting	X	X	-
- Advisory Board	X	X	X
- Congress	X	X	X
- Others	X	X	X
Fee for service	X	X	-
Clinical trials / study			
- Interventional	X	X	-
- Non interventional	X	X	-
- Research activities	X	X	-
- Market research	X	X	X
- Others	X	X	X

3rd party: definition of deliverables mandatory

Looking beyond ….

Plan

Prepare

Contract

Invite

Realize

Check

Pay

Disclose

Justification & objectives
Duration, location & documentation

No. of attendees, countries, specification
Level of expertise & identification of KOLs

Nationalities, check,
country specific regulations
Fair market value

Attendee list,
Outcome,
Documentation
Check invoices

Check payments
Inform customer
Disclose …. changings ??

The IT challenge
The processes

How the process could look like

- Select kind of activity
- Identify customer
- Start process
- Realize activity
- Pay
- Disclose

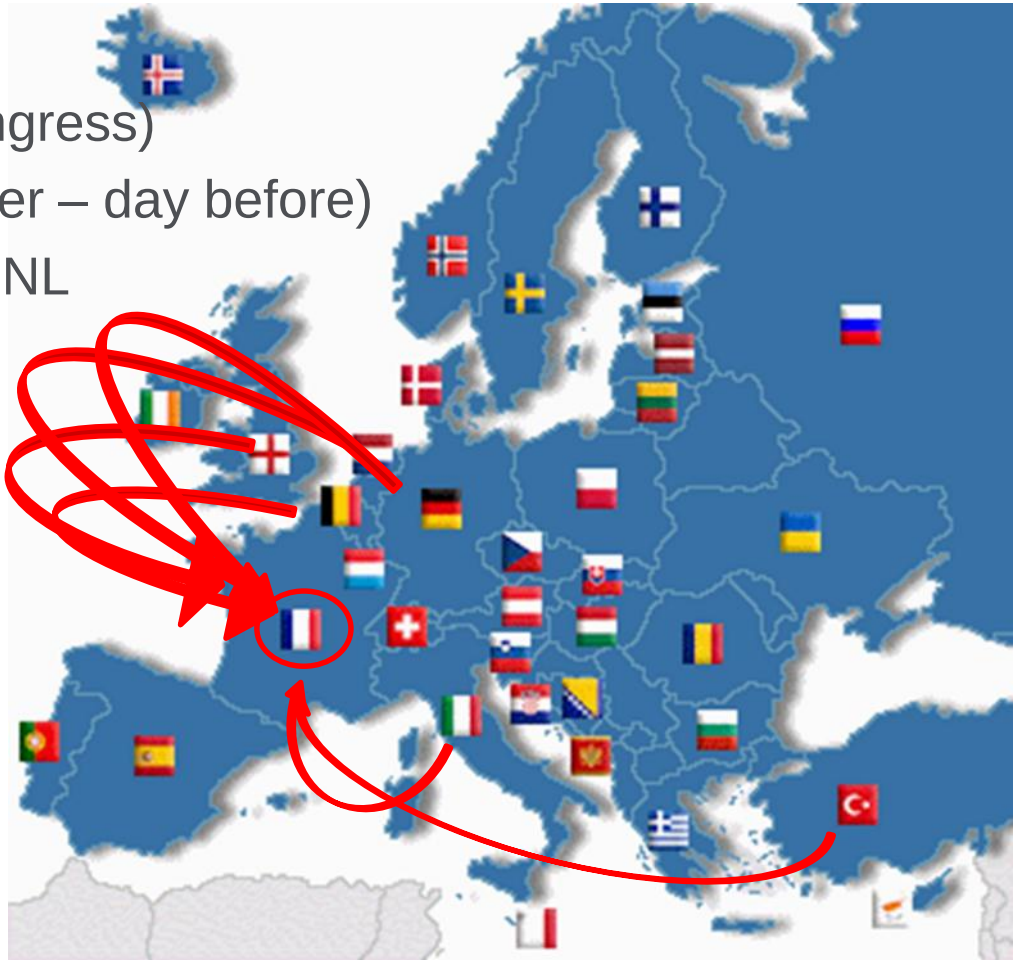
…a common e-system:

- Workflows ? Contract system..?
- Unique customer data base ?
- Event and expense tool ?
- SAP / financial system interfaces ?
- Customer info & automatic extraction / reporting ?

Local variations
example

Local laws & regulations have to be respected …

- International Advisory Board
- Location: Paris (adj. to a congress)
- Time: Full day (working dinner – day before)
- Advisors: F, UK, D, B, I, TR, NL
- Support: by a local agency



Local variations
… national challenges

France:

- CNOM check in advance (by HCP or Company)
- Disclosure: by “Loi Bertrand” (L.1453-1) <u>and</u> LEEM code

Fees & Cross border activities (?)

Definitions, website, threshold > € 10 (no fees)

HCP/ HCO definition

HCPs

HCOs

Students & Ass. / groups

Non profit Health Care Ass.

Health Care facilities

Foundations, Learned societies, Consulting Companies

Publishers (Press, Radio TV ..)

Legal persons (Training for HCPs)

Publishers (Rx /dispensing software..)

Local variations
… national challenges (examples)

Italy:

- Employers consent mostly needed (“dichiarazione”)
- Law decrees: e.g. 219/2006 and 231/2001
- Notification to AIFA in advance (60 day) for speaker activity
- HCP fees must be communicated to the relative health structure within 15 days from payment
- Congress sponsorships need to be authorized by AIFA – at least 60 days before congress starts
- Local GM of affiliate is responsible ….

UK:

- Transparency obligation already in place (accumulated)
- Check ABPI Code

Local variations
… national challenges (examples)

Germany:

- Employers consent needed mandatory

Belgium:

- Special local (university) regulations
- Mdeon ticket mandatory (request by HCP or company 10 days in advance)

The Netherlands:

- Special local (university) regulations
- Local Nefarma transparency Code already in place

Turkey:

- Limitation for (foreign) events (HCP can accept max 2 events from a company and 1x international event / year)
- Notification to MoH

Local variations

Hospitality thresholds (selected)

	countries	Lunch	Dinner	comments
Transparency laws / regulations in place	Denmark	53	93	incl. VAT
	Finland	45	100	incl. VAT
	France	60		incl. VAT
Self regulation	Turkey	60		Excl. VAT
	The Netherlands*)	75		incl. 21% VAT
	Belgium	40	75	incl. VAT
	Germany	60		incl. VAT
	Switzerland	121		Incl. VAT
	UK	87		excl. VAT

*) agreed by multi stakeholder

Local variations
Release procedure

How can the process organized to be compliant ?

Initiate / Plan

- **Central (HQ) sign off re kind of activity**
- **Additional local loop /sign off may needed**

Realize

- Check & control (central)

Pay / Disclose

- (organize central disclose local)

Local variations
Release procedure

Advisory Board:

- Central (HQ) release of activity & French affiliate
- 6 local sign off of affiliates re

Local sign off for standard activities not needed, if contract tool (..incl. FMV matrix) etc. available

Local variations

ToV transaction types and possible data flow

Example

Example: Business transaction with transfer of value	System for data capture	ToV Reporting Output
1. Speaker Contract with Dr. X: 1.500 EUR	IT financial → ToV Reporting Module	Dr. X: Speaker Fees: 1.500 EUR
2. Event Travel /Accommodation via Agency: 5.000 EUR	IT financial	
a. Dr. A – Travel: 242 EUR	File Attach-ment → CRM or IT financial → ToV Reporting Module	Dr. A – Travel: 242 EUR
b. Dr. A – Accomodation 130 EUR		Dr. A – Accomodation 130 EUR
c. Dr. B – Travel: 500 EUR		Dr. B – Travel: 500 EUR
d. Dr. C – Travel: 6,50 EUR		Dr. C – Travel: 6,50 EUR
...		...
3. Expenses SR 1: Meals/Drinks* for Round table: 85 EUR	Expense Tool → IT financial	
a. Dr. D: 25 EUR	CRM or Expense Tool → ToV Reporting Module	Dr. D: 25 EUR
b. Dr. E: 32 EUR		Dr. E: 32 EUR
c. Dr. F: 28 EUR		Dr. F: 28 EUR
4. Hotel Group Buffet Package Invoice : 90 EUR	IT financial	
a. Dr. G: 30 EUR	CRM → ToV Reporting Module	Dr. G: 30 EUR
b. Dr. H: 30 EUR		Dr. H: 30 EUR
c. Dr. I: 30 EUR		Dr. I: 30 EUR

* Not relevant in some countries

Local variations

Prerequisites for a common IT system

Prerequisites to organize a compliant process:

1. Unique customer data base
   - Unique local and regional/global
   - Defined on local needs (e.g. France…)
   - No double / “dead” customers
   - Regular updates and checks needed
2. Common CRM Tool
   - Core processes/ activities
   - Local adaptions
   - .. **Tools: nomination, FMV, contract management .. desirable**
3. Common financial system (e.g. SAP)
   - Interfaces with systems above…

3 rd parties (agencies) need to comply with company systems / procedures !

Local variations

Questions to be raised

- Unique customer / recipient existing ?
- All terms & processes harmonized ?
- Correctness & accuracy of data guaranteed ?
- Policies and controls in place ?

Local variations

… if you are not ready so far ..

- Customer master data: local or central ?
- Server: local or central (by company or provider) ?
- CRM and support tools: Company owned or external (Buy or monthly fees ..) ?

- Harmonizing processes – Change management !

The data protection challenge

…. EU data protection directive 95/45/EC (“DP Directive”) – differ across countries

… personal data & processing

transfer of value collect, record, organize, store..

The data protection challenge

Inform consent mandatory:

- In writing
- Clear
- Unambiguous
- Revocable at any time

Not “stashed / hidden” e.g. within a contract ..

…a separate consent

The data protection challenge

Data protection consent (FSA / VfA Germany) 1

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Created by Clifford Chance

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FSA Arzneimittel-industrie e.V.

vfa. Die forschenden Pharma-Unternehmen

DATA PROTECTION
AND
CONSENT TO USE OF PERSONAL DATA

Dear Sir/Madam [•[1]],

In accordance with the new FSA Transparency Code (*FSA-Transparenzkodex*) which was enacted on [•[2]], we, as a member of the Association for the Voluntary Self-regulation of the Pharmaceutical Industry (*Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.*, "**FSA**"), are obliged in future to disclose and publish details of non-monetary benefits provided to association and organisation members. [*optional: "The relevant provision of the new FSA Transparency Code is attached as an annex hereto."*]

We are committed to protecting your personal data and upholding applicable data protection laws and regulations and will therefore discharge our aforementioned obligations only with your prior consent and knowledge.

Data protection and consent to use of personal data

This declaration of consent relating to data protection ("**Data Protection Declaration**") explains which types of personal data may be collected, stored and published in connection with non-monetary benefits made to you. For the purposes of this Data Protection Declaration, personal data means any data relating to your person and your personal circumstances.

"[•[3]]" refers to [•[4]] (hereinafter also referred to as "**we**", "**us**" or "**our**").

By signing this Data Protection Declaration, you hereby consent to your personal data being processed in accordance with the procedure set out in this Data Protection Declaration.

1. We may collect the following personal data about you ("**Personal Data**"):

[1] Insert name of member of the association.

[2] Insert date when the FSA Transparency Code entered into force.

[3] Insert abbreviated name of the company collecting the data (competent body/controller).

[4] Insert full corporate name of the company collecting the data (competent body/controller).

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FSA Arzneimittel-industrie e.V.

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- ***Personal Data***: We may collect your name, practice or business address, contact details and (if applicable) your "lifelong physician number" (*lebenslange Arztnummer*, LANR).
- ***Non-cash benefits***: We are obliged to record the precise amount of non-monetary benefits which we provide you, directly or indirectly ("**Non-Monetary Benefits**"). This includes, but is not limited to, the following:
  - *Non-Monetary Benefits in connection with attending continuing medical education conferences* including conference/registration fees including travel and accommodation expenses;
  - *service and consultancy fees*; and
  - *funding for research and development*, including but not limited to, studies, clinical trials and non-interventional studies[5].
- ***Additional information***: We may collect further data, which may aid us in determining when the Non-Monetary Benefits were made and in what amount (such as contracts, payment receipts, etc.)[6].

2. We may use your Personal Data for the following purposes:

- ***Publication***: We may publish your Personal Data on a publicly accessible website to enable us to comply with the requirements of the FSA Transparency Code[7]. [*optional: "A sample publication is attached as an annex hereto"*.]
  - We may publish your Personal Data on any of our publicly accessible company websites[8].

[5] Note: Where companies grant other Non-Monetary Benefits, they must also be disclosed. In such case, any such income must be disclosed in a fourth sub-bullet point entitled "*other benefits in kind*" inserted under "Non-cash benefits". For clarification purposes, examples of benefits in kind may be provided, e.g. by adding "*including but not limited to, by us directly or indirectly, e.g. services rendered by a third party commissioned by us*" as a supplement.

[6] Note: Where additional information is collected and stored on members of the association, this must be disclosed and further details must be provided thereon. Where companies require greater differentiation or require a more detailed breakdown, e.g. the services/benefits, amounts involved or types of conferences held must be itemised separately or insofar as information is provided on the topics under discussion at the conference, the subject matter of the conference or conference venues, further details must be provided in respect thereof!

[7] Note: It is advisable to attach a sample publication provided by EFPIA (European Federation of Pharmaceutical Industries and Associations) which states as clearly as possible what form the publication takes and what is to be disclosed therein.

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The data protection challenge

Data protection consent (FSA / VfA Germany) 2

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[*Alternative 1*: Your Personal Data may be published on any of [•[9]] publicly accessible company websites. [•] will publish your Personal Data on its website on our behalf[10]. The data may be downloaded separately on the website on behalf of [•[11]].]

[*Alternative 2*: Your Personal Data may be published on any of [•[12]] publicly accessible company websites. [•[13]] will publish your Personal Data on its website on our behalf as the party which commissioned data processing within the meaning of section 11 German Federal Data Protection Act (*Bundesdatenschutzgesetz*, BDSG) [14]. The data may be downloaded separately on the website on behalf of [•[15]].][16]

- Any publication will include your name and other Personal Data and detailed information on the types of Non-Monetary Benefits you received from us during the relevant reporting period and for what purpose[17]. The reporting period is the calendar year.

[8] Note: Where such details are also published in English, reference should be made to this. Supplement: "*Details may be published in both German and English*".

[9] Note: Insert corporate name of group company and (if applicable) including the "parent company" or "subsidiary" as supplementary information.

[10] Note: The Declaration of Consent template is based on the assumption that the group company will only publish the data on behalf of the company collecting the data (competent body/controller) and that the data will not otherwise be analysed or used in any way by the group company. Insofar as data undergoes further analysis or is otherwise used in any way, express reference must be made thereto.

[11] Insert abbreviated name of member company as per the definition stated on page 1 (footnote 3).

[12] Insert corporate name of third-party provider.

[13] Insert corporate name of third-party provider.

[14] Note: An agreement on commissioned data processing (*Auftragsdatenverarbeitungsvertrag*) needs to be concluded.

[15] Insert abbreviate name of member company as per the definition state on page 1 (footnote 3).

[16] Note: Insofar as the information is published on a group company's website, and such group company commissions a third party to conduct data processing on its behalf, both alternatives must be inserted.

[17] Note: Where more than just information on the said recipients is provided, further details need to be provided thereon. In particular, where companies require greater differentiation or require a more detailed breakdown, e.g. the services/benefits, amounts involved or types of conferences held must be itemised separately or insofar as information is provided on the topics under discussion at the conference, the

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- Insofar as funding was provided for the purpose of "research and development", this information shall be published in anonymous form (on an aggregate basis) without disclosing your identity.
- Disclosures shall be made once a year, as a rule no later than 30 June for the preceding calendar year. Information disclosed shall be required to remain in the public domain for a minimum of four years after the time such information is first disclosed.

- ***Storage***: Irrespective of publication, we shall store your Personal Data for a minimum of six years after the end of the relevant reporting period. [*Optional: Statutory record-keeping obligations shall remain unaffected thereby.*]
- [*Optional: **Statutory notification and reporting duties**: Statutory notification and reporting duties, including but not limited to, section 67 para 6 Pharmaceuticals Act (Arzneimittelgesetz, AMG), will continue to apply in the case of consent being withheld.*]

3. [***Optional**: **Prior notification of publication**: We shall give you advance notice of the publication of your Personal Data and shall inform you precisely what information will be disclosed therein.*[18]]

4. ***Your rights***: You may at any time request to be provided with information on your Personal Data stored by us and demand that we correct, delete or block any incorrect data. For further information, please contact: [*insert contact details*]

5. ***Right of revocation***: The granting of your consent is voluntary and may be revoked at any time without any detrimental effect on you[19].

conference programme or conference venues, reference must be made thereto in the Declaration of Consent and further details must be duly provided in respect thereof.

[18] Note: This clause is optional. Providing additional advance notice may prevent disputes arising after publication.

[19] Note: Optional: You may insert a reference here to the fact that the statutory notification and reporting duties, including but not limited to, section 67 para 6 Pharmaceuticals Act (Arzneimittelgesetz, AMG), will continue to apply.

The data protection challenge

Data protection consent (FSA / VfA Germany) 3

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Declaration of consent

_____
(*insert name*)

_____
(*insert practice or business address*)

I herby consent to my personal data being processed in accordance with the procedure set out in this Data Protection Declaration [20].

My attention has been drawn to the fact that the granting of my consent is voluntary and may be revoked at any time and that I will not suffer any detriments should I choose not to sign this declaration.

_____ _____
(Place, date) (Signature)

[20] Note: Optional: It is also possible to insert boxes and healthcare professionals are asked to tick the appropriate box, i.e. that they grant their consent or, conversely, do not grant their consent. Optional supplementary information: " [] I hereby **withhold** my consent to my personal data being processed in accordance with the procedure set out in this Data Protection Declaration" and conversely, " [] I hereby consent to [...]."

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The data protection challenge

…… issues to keep in mind …..

- Inform your customer in advance
- Consent is revocable at any time (time!)

Need to be included in CRM/ reporting system as well - system supports you

- Customer orientation
- Flexible re any changings
- Avoid mistakes (…and fines)

Sum up

- Transparency disclosure obligation cannot be seen alone – the whole interaction process needs to keep in mind
- To avoid non compliance and to support colleagues – common IT system strongly recommended

Sum up

Transparency will not only increase the reputation of the pharmaceutical companies …but companies benefit also:

- Speed up organizational processes
- Fulfill business needs and
- Prepare for the future challenges
- Create a compliant system (protect company and customer) and minimize risks
- Provide full transparency – also for management
- Learn and improve

What system(s) fit at best for your company ?

Dr. Michael Bartke

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