EFPIA disclosure: The Spanish case. Implications under GDPR.

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EFPIA disclosure

Code requirements: Individual and aggregate disclosure

- Section 3.01.- *Individual Disclosure*. "**Except as expressly provided by this Code, Transfers of Value shall be disclosed on an individual basis**. Each Member Company shall disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to Transfers of Value to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below (..)"

- Section 3.02.- *Aggregate Disclosure*. "For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 3.01, **cannot be disclosed on an individual basis for legal reasons**, a Member Company shall disclose the amounts attributable to such Transfers of Value in each Reporting Period on an aggregate basis. (…)"

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Individual disclosure under EU Data Protection Directive 95/46

- **Consent of Data Subject**
  - Safe but long process
  - Data subject may withdraw consent at any time
- **Legitimate interest of Data Controller**
  - Data processing is lawful and necessary for the purposes of the legitimate interests pursued by the controller
    - ✓ Pharma companies: transparency; building trust in its interactions with HCPs
  - Such legitimate interests must not be overridden by the fundamental rights and freedoms of the data subject
  - Adequate balance between the two conditions is needed on a case by case basis
    - ✓ National Data Protection Agencies may reach different conclusions in their appreciation of the balance between legitimate interests and request for additional measures
  - Data subject right to object
- **Different disclosure requirements in some EU national laws**

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The Spanish case - background

- Art. 18.3 of Farmaindustria Code (2014 version):
  - Except as expressly provided by the Code, Transfers of Value shall be disclosed on an individual basis
  - Individual disclosure shall require prior express consent of HCPs
  - In case of lack of consent aggregated disclosure shall apply

- Most Spanish pharma companies raised the issue of getting consent and the need for publishing ToV on an aggregated basis.

- GSK decided to keep the individual disclosure principle for all its interactions with HCPs and implement, in line with GSK global position, the “no consent, no contract” approach.

- Since 2014 GSK Spain has obtained around 7,500 consents for individual disclosure. 96% of the GSK ToVs disclosed in 2016 and 2017 relies on HCPs’ consent.

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The Spanish case – local DPA decision

On 22nd April 2016 and in response to a Farmaindustria question Spanish Data Protection Authority (AEPD) issued a legal report (143318/2016) confirming that **individual disclosure is compatible with legitimate interests principle and therefore HCPs' consent is not needed** based on the following rationale and requirements:

- Art. 7 (f) of the Directive 95/46 has direct effect as recognised by the EU Court of Justice
- Phama industry has a legitimate interest (to promote the integrity in its transactions with HCPs and ultimately reveal the independency of such HCPs) expressly considered by Spanish legislator
- The conditions of need, suitability and strict proportionality are met in this case and so there is an adequate balance between legitimate interests and data subject rights (information, accuracy, access, rectification, cancellation and opposition).
- Additional protection measures should be implemented in order to avoid further excessive processing:
  - ✓ apply protocols in companies' websites preventing its indexation through search engines
  - ✓ clearly indicate the purpose of the publication excluding other uses such us crossing the data with information published in other companies' websites

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The Spanish case – current situation

- Article 18 of Farmaindustria Code has been amended in order to include local DPA decision:
  - In the case of HCPs, in accordance with Directive 95/46/EC article 7f) **there is a legitimate interest** for the companies subject to the Code, recognized by the report issued by the SDPA, of 22 April 2016 (Code Annex I), **so that the Healthcare Professionals´ consent is not necessary for the disclosure, on an individual basis**, the Transfers of Value made to Healthcare Professionals.
  - **Pharmaceutical companies will inform HCPs**, under Organic Law 15/1999, of 13 December, for Personal Data Protection, **that their data will be disclosed** in accordance with the Code.
  - **Pharmaceutical companies must adapt their web sites, with the aim of avoiding further processing of this data** in a manner which is not relevant or excessive for the purpose that justifies it.
  - Data disclosed shall remain in the public domain for 3 years unless a shorter period is required under applicable national law.

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The Spanish case – consequences

- From 2018 individual disclosure in Spain shall rely on legitimate interest principle.

- Both Spanish HCPs at individual level and HCPs associations have raised concerns in relation to local DPA decision which makes it possible individual disclosure without consent mainly due to tax reasons:
  - A public debate is now open on the ToVs related to sponsorship HCPs to attend congress/events (registration fees, travel & accommodation):
    - ✓ Tax authorities consider such ToVs as remuneration in kind subject to taxation
    - ✓ Some political parties have approved a proposition to set out a taxation exempt status to these ToVs

- A good news from the legal point of view (consent is not longer needed for individual disclosure) could become an issue for the relationship between Spanish pharma industry and local HCPs' community.

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Individual disclosure under GDPR - Consent

- **Consent of data subject**. New requirements for consent:
  - Active: silence, inactivity or pre-ticked boxes are not longer valid.
  - Clearly distinguishable from other matters.
  - In an intelligible and easily accessible form.
  - Using clear and plain language.
  - As easily revoked as given: simple methods for withdrawing consent.
- **Consent will be presumed not to be freely given if:**
  - There is no provision for separate consents for distinct processing operations.
  - The performance of a contract is dependant on consent despite such consent not being necessary for such performance.

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Individual disclosure under GDPR - Transparency

- **Transparency obligation.** Information notices to HCPs:
  - More extensive information to be provided although much of the additional information is already mandatory in some Member States:
    - ✓ Legal basis for processing (including legitimate interest where applicable)
    - ✓ Contact details of Data Protection Officer
    - ✓ Details of data transfers outside EU (safeguards)
    - ✓ Retention period for the data (or the criteria used)
    - ✓ New data subject rights (portability, restrict processing, complain to DPA)
  - No need to provide information notice if there is a EU/Member State law obligation for the controller to obtain/disclose the data.

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Individual disclosure under GDPR - Legitimate interest

- **Legitimate interest of Data Controller**
  - Not substantially changed.
  - Reasonable expectations of data subjects must be taken into account when assessing the balance between controller's interests and data subjects' rights.
  - The decision-making (balance assessment) should be documented and recorded.
  - International data transfer requirements will still apply except in limited cases and subject to notification to local DPA.
  - Specific and enhanced right to object:
    - ✓ the burden now lies on data controllers to prove they have compelling reasons to continue processing the data
    - ✓ Data subject must be specifically informed on his right to object in a clear way and separately from other information
  - The creation of codes of conduct in relation to legitimate interests in specific contexts is encouraged (trade associations).

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Individual disclosure under GDPR – Practical implications

Practical implications:

- Existing information notices and consents for individual disclosure will only be valid provided that they comply with new GRPR requirements.
- Review and amendment of notices and consents if required.
- Review internal processes to address new data subject's rights, documentation of processing operations and privacy impact assessments.
- Re-evaluate the rule "no consent, no contract".
- Confirm if DPA resolutions on EFPIA disclosure (where applicable) are still in force.
- Consider that Member States could approve national laws to complete and adapt GDPR to local framework and set out additional requirements.

THANK YOU