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## WORKING DOCUMENT

From:	Presidency
To:	Delegations
Subject:	Presidency working document on the European Health Data Space proposal

On pages 6 and 7, on the [MOD.GA.1] Clarification of exclusion from the scope of the EHDS of certain judicial activities. [article 1(7), recital (16A), recital (41A)]

Where:  
article 33A(c)

Read:  
article 33A(3)

Where:

### Article 33A

#### Applicability to health data holders

The requirement in ~~(This article Chapter shall not apply to: individual researchers and~~ [MOVED FROM  
ARTICLE 35B(5)]

(...)

(c) courts and other entities of the justice system. [MOD.GA.1]

Read:

Article 33A

Applicability to health data holders

(...)

3. This Chapter shall not apply to courts and other entities of the justice system. [MOD.GA.1]

On pages 8 and 9, on the [MOD.SU.1] Clarification of scope of secondary use of health data.  
[article 1(6A), recital (37)]

Where:

1) Wording of the Swedish compromise text:

(...)In the case where the health data user has access to personal electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the health data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 or pursuant to Articles 5(1), points (e) or (f) of Regulation (EU) 2018/1725(...)

New proposed wording:

(...) In the case where the health data user has access to personal electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the health data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 or pursuant to Articles 5(1), points (e) or (f) of Regulation (EU) 2018/1725 (...)

**Justification:** The grounds for lawful processing have a different order in EUDPR - "performance of a task in the public interest" is (a), legitimate interest doesn't exist.

2) Wording of the Swedish compromise text:

(...) If the lawful ground for processing by the health data user is Article 6(1), point (f), of Regulation (EU) 2016/679 or Article 5(1), point (f), of Regulation (EU) 2018/1725, in this case it is this Regulation that provides the safeguards. (...)

Read:

2) Wording of the Swedish compromise text:

(...)In the case where the health data user has access to personal electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the health data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 or pursuant to Articles 5(1), points (e) or (f) of Regulation (EU) 2018/1725(...)

New proposed wording:

(...) In the case where the health data user has access to personal electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the health data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 or pursuant to Articles 5(1), point (a) points (e) or (f) of Regulation (EU) 2018/1725

**Justification:** The equivalent provision to Art. 6(1)(e) GDPR ("processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller") in EUDPR is Art. 5(1)(a) ("processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body").

3) **Wording of the Swedish compromise text:**

(...) If the **health data** user relies upon a legal basis offered by Article 6(1), point (e) **of Regulation (EU) 2016/679 or Article 5(1), point (e) of Regulation (EU) 2018/1725**, (...)

**New proposed wording:**

(...) If the **health data** user relies upon a legal basis offered by Article 6(1), point (e) **of Regulation (EU) 2016/679 or Article 5(1), point (a) of Regulation (EU) 2018/1725**, (...)

**Justification:** same as above.

4) **Wording of the Swedish compromise text:**

(...) If the lawful ground for processing by the **health data** user is Article 6(1), point (f), of Regulation (EU) 2016/679 **or Article 5(1), point (f), of Regulation (EU) 2018/1725**, in this case it is this Regulation that provides the safeguards. (...)

On page 10 on Recital 37

*Where:*

In the case where the **health data** user has access to **personal** electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the **health** data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 **or pursuant to Articles 5(1), points (e) or (f) of Regulation (EU) 2018/1725** and explain the specific legal basis on which it relies as part of the application for access to electronic health data pursuant to this Regulation: on the basis of the applicable legislation, ~~where the legal basis under Regulation (EU) 2016/679 is Article 6(1), point (e), or on Article 6(1), point (f), of Regulation (EU) 2016/679.~~ If the **health data** user relies upon a legal basis offered by Article 6(1), point (e) **of Regulation (EU) 2016/679 or Article 5(1), point (e) of Regulation (EU) 2018/1725**,

*Read:*

In the case where the **health data** user has access to **personal** electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the **health** data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 **or pursuant to Articles 5(1), point (a) points (e) or (f) of Regulation (EU) 2018/1725** and explain the specific legal basis on which it relies as part of the application for access to electronic health data pursuant to this Regulation: on the basis of the applicable legislation, ~~where the legal basis under Regulation (EU) 2016/679 is Article 6(1), point (e), or on Article 6(1), point (f), of Regulation (EU) 2016/679.~~ If the **health data** user relies upon a legal basis offered by Article 6(1), point (e) **of Regulation (EU) 2016/679 or Article 5(1), point (a) of Regulation (EU) 2018/1725**,

On pages 12 and 13 on the definition of health data holder in article 2(2)(y)

*Where:*

article 33A(c)

*Read:*

article 33A(3)

*Where:*

- **which is an entity or body of the health,** healthcare or care sectors,
  - **as well as and any** Union institution, body, office or agency;

who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law **either:**

**(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of healthcare or**

**care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or**

- **(b) the ability to make available, including to register, provide, restrict access or exchange anonymous electronic health data** non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;

#### **Additional explanations:**

- In **article 33A(b)** natural persons are excluded from the obligations of being data holders, but the possibility of including them at the Member State level is also provided (some MS wish to include GPs who are natural persons or individual researchers in the scope). For that to be possible, natural persons are included in the potential scope of article 2(2)(y).

The reference to 'legal persons' is removed and replaced by the more generic 'entities or bodies'<sup>1</sup>, to avoid any loopholes for entities or bodies which may not be clearly a natural or a legal person, but may still be data holders<sup>2</sup>.

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<sup>1</sup> **Note about 'entities or bodies'**. In EU law, the terms "entity" and "body" are used in various contexts and their meanings can differ based on that context. Both terms can refer to organizations or units that might have specific roles or functions within the EU legal framework, but they don't necessarily imply the same thing as "legal persons" in the sense of entities that can hold rights and obligations.

- **Entity**: This term is broader and can encompass a wide range of organizations, units, or structures. It can refer to public entities, private entities, non-governmental organizations, and more. Depending on the context, an "entity" in EU law might refer to any organized body, irrespective of its legal personality. It's often used in contexts where the law wants to cast a wider net, encompassing all possible types of organized groups or units, without necessarily specifying their legal form or nature.
- **Body**: In the context of the EU, when you encounter the term "body," it often refers to specific institutional structures or agencies within the European Union itself, like the European Central Bank, the European Institute of Innovation & Technology, or the various agencies and decentralized bodies. The term can also be found in national contexts when referring to specific public institutions or authorities.

Both "entity" and "body" might refer to what we think of as "legal persons" in the sense that they can hold rights, enter into agreements, or be bound by EU law. However, not every entity or body will automatically have the full scope of rights and obligations that legal persons have under civil or commercial law. There may be "entities" that do not neatly fit in the definition of "legal person" (or "natural person"). Please, see the next footnote comment for details.

<sup>2</sup> **Note about entities which may not be legal or natural persons**. From a legal perspective, both natural persons (individual human beings) and legal persons (entities like corporations, partnerships, or governmental entities) have rights and obligations under the law. However, there are constructs or entities that don't neatly fit into either of these categories. Here are some examples:

- **Research groups and infrastructures**: A group of researchers from several universities or institutions may not constitute a legal person. Rather, they would, most likely, be joint controllers of a database with health data.
- **Trusts**: In many jurisdictions, a trust is not a legal person, but rather a relationship where assets are held by one party (the trustee) for the benefit of another (the beneficiary). The trust itself does not have separate legal personality, though the trustee does.
- **Unincorporated Associations**: Some groups or associations don't have a separate legal personality, even though they might have a distinct existence and specific members. They might have some rights and obligations but don't fully fit the definition of a legal person.
- **Partnerships (in some jurisdictions)**: In some legal systems, certain types of partnerships don't have a separate legal personality, unlike corporations. This means that the individual partners are personally liable for the partnership's debts and obligations.
- **Joint Ventures**: Sometimes two or more entities might collaborate on a specific project without creating a new legal entity. The joint venture might have its own assets, liabilities, and operations, but it might not be a legal person.
- **Digital and Artificial Entities**: With advancements in technology, new questions arise about the status of digital entities or advanced AI systems. There's ongoing debate about whether such entities could or should have any legal status independent of being property of natural or legal persons.

In all these cases, while these entities might have certain rights, obligations, or roles in the legal system, they don't neatly fit into the categories of "natural" or "legal" persons. The specifics can vary widely based on the jurisdiction and the context.

- Several delegations have proposed clarifications and corrections, which do not imply a significant expansion or reduction of scope. In particular, several delegations have requested a more verbose, but more precise and consistent definition of health data holder. We thus reiterate several times ‘any entity or body’, ‘healthcare or care sectors’ in paragraph 1 of the definition.

- two delegations believe that the scope of data holder is too wide and believed that an impact assessment must be carried. Whilst this concern is very legitimate and justified, this is currently a minority position and the Presidency has chosen to move forward with the majority position which wants to expand scope compared to COM’s initial proposal.

- two delegations suggested the removal of *an entity or a body [performing activities] in the health or care sector*;, stating that it was redundant with *any natural or legal person entity or body developing products and services intended for the healthcare or care sectors*. Although there is indeed some redundancy, the Presidency has chosen to refrain from this modification. The phrase *any natural or legal person entity or body developing products and services intended for the healthcare or care sectors* mainly has the intention to include private companies developing products and services, such as software providers, providers of medical devices and pharma companies. On the other hand, the phrase *any entity or body of the healthcare or care sectors*; refers to healthcare or care providers themselves.

Read:

- ~~which is an entity or body of the health,~~ healthcare or care sector;
  - ~~as well as~~ and any Union institution, body, office or agency;

who has either:

(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of healthcare or care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or

(b) the ability to make available, including to register, provide, restrict access or exchange anonymous electronic health data ~~non-personal data~~, through control of the technical design of a product and related services ~~the ability to make available, including to register, provide, restrict access or exchange certain data;~~

#### Additional explanations:

- In **article 33A(1)(a)** natural persons are excluded from the obligations of being data holders, but the possibility of including them at the Member State level is also provided in **article 33A(2)** (some MS wish to include GPs who are natural persons or individual researchers in the scope). For that to be possible, natural persons are included in the potential scope of article 2(2)(y). The reference to ‘legal persons’ is removed and replaced by the more generic ‘entities or bodies’<sup>3</sup>, to avoid any loopholes for entities or bodies which may not be clearly a natural or a legal person, but may still be data holders<sup>4</sup>.

<sup>3</sup> Note about ‘entities or bodies’. In EU law, the terms "entity" and "body" are used in various contexts and their meanings can differ based on that context. Both terms can refer to organizations or units that might have specific roles or functions within the EU legal framework, but they don't necessarily imply the same thing as "legal persons" in the sense of entities that can hold rights and obligations.

- Entity: This term is broader and can encompass a wide range of organizations, units, or structures. It can refer to public entities, private entities, non-governmental organizations, and more. Depending on the context, an "entity" in EU law might refer to any organized body, irrespective of its legal personality. It's often used in contexts where the law wants to cast a wider net, encompassing all possible types of organized groups or units, without necessarily specifying their legal form or nature.
- Body: In the context of the EU, when you encounter the term "body," it often refers to specific institutional structures or agencies within the European Union itself, like the European Central Bank, the European Institute of Innovation & Technology, or the various agencies and decentralized bodies. The term can also be found in national contexts when referring to specific public institutions or authorities.

- Several delegations have proposed clarifications and corrections, which do not imply a significant expansion or reduction of scope. In particular, several delegations have requested a more verbose, but more precise and consistent definition of health data holder. We thus reiterate several times ‘any entity or body’, ‘healthcare or care sectors’ in paragraph 1 of the definition.

- two delegations believe that the scope of data holder is too wide and believed that an impact assessment must be carried. Whilst this concern is very legitimate and justified, this is currently a minority position and the Presidency has chosen to move forward with the majority position which wants to expand scope compared to COM’s initial proposal.

- two delegations suggested the removal of *an entity or a body [performing activities] in the health or care sector*;, stating that it was redundant with *any natural or legal person entity or body developing products and services intended for the healthcare or care sectors*. Although there is indeed some redundancy, the Presidency has chosen to refrain from this modification. The phrase *any natural or person, entity or body (...) developing products and services intended for the healthcare or care sectors* mainly has the intention to include private companies developing products and services, such as software providers, or providers of medical devices and pharma companies. On the other hand, the phrase *any natural or person, entity or body (...) of the healthcare or care sectors*; refers to healthcare or care providers.

On pages 14,15 and 16, on the Exclusions of applicability of Chapter IV to certain data holders

Where:

#### Article 33A

#### Applicability to health data holders

~~The requirement in (This article Chapter shall not apply to: individual researchers and~~ **[MOVED FROM ARTICLE 35B(5)]**

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Both "entity" and "body" might refer to what we think of as "legal persons" in the sense that they can hold rights, enter into agreements, or be bound by EU law. However, not every entity or body will automatically have the full scope of rights and obligations that legal persons have under civil or commercial law. There may be "entities" that do not neatly fit in the definition of "legal person" (or "natural person"). Please, see the next footnote comment for details.

- <sup>4</sup> **Note about entities which may not be legal or natural persons.** From a legal perspective, both natural persons (individual human beings) and legal persons (entities like corporations, partnerships, or governmental entities) have rights and obligations under the law. However, there are constructs or entities that don't neatly fit into either of these categories. Here are some examples:
- Research groups and infrastructures: A group of researchers from several universities or insitutions may not constitute a legal person. Rather, they would, most likely, be joint controllers of a database with health data.
  - Trusts: In many jurisdictions, a trust is not a legal person, but rather a relationship where assets are held by one party (the trustee) for the benefit of another (the beneficiary). The trust itself does not have separate legal personality, though the trustee does.
  - Unincorporated Associations: Some groups or associations don't have a separate legal personality, even though they might have a distinct existence and specific members. They might have some rights and obligations but don't fully fit the definition of a legal person.
  - Partnerships (in some jurisdictions): In some legal systems, certain types of partnerships don't have a separate legal personality, unlike corporations. This means that the individual partners are personally liable for the partnership's debts and obligations.
  - Joint Ventures: Sometimes two or more entities might collaborate on a specific project without creating a new legal entity. The joint venture might have its own assets, liabilities, and operations, but it might not be a legal person.
  - Digital and Artificial Entities: With advancements in technology, new questions arise about the status of digital entities or advanced AI systems. There's ongoing debate about whether such entities could or should have any legal status independent of being property of natural or legal persons.

In all these cases, while these entities might have certain rights, obligations, or roles in the legal system, they don't neatly fit into the categories of "natural" or "legal" persons. The specifics can vary widely based on the jurisdiction and the context.



(a) health data holders that qualify as micro-enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC. **Member States may provide by law that this Chapter shall apply to these health data holders.**

(b) natural persons. **Member States may provide by law that this Chapter shall apply to these health data holders.**

(...)

#### Additional explanations:

Article 33A clarifies that the whole Chapter IV (not just one article) does not apply to the entities excluded from the obligations of data holders. In particular,

- natural persons are excluded, as there seems to be an ample consensus in this regard. Generally speaking, from an implementability point of view, it is rather complicated to foresee how a natural person would become aware of his/her obligations as a data holder, and how he/she would be able to comply with the obligations of a data holder. However, one important exception are individual general practitioner/medical professionals as "profession libérale". They should be able to keep abreast of regulatory developments in their field (possibly with help of professional associations) and they could be expected to share their datasets. Also, in some cases, individual researchers who are natural persons could also be included in the scope. Since some MS wish to include GPs and individual researchers in the scope, we have allowed this possibility at the national level.

micro-enterprises<sup>5</sup> are excluded. This was in COM's original proposal. Some MS have stated the desire to include micro-enterprises, and the Swedish Presidency decided to include this possibility in the text. No delegation opposed this change and the Spanish Presidency has also kept it

#### Modifications in articles:

##### Article 2

##### Definitions

(ba) 'care' means a professional service the purpose of which is to address the specific need of a person who, on account of impairment or other physical or mental conditions requires assistance from another person or persons to carry out essential activities of daily living in order to support their personal autonomy. [MOD.SU.2]

(y) 'health data holder' means any natural or legal person, entity or body

- any natural or legal person developing products or services intended for the health, healthcare or care sectors,
- developing or manufacturing wellness applications,
- any natural or legal person performing research in relation to the health, healthcare or care sectors,
- which is an entity or body of the health, healthcare or care sectors,
- as well as and any Union institution, body, office or agency; [MOD.SU.2]

who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law either:

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<sup>5</sup> 'micro-enterprises' within the EU can be found in the Recommendation 2003/361/EC concerning the definition of micro, small, and medium-sized enterprises. According to this recommendation, micro-enterprises are defined as enterprises which:

- Have fewer than 10 employees, and
- Have either an annual turnover not exceeding EUR 2 million or an annual balance sheet total not exceeding EUR 2 million.

- (a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of healthcare or care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or
- (b) the ability to make available, including to register, provide, restrict access or exchange anonymous electronic health data non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;

#### Article 33A

##### Applicability to health data holders

~~The requirement in this article Chapter shall not apply to: individual researchers and~~

(a) health data holders that qualify as micro-enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC. Member States may provide by law that this Chapter shall apply to these health data holders.

(b) natural persons. Member States may provide by law that this Chapter shall apply to these health data holders. [MOD.SU.2]

(...)

#### Modifications in recitals:

[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.

(40) The data holders can be public, non for profit or private health or care providers, public, non for profit and private organisations, associations or other entities, public and private entities that carry out research with regards to the healthcare or sectors, entities developing products and services intended for the healthcare or care sectors and Union institutions, bodies, offices or agencies that process the categories of health and health care related data mentioned above. In order to avoid a disproportionate burden on small entities, natural persons and micro-enterprises are as a general rule, excluded from the application of Chapter IV ~~excluded from the obligation to make their data available for secondary use in the framework of EHDS.~~

Read:

#### Article 33A

##### Applicability to health data holders

1. The following categories of health data holders shall be exempted from the obligations incumbent on health data holders laid down in this Chapter: [MOVED FROM ARTICLE 35B(5) AND AMMENDED]

(a) individual researchers and Natural persons;

(b) Health data holders that qualify as micro-enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC.

2. Member States may provide, by virtue of national law, that the obligations of health data holders laid down in this Chapter shall apply to the health data holders referred to in paragraph 1 which fall under their jurisdiction.



(...)

#### Additional explanations:

Article 33A(1) clarifies that the whole Chapter IV (not just one article) does not apply to the entities excluded from the obligations of data holders. In particular,

- natural persons are excluded from the obligations as data holders (but they may still be data users), as there seems to be an ample consensus in this regard. Generally speaking, from an implementability point of view, it is rather complicated to foresee how a natural person would become aware of his/her obligations as a data holder, and how he/she would be able to comply with the obligations of a data holder. However, one important exception are individual general practitioner/medical professionals as "profession libérale". They should be able to keep abreast of regulatory developments in their field (possibly with help of professional associations) and they could be expected to share their datasets. Also, in some cases, individual researchers who are natural persons could also be included in the scope. Since some MS wish to include GPs and individual researchers in the scope, we have allowed this possibility at the national level.
- micro-enterprises<sup>6</sup> are excluded from the obligations as data holders (but these may still be data users), as stated in **Article 33A(1)(b)**. This was in COM's original proposal. Some MS have stated the desire to include micro-enterprises, and the Swedish Presidency decided to include this possibility in the text. No delegation opposed this change and the Spanish Presidency has also kept this possibility, in **Article 33A(2)**.
- Two delegations wanted to exclude small enterprises<sup>7</sup> from the scope of the obligations of data holders. However, this approach would significantly limit the amount of data available, as the only entities left as data holders would be medium and large enterprises or organizations, and could -in some countries- lead to the exclusion of a sizable amount of their healthcare sector. Also, given the definition of small enterprise, it would seem that those entities should have sufficient resources to comply with their obligations as data holders.

#### Modifications in articles:

##### Article 2

##### Definitions

**(ba) 'care' means a professional service the purpose of which is to address the specific need of a person who, on account of impairment or other physical or mental conditions requires assistance from another person or persons to carry out essential activities of daily living in order to support their personal autonomy. [MOD.SU.2]**

(y) 'health data holder' means **any natural or legal person, entity or body**

- **any natural or legal person developing products or services intended for the health, healthcare or care sectors,**
- **developing or manufacturing wellness applications,**
- **any natural or legal person** performing research in relation to the **health**, health**care** or care sectors,
- **which is an entity or body of** the **health**, healthcare or care sectors,
- **as well as and any** Union institution, body, office or agency; **[MOD.SU.2]**

who has **either:**

**(a) the right or obligation, in accordance with applicable Union law or national legislation, to process personal electronic health data for the provision of healthcare or**

<sup>6</sup> 'micro-enterprises' within the EU can be found in the Recommendation 2003/361/EC concerning the definition of micro, small, and medium-sized enterprises. According to this recommendation, micro-enterprises are defined as enterprises which:

- Have fewer than 10 employees, and
- Have either an annual turnover not exceeding EUR 2 million or an annual balance sheet total not exceeding EUR 2 million.

<sup>7</sup> According to Recommendation 2003/361/EC, 'small enterprises' are defined as enterprises which:

- Have fewer than 50 employees, and
- Have either an annual turnover not exceeding EUR 10 million or an annual balance sheet total not exceeding EUR 10 million.

care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller; or

(b) the ability to make available, including to register, provide, restrict access or exchange anonymous electronic health data non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;

#### Article 33A

##### Applicability to health data holders

1. The following categories of health data holders shall be exempted from the obligations incumbent on health data holders laid down in this Chapter: **[MOVED FROM ARTICLE 35B(S) AND AMMENDED]**

(a) individual researchers and Natural persons;

(b) Health data holders that qualify as micro-enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC.

2. Member States may provide, by virtue of national law, that the obligations of health data holders laid down in this Chapter shall apply to the health data holders referred to in paragraph 1 which fall under their jurisdiction.

**[MOD.SU.2]**

**(...)**

Modifications in recitals:

**[MOD.SU.2] Definition of data holder + definition of healthcare + definition of care + exclusions to the definition of data holder.**

(40) The data holders can be public, non for profit or private health or care providers, public, non for profit and private organisations, associations or other entities, public and private entities that carry out research with regards to the healthcare or sectors, entities developing products and services intended for the healthcare or care sectors and Union institutions, bodies, offices or agencies that process the categories of health and healthcare related data mentioned above. In order to avoid a disproportionate burden on small entities, natural persons and micro-enterprises are as a general rule, excluded from the obligations as data holders for secondary use in the framework of EHDS.