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Guiding principles for eHN Multilateral Agreement (MLA)

At the eHN meeting on 18 November 2014 the eHN decided on the need for creating a common legal framework for the cross-border exchange of data, preferably a voluntary agreement.

The Legal Subgroup drafting team has identified the following principles as the basis to be used in the voluntary multilateral agreement (MLA).

• **A common legal framework: MLA**

The aim is to create a stable and durable legal framework. The eHN has no legislative powers and therefore the framework has to be a voluntary multilateral agreement. For the sake of durability the MLA should be signed at the highest possible level in each MLA (state/government). It's preferable to have the same level of signing in all participating MSs.

The need for stability means that the MLA must include a special procedure both for entering or terminating participation. Any MS wanting to participate will have to fulfil the requirements before entering the MLA. In a case of a MS wanting to terminate its' participation there will be a prolonged procedure for this, including announcing the intention of termination several months ahead.

• **MLA should state the main principles for the exchange**

As the MLA is an agreement between several countries its' contents should be held mainly on the basic principles and avoiding as far as possible too detailed requirements e.g. on technical solutions. Needed details will be specified in annexes.

The need for a stable and durable agreement also requires a prolonged procedure for change.

- **Applicable EU legislation**

All EU legislation is applicable for the exchange and the MLA will in its preamble reflect this principle. The preamble will also have a clarification that a specification in the text does not exclude other legislation that may be applicable.

When it is needed each chapter or article will have specifications on applicable EU legislation.

- **National legislation**

The MLA in itself cannot require changes or alter national legislation. This principle is valid for all matters including e.g. liability and compensation procedures.

However, to make the exchange possible the MLA must set common requirements for participation e.g. the level for data security and technical solutions. These requirements may result in the need of changes in national legislations. If this happens it is for the participating MS to decide upon the needed changes of its legislation.

- **The MLA will not deal with divergent national regulations, legislations and procedures**

As the MLA sets a level or requirements for participation then the question shouldn't arise as each country will have to decide if they can participate or not.

- **Requirements for participation**

The MLA will set a basic level for participation by setting the goal but not the means for achieving a required result.

MLA will set requirements that participants must fulfil and these requirement must be met by MS wanting to participate but it is for an MS to decide how the execution will be met within its' own national legislation.

- **Definition of the planned exchange**

The MLA need to have an exact definition of the data for exchange.

The existing guidelines on ePrescription and Patient Summaries will be used as far as possible.

- **MLA will mainly cover legal questions but when needed also other questions**

As the aim for the MLA is to create a common legal framework most of its' contents will be on legal matters but it is not possible to exclude other areas e.g. technical and medical matters.

- **Technical solution (security for exchange)**

The technical solution will be set up and decided by other subgroups working on this matter. The MLA will state the decided technical solution but will strive to be as “technology neutral” as possible.

- **Jurisdiction**

Transactions within the borders of any MS are to be executed in accordance with the jurisdiction of that country. This principle is important for matters on liability but also for the principle of a formal acceptance by the NCP/B for the transmission of data.

- **Forum-shopping**

If possible this should not be used for the exchange.

- **All exchange of data will be exchanged through NCPs (preferable one NCP per country).**

To minimize the risks in the use and processing of sensitive personal data, all transmission of data will be through secure channels for sending/receiving data using secured and supervised technology. The amount of channels used should be as few as possible, preferably only one per MS.

This principle in itself also requires the use of the same technical solution/structure for the actual bilateral exchange between two MSs.

- **Guarantee by the NCP/A and formal acceptance NCP/B**

In the chain of transfer the legally most critical situation is to pinpoint the exact moment the data crosses the border and thus changes applicable jurisdiction. This issue can be solved by the use of a formal acceptance of transmission of data by NCP/B.

In the exchange the NCP/A will be responsible for all processing of data as long as the data is within country A's borders. When data is transferred across a border the NCP/A will guarantee that the sent data is in compliance with the legislation of country A. NCP/A is responsible for the data until the formal acceptance has been concluded.

NCP/B must formally accept all data sent by NCP/A. This acceptance will also constitute the formal change of jurisdiction. Once NCP/B has accepted the transferred data the legislation of NCP/B applies for the further processing of the sent data. Until acceptance is completed the jurisdiction of NCP/A is in force.

- **Consent and information**

Patients' consent is the basis for exchange as this is essential for the exchange of sensitive personal data. Patients' who want to participate will have to give their consent.

Before giving consent patients must be given full information on the significance on the exchange of sensitive data especially as sensitive data can be processed (used) differently in different countries.

- **Liability**

In cases of liability the situation should be treated in accordance with the national legislation of the country where the cause occurs (where the actual harm is done). For applying this principle in a cross-border exchange it is essential to be able to pin-point the exact moment when the data crosses the border between two countries, therefore the data-exchange will have to be formally accepted by the receiving NCP/B.

- **Reimbursement**

Reimbursement will not be part of MLA. It is for each MS to decide on this possibility for its inhabitants.

- **Identification of patients**

All countries have their own system for identification and the MLA will set a common level. All specific details will be in annexes.

- **Changes of the MLA contents**

For the sake of stability changes of the contents must be done through a prolonged procedure so as to give time adaption.

- **Termination of participation**

To be able to use the MLA to its full extent it must be stable to its content including the process for termination. Countries who wants to terminate its' participating must have the possibility to do so but for the sake of stability the remaining countries must also have the possibility to adapt to the changed situation; therefore there will be a prolonged procedure for terminating participation.

- **Annexes**

The MLA will set a basic level for participation with a prolonged process for changes. However there are several matters that will need to be changed; sometimes continually. These detailed requirements should therefore be stated in annexes with a quick process for changes and with the possibility for MSs to assign public authorities as responsible for different matters.

Examples of detailed requirements to have in the annexes are:

- chosen technical solutions
- requirements for eP

- requirements for PS
- requirements on validation of information in e.g. prescription, prescribing physician, patient information, pharmacist etc.
- requirements for the identification of patients
- authorization of HCP
- semantics
- encrypted communication
- logging of transactions
- logging made available to patients