The Danish Data Protection Authority criticizes the Capital Region

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Decision

Public authorities

Criticism

Supervision / self-management case

Obligation to provide information

Exercise of rights

The Danish Data Protection Authority criticizes the Capital Region for not fulfilling its obligation to provide information in a transparent and easy-to-understand form.

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Summary

In 2021, the Danish Data Protection Authority initiated an investigation into the Capital Region's fulfillment of the obligation to provide information in connection with the region's processing of information for use in (future) research.

In this connection, the Danish Data Protection Authority found that the Capital Region had not provided the necessary information to the data subjects in a transparent and easy-to-understand form, which gave the authority reason to express criticism. In addition, the Danish Data Protection Authority recommended to the Capital Region that the region considers how it will fulfill its obligation to provide information to patients in the future.

In its decision, the Danish Data Protection Authority, among other things, emphasis on the fact that if you as a data controller are aware that your services are available to vulnerable members of society, this vulnerability must be included in the data controller's assessment of how to comply with the requirement for transparency in relation to the data subjects.

Decision

The Danish Data Protection Authority hereby returns to the case where, by letter of 12 March 2021, the Danish Data Protection Authority initiated an investigation into the Capital Region's fulfillment of the obligation to provide information pursuant to Article 13 of the Data Protection Regulation in connection with the region's processing of information for use in (future) research.

1. Decision

After a review of the case, the Danish Data Protection Authority finds that the Capital Region - in connection with the region's processing of information for use in (future) research - has not provided the information in accordance with Article 13 of the Data Protection Regulation[1] in a transparent and easy-to-understand form, cf. Article 12, PCS. 1, which gives the inspectorate reason to express criticism.

The Norwegian Data Protection Authority recommends that the Capital Region consider how the region will fulfill its obligation to provide information to patients going forward.

Below follows a closer review of the case and a rationale for the Data Protection Authority's decision.

2. Case presentation

2.1. As a result of inquiries from several citizens, the Data Protection Authority became aware of an information letter issued by the Capital Region in November 2020 to former and current patients in the region.

According to the information letter, the citizen received the letter because, in the period from February 2009 to March 2020, he had had a blood sample taken in connection with patient treatment at one of the hospitals in the Capital Region. This was followed by information that the blood sample was used for research and further information on, among other things, how the region processes personal data.

It appeared from the inquiries received from citizens that the citizens were of the opinion that they had not previously received information that the blood samples would be processed for research purposes.

2.2. The Capital Region has stated that patients are informed that excess residual material from diagnostic samples is stored in the region's biobank for future research.

The region's handling of the obligation to provide information, including in connection with patient treatment, is described in a supplementary guideline for information security and data protection. This includes, among other things, following:

"There are 2 standard texts regarding the obligation to provide information, both of which have a reference to the region's Personal Data Policy. The texts are repeated in several of the standard products and must also be used ad hoc when there is a need to communicate with citizens and patients in e.g. in letters or the like.

The standard texts are also available in English and, in addition to Templafy, are also available on the central intranet pages on information security and data protection.

The two standard texts have the following wording:

The short standard text:

"Region Hovedstaden uses the personal data you give us in connection with your inquiry. You can read more about the purpose of use and your rights on our website: www.regionh.dk/persondatapolitik."

The long standard text:

"When we process personal data about you, according to the data protection regulation, we must provide you with a number of information, including:

That the purpose of processing your personal data is to process your inquiry. We therefore register your personal data in our electronic case management system.

That you can make use of a number of rights, including the right to see your information and the right to object to our processing of your information.

More info:

You can read more at www.regionh.dk/persondatapolitik

You are also welcome to contact the Capital Region's data protection advisor, [x] at www.region.dk/dpo." "

Furthermore, it appears from the guideline that the Capital Region's personal data policy is the central focal point for the region's handling of the obligation to provide information. The personal data policy is publicly available on the region's website, just as it is the central product referred to in the vast majority of other products.

The Capital Region has stated that the obligation to provide information in connection with patient treatment is concretely handled based on the following standard products:

The regional declaration of consent,

SP visit summary,

Material targeted at patients in the emergency department and

Standard texts in Templafy which are inserted ad hoc when communicating with citizens and patients in letters or similar.

According to the Capital Region, the products have in common that they incorporate a text on the processing of personal data and a reference to the region's personal data policy. The region's personal data policy contains a section on research, which is referred to in the standard products for patient care. The following appears about research in the personal data policy:

"What does the region collect personal data for?

In the Capital Region, we collect personal data for a number of different purposes as part of our daily tasks with the following objectives:

[…]

Research

Research and innovation are an important path to new knowledge and better patient treatment. The Capital Region uses personal data in connection with research activities.

Processing of personal data in connection with research is regulated in i.a. the Health Act, the Committee Act, the Medicines Act, the Medical Devices Act, Sections 10 and 11 of the Data Protection Act and Article 6, subsection 1 of the Data Protection Regulation. 1, letter a, and Article 9, subsection 2, letter a."

The Capital Region has stated that when patients receive a digital summons from the region, it follows from the guideline that, as a minimum, a preparation appendix must be attached to newly referred patients. It is the hospital departments that ensure that the preparation supplement is attached when they send a summons to a patient.

The Capital Region has sent an example of a preparation appendix from November 2020, which appears as an overview of patient rights, of which i.a. the following appears:

"Use of blood and tissue samples for research

Remains of blood and tissue samples can be used for research. You have the right to decide that your blood and tissue samples may only be used for the treatment of yourself and for purposes directly linked to your treatment. Read about your rights at www.regionh.dk/patientrights.

According to the Capital Region, the content of the preparation supplement varies depending on the hospital department. However, there are some mandatory phrases/sections in the preparation supplement, which the departments must always make sure to include in the preparation supplement. One of the mandatory phrases is "read about your rights", which links to www.regionh.dk/patientrights.

On this website, there is a section on "use of tissue", which explains in more detail that excess residual material from diagnostic samples is stored in the Capital Region's biobank for future research.

In the period 2016-2020, patients were thus informed by a written reference to the region's website about the storage of excess residual material from diagnostic samples in the Capital Region's biobank for future research. From November 2020,

information on this was provided by updating the preparation annex with a mandatory phrase about "use of blood and tissue samples for research", which is quoted above. One of the purposes of the new phrase was to clarify that residual material from diagnostic samples can be used for research.

Finally, the Capital Region has stated that, on the basis of the present case, the region has initiated work to update the region's standard products for handling the obligation to provide information in patient treatment, so that in the future it will be clearer that excess residual material will be stored in the Capital Region's biobank for future research.

3. Reason for the Data Protection Authority's decision

3.1. It follows from Article 13 of the Data Protection Regulation that if personal data about a data subject is collected from the data subject, the data controller at the time the personal data is collected provides the data subject with a range of information about the processing.

This appears from the data protection regulation's article 12, subsection 1, that the data controller takes appropriate measures to provide any information as referred to in i.a. Article 13 to the data subject in a concise, transparent, easily understandable and easily accessible form and in clear and simple language, in particular when information is specifically directed at a child. The information is provided in writing or by other means, including, if appropriate, electronically.

When the data protection regulation's article 12, subsection 1, states that the information must be provided in a "transparent" form, this implies that the data subject must be able to ascertain in advance the scope and consequences of the processing, and that it must not later become known to the data subject how his personal data has been used .[2]

If a data controller is aware that its services are available to vulnerable members of society, including people who have difficulty accessing information, the vulnerability of these data subjects must also be included in the data controller's assessment of how to comply with the requirement for transparency in relation to these registered. [3]

3.2. Based on the information provided, the Danish Data Protection Authority must assume that it is general practice in the Capital Region that excess biological material from patient treatment is stored in the region's biobank with a view to using the material for future research.

The Capital Region has stated that the region fulfills the obligation to provide information by referring and linking to the region's privacy policy in a number of standard products that patients receive. The privacy policy contains a section on processing the information for research purposes. When newly referred patients receive a digital invitation from the Capital Region, they also

receive a preparation supplement with information on patient rights. In the preparation annex, reference is also made to the personal data policy, and since November 2020 the annex contains a section stating that the region uses blood and tissue samples for research, as well as a link to the region's website, where you can read more.

However, the region's privacy policy is of a general nature and is aimed at patients, employees and citizens, just as the text on research only states that the region uses personal data in connection with research activities without providing further information about the context of the processing.

On that basis, in the Data Protection Authority's view, it cannot be assumed to be clear to a patient that the section on research is addressed to that person, including that the section is addressed to all patients and not just patients, such as e.g. has signed up for a research trial and is thus aware that information is processed for this purpose.

Overall, the Danish Data Protection Authority then finds that the Capital Region – in connection with the region's processing of information for use in (future) research – has not provided the information in accordance with Article 13 in a transparent and easy-to-understand form, cf. Article 12, subsection 1. This gives the inspectorate reason to express criticism.

The Danish Data Protection Authority recommends that the Capital Region consider how the region will fulfill its obligation to provide information in this regard in the future.

[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons in connection with the processing of personal data and on the free exchange of such data and on the repeal of Directive 95/46/EC (general regulation on data protection).

[2] Article 29 Working Party, Guidelines on transparency under Regulation 2016/679, WP 260 recital 10.

[3] Article 29 Working Party, Guidelines on transparency under Regulation 2016/679, WP 260 recital 16.