LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

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Data Ethics Charter of the Danish Medicines Agency

The Danish Medicines Agency carries out concrete scientific and statistical analyses based on collected health data, in particular with the purpose of qualifying the Danish Medicines Agency's efforts in creating value for people, animals and society through effective, safe and available medicines and safe medical devices.

These analyses – and any other work of the Danish Medicines Agency – must be brought about respecting every individual's right to privacy and right to data protection. These are fundamental rights that appear from, for example, the UN's Universal Declaration of Human Rights, and the rights are also recognised in the EU Charter of Fundamental Rights.

Consequently, the work of the Danish Medicines Agency primarily takes place in compliance with Danish and European data protection legislation, including in particular the General Data Protection Regulation (GDPR) and the Danish Data Protection Act.

While the Danish Data Protection Act includes rules on when and how data can be processed, it does not regulate if such processing should take place. This is a data ethical question. The data protection rules represent to a great extent legal norms based on concrete assessments. Whenever such assessments are to be made, data ethical considerations are also important.

The Danish Medicines Agency has approved this Data Ethics Charter to guide its considerations. The charter aims to set a high standard for the protection of the rights of those whose health data are being processed in the concrete analyses performed by the Danish Medicines Agency. The charter sets a framework for the Danish Medicines Agency's considerations and assessments within the data protection rules in force. The charter will apply to all forms of data analyses carried out by the Danish Medicines Agency.

The charter is inspired by recommendations from the Danish Expert Group

on Data Ethics[1], the national strategy for artificial intelligence[2], the European Commission's high-level expert group on artificial intelligence[3] and OECD's expert group on artificial intelligence[4]. The principles of the charter have been adapted to the Danish Medicines Agency.

The charter has been prepared based on input from the Danish Medicines Agency's Citizens' Council[5] and the data ethics event held at the Danish Medicines Agency on 28 March 2022 which featured presentations from experts in ethics from Aalborg University and the University of Copenhagen and Danish Patients[6].

The Danish Medicines Agency's seven principles of data ethics are:

1) Trust

[1] https://www.regeringen.dk/nyheder/2018/regeringens-ekspertgruppe-klar-med-anbefalinger-om-dataetik/

[2] https://www.regeringen.dk/media/6537/ai-strategi_web.pdf

[3] https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai

[4] https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449

[5] https://laegemiddelstyrelsen.dk/da/om/maal-og-opgaver/naevn-og-raad/laegemiddelstyrelsens-borgerraad/

[6] Watch the data ethics event here: https://www.youtube.com/watch?v=yOa82HxKd4s

In certain circumstances, the Danish Medicines Agency may lawfully perform scientific and statistical analyses based on collected health data without first having obtained the consent of data subjects. Since the data subjects have practically no influence on how the Danish Medicines Agency processes their data as part of the concrete analyses, it is crucial that they can trust that their personal data are being processed properly. To ensure the public can trust that the Danish Medicines Agency fulfils its responsibilities, an analytical team must declare that they have followed the principles of this charter before starting any analysis. The director general of the Danish Medicines Agency bears ultimate responsibility for ensuring that the agency follows the principles of data ethics.

Example 1: Asking ethical questions when an analysis is started

Before the Danish Medicines Agency starts an analysis, it will prepare an analytical protocol. In the analytical protocol, the Danish Medicines Agency accounts for a number of aspects of the planned analysis, e.g. what will be studied and what data will be used, etc. In the analysis protocol, the analytical team must also declare that the ethical pitfalls set out in this charter have been taken into account. The purpose is to ensure that the analytical team is aware of the ethical precautions they need to take in their analytical work.

2) Fairness

The mission of the Danish Medicines Agency is to: create value for people, animals and society through "efficient, safe and available medicines and safe medical devices". Most likely all of us will need medicines or medical devices at some point in our lives, and therefore the analyses of the Danish Medicines Agency will benefit the wider public. The analyses will contribute to the improvement of existing medicines and treatment options and will also support the development of medicines and medical devices. Companies will also benefit from the analyses because they can support the commercial development of medicines and medical devices. The Danish Medicines Agency must ensure a fair balance between the rights of data subjects, on one hand, and the good of the community, on the other.

Example 2: Keeping a balance between the respect of the individual's interests and the good of the community

The Danish Medicines Agency has formed a citizens' council with representatives of a number of patient and consumer organisations. With the aim of pressure testing that the Danish Medicines Agency in practice has found a proper balance between the respect of the individual's interests and the good of the community, analyses will at regular intervals be presented to the citizens' council for commenting.

3) Equality

The Danish Medicines Agency will ensure that different groups are treated equally in all aspects of its work. The agency will endeavour to ensure that the analyses and algorithms applied do not reproduce prejudice or discriminate against certain populations. The agency will also endeavour to promote analytical work that targets rare diseases and neglected patient populations, e.g. children and pregnant women and others.

Example 3: A poor data set can lead to reinforcement of prejudice

An artificial intelligence algorithm needs to be trained before it can be used to make analyses. The data used to train an algorithm will impact how the algorithm works. If, for example, we use training data that do not reflect real life, e.g. if only data about men are included, there is a risk that the algorithm will subsequently discriminate against women. By being aware of these factors, we can reduce the risk of using data sets that reinforce prejudice and lead to discrimination.

4) Accountability

The Danish Medicines Agency works systematically to ensure it complies with its obligations under data protection legislation, including maintaining high IT security standards, and that it observes this charter. The aim is to ensure that the persons about whom we hold data (the data subjects) can have absolute trust in the safety of our work. In this connection, we must ensure confidentiality of the health data of each individual to make sure that no one in any way has information about their health compromised through the fault of the Danish Medicines Agency.

Example 4 – analyses will be run on a maximum security super computer

The analyses of the Danish Medicines Agency will be carried out on platforms meeting the highest international data security standards, e.g. the public administration computer (Forvaltningsmaskinen) of the Danish Health Data Authority and the super computer of the National Genome Centre.

5) Transparency and explainability

The Danish Medicines Agency must at any time endeavour to ensure transparency and explainability of its prioritisations and data analyses. This is especially important for the use of artificial intelligence because confidence in artificial intelligence – and in the Danish Medicines Agency as an organisation – is fully dependent on analysis results that can be explained and reproduced. The Danish Medicines Agency will keep abreast of the development on how to ensure transparency in the use of artificial intelligence and seek to implement best practice in its working procedures.

Example 5: Transparency and prioritisation of analysis results

The Danish Medicines Agency will endeavour to achieve maximum transparency in relation to the prioritisation of completed analyses and post-analyses publication of results. The process of prioritising analyses to be started and the post-analysis results will be updated regularly and shared on the website of the Danish Medicines Agency.

6) Diversity

The Danish Medicines Agency must contribute to positive developments in society with regard to data application to ensure public health is promoted in an ethically acceptable manner. The Danish Medicines Agency will therefore endeavour to ensure that analytical teams reflect society as a whole and as far as possible consist of people from different professions of different gender, age and ethnic origin.

Example 6: Creating diversity in analytical teams to reduce blind spots

A major source of analytical fallacies and bias are non-recognised prejudice. We all hold some kind of prejudices that we are not always aware of. By making sure to compose analytical teams of people who are different on as many parameters as possible, e.g. profession, race, gender, ethnic origin, age, etc., we lower the risk that all team members hold the same non-recognised prejudices. And by doing so, we reduce the risk of analytical fallacies and bias.

7) Global perspective – and responsibility

Data flow between countries and many of the challenges with data ethics have to do with cross-border concerns. The Danish Medicines Agency will work actively to ensure the widest possible dissemination of its principles of data ethics as specified in this charter among relevant European and global forums.

Example 7: The Danish Medicines Agency has international reach

The Danish Medicines Agency represents Denmark in a number of international organisations and forums including the EU, the European Medicines Agency (EMA), the Heads of Medicines Agencies (HMA) and in the Nordic collaboration. Thanks to the professional respect held in us as a European authority, the Danish Medicines Agency has a wide international reach and are in a position to influence the course of the international collaboration, which includes directing increased focus on data ethics.