HELSE NORD

HELSE MIDT-NORGE

HELSE VEST

HELSE SØR-ØST

LMI
LEGEMIDDELINDUSTRIEN
Medisinske fremskritt for bedre helse

MedtekNorge
Bransjeorganisasjonen for helse- og velferdsteknologi

Cooperation Agreement

between
the regional health authorities, LMI and Medtek Norge
concerning
cooperation on medical quality register data

1. The agreement, purpose and parties

1.1 Joint declaration – the purpose of the agreement

This agreement sets out a binding framework for cooperation between the data controllers for medical quality registers in the four regional health authorities in Norway and members of the Association of the Pharmaceutical Industry in Norway (LMI) and Medtek Norge – the Norwegian Association for Health and Welfare Technology, within the legislation, instructions, agreements and ethical guidelines that they are bound by at all times.

The agreement does not regulate what constitutes lawful disclosure of data/information or the conditions for the recipient's processing of disclosed data/information. Decisions to disclose information must comply with the governing documents in force at all times at the data controller institution, and must be in accordance with license conditions, the register's statutes, consents and applicable laws and regulations.

The main purpose of the agreement is to help to ensure that all interaction between the RHAs' and health trusts' medical quality registers and the members of LMI and MedTek Norge take place in a manner that is professionally, legally and ethically appropriate.

All cooperation under this agreement shall be motivated by a wish for patients to benefit from knowledge and expertise and shall take place in such a manner that society cannot call into question the independence, integrity or medical assessments of the medical quality registers and their staff. This makes particular demands as regards transparency and possibilities for control in connection with interaction and agreements entered into. Cooperation must be characterised by orderly, open and transparent practices.

Cooperation must comply with the applicable regulatory framework and recognised standards/guidelines.

This agreement is intended to ensure that access to medical quality register data is not granted as an exclusive right and that financial compensation for services provided by medical quality registers shall be based on cost price and shall not cast doubt on the independence of the medical quality registers and their staff.

1.2 Definitions

For the purpose of this agreement, the following definitions shall apply:

- *Medical quality register*: A structured collection of medical information about patient assessment and treatment that provides an indication of how certain processes work and whether certain results have been achieved by referring to quality characteristics.
- *RHAs and health trusts*: Regional health authorities and health trusts (at the operational level: the managing director)
- *Owner:* The State represented by the Ministry for the regional health authorities and the State represented by the regional health authority for health trusts.
- *Data controller*: The party deciding the purposes for which and the means by which health information is processed, unless the data controller responsibility is specifically assigned by law or regulations issued pursuant to law.
- *Indirectly identifiable health data*: health data from which the name, personal identity number and other characteristics serving to identify a person have been removed, but where the data can nevertheless be linked to a natural person.
- *Anonymous data:* data from which the name, personal identity number and other characteristics serving to identify a person have been removed, so that the data can no longer be linked to a natural person.

1.3 About the parties

The agreement regulates the framework conditions for cooperation and interaction between data controllers for medical quality registers in all four health regions in Norway and enterprises that are members of LMI and MedTek Norge.

Employees of the RHAs and health trusts must comply with the provisions of this agreement in their interaction with all types of suppliers, regardless of whether or not they are members of the industry associations.

LMI and MedTek Norge instruct their members to comply with this agreement. The industry's ethical guidelines instruct the head of each enterprise that is a member of the associations to ensure that the enterprise has a well-functioning system in place for following up various laws and regulations. In accordance with the associations' own regulations, member enterprises must have a contact person responsible for following up this agreement. LMI and MedTek Norge instruct their members to familiarise themselves with and actively follow up the regional health authorities' ethical guidelines.

1.3.1 Medical quality registers in Norway

Medical quality registers are structured collections of clinically relevant information about patients compiled for the purpose of providing a knowledge system for use at all levels of the health service for continuous learning, improvement, prioritisation and management.

The primary purpose of the medical quality registers is, as the name indicates, to improve the quality of medical diagnostics and treatment. Quality register data can also be used in research on treatment methods and outcomes and to map the prevalence of diseases.

The content of medical quality registers often cover details concerning the diagnosis and treatment for a particular group of patients or treatments. An 'event' in the register arises from contact with the health service in connection with one specific disease or treatment. The quality registers have mostly been developed by health personnel, often with an academic affiliation, who are to report data and ensure that the results are made use of. The quality registers were established by the medical specialist communities.

Medical quality registers can have different bases in law. At present, most of them are established under a license from the Norwegian Data Protection Authority and are based on the informed consent of the data subjects.

The data controller for medical quality registers is mostly specific health trusts within the four health regions.

1.3.2 The Norwegian Advisory Unit for Medical Quality Registries

The Norwegian Advisory Unit for Medical Quality Registries comprises the Centre for Clinical Documentation and Evaluation (SKDE) in the Northern Norway Regional Health Authority and regional advisory units in the Western Norway, Central Norway and South-Eastern Norway RHAs, respectively. The Norwegian Advisory Unit for Medical Quality Registries possesses expertise on the establishment and running of quality registers, law, protection of privacy, funding, statistics, IT, and analysis and reporting.

Its purpose is to help to achieve the goal of medical quality registers contributing to improving healthcare for the Norwegian population through documentation and evaluation of clinical activities.

1.3.3 The Association of the Pharmaceutical Industry in Norway

The Association of the Pharmaceutical Industry in Norway (LMI) is the industry association for the Norwegian pharmaceutical industry. Membership of the association is open to pharmaceutical companies that develop, manufacture, sell or market pharmaceutical products in Norway. Many of LMI's members are very active in research and innovation, and the pharmaceutical industry invests a total of around NOK 1 billion a year in clinical research and development. Most of the R&D investments are spent on clinical studies. The purpose of this research is to ensure that safe and effective pharmaceuticals are placed on the market. The industry also helps to provide documentation for use in cost assessments and health economics analyses, and monitors products that are already available to Norwegian patients.

The Norwegian health service has a longstanding tradition of participating in clinical studies in cooperation with the industry, and has contributed data to an extent far exceeding what one would expect from a country with a population the size of Norway's. The research and development model is changing, however, and globalisation, rationalisation and new regulatory requirements concerning documentation are leaving their mark. This development makes it difficult to attract industrial research cooperation. However, Norway has some advantages that make it particularly attractive for the industry to conduct research activities here. Our medical quality registers and national health registers are among the resources on which our advantages are based.

1.3.4 The Norwegian Association for Health and Welfare Technology

Medtek Norge – the Norwegian Association for Health and Welfare Technology organises around 115 suppliers of medical technology equipment, medical consumables, assistive technology equipment for people with functional impairments and other forms of welfare technology. The organisation's members supply products to RHAs and health trusts, the Norwegian Labour and Welfare Administration (NAV), municipalities and the private healthcare market in Norway. Their turnover in Norway totals nearly NOK 9 billion, which corresponds to nearly 90% of the total turnover for these product groups.

The term medical equipment covers all products used in the field of medicine except pharmaceuticals. It includes products such as radiology technology, dialysis machines, orthopaedic implants, stents, pacemakers, products used in minimally invasive surgery, medical consumables and assistive technology products for disabled people. Medical equipment also includes hospital beds, operating tables and delivery tables. Medical equipment thus saves lives and improves a great many people's quality of life.

1.4 About the agreement

The agreement consists of this main document. Any other agreements entered into between the parties must be in accordance with this agreement as long as it remains in force. The parties are responsible for communicating this agreement to their own enterprises/members. The intention set out in this agreement should govern practice and also apply to suppliers that are not members of the associations that are parties to the agreement.

2. General provisions

2.1 Formal requirements

All agreements on interaction (see Clause 3) require management support from the RHAs and health trusts. All other matters not covered through this agreement must be agreed in writing.

2.2 Access

The Freedom of Information Act applies to the activities of the RHAs and health trusts. Among other things, this means that they are obliged to consider enhanced access to information unless the information is subject to a statutory duty of secrecy. Examples of cases where a statutory duty of secrecy applies include information about an individual's personal affairs, cf. the Public Administration Act Section 13, patient information, cf. the Health Personnel Act Section 21 ff., and information about certain operational and business matters, cf. the Public Administration Act Section 13 and the Medicinal Products Act Section 30.

2.3 Transparency

The parties shall, to the extent it has a bearing on the cooperation and is possible under Clause 2.2, give each other access to information about their own activities in relation to external partners. This includes relationships with the hospital pharmacies, NAV and patient organisations.

If the owner requests access to information about existing and planned contacts between RHAs and health trusts and member enterprises of LMI and MedTek Norge, such requests shall be granted. The management of RHAs and health trusts have a corresponding right of access regarding the member enterprises' completed contacts with their own RHA or health trust.

2.4 Impartiality

The Public Administration Act's provisions concerning impartiality apply between the parties to this agreement. If stricter provisions are set out in the parties' ethical guidelines or other regulations by which the parties are bound, these provisions shall apply.

3. Interaction

3.1 Need for cooperation and examples of possible services under this agreement

Close cooperation between the health sector and industry has for many years been important to the development and evaluation of new diagnostic methods and treatments in Norway. A well-functioning cooperation between the health service, research and industry has resulted in a mutual commitment to faster collection of knowledge, controlled implementation and evaluation of treatment methods that has been very important both to the patients and the parties. The point of departure for further development of this cooperation will be to guarantee patients efficient, knowledge-based and safe diagnosis and treatment.

The pharmaceutical industry and the medical technology industry are a knowledge-intensive sector of great importance to Norway. Efficient development of methods and products is contingent on a trusting cooperative relationship between enterprises in these sectors and the health and care services.

The industry represents a wealth of knowledge about statistics, health economics and epidemiology. In cooperation with the medical quality registers, industry players can contribute information that can help to further develop the use of quality registers to improve health and care services.

Data from medical quality registers can be of interest to the industry in many ways. The results the industry wants from the medical quality registers are often the same as the results that the patients, health personnel and healthcare institutions need continuous information about. In connection with approval of new pharmaceuticals, reconsideration of pharmaceuticals' reimbursement status, and requirements for lifetime monitoring of pharmaceuticals, the authorities can instruct pharmaceutical enterprises to report effect and safety data, for example long-term effects following the introduction of pharmaceuticals for large groups of patients and cost-efficiency. Cooperation on relevant medical quality registers and aligning of quality registers and other health registers can form an important basis for such reporting. One can also expect an increasing demand for medical quality registers to be used in prospective randomised end-point studies as part of the documentation forming the basis for a marketing authorisation.

An expedient form of cooperation between the health service and suppliers is necessary in order to ensure quick and accurate reporting of problems relating to medical technology equipment. Cooperation on data from medical quality registers could further strengthen the quality assurance of health and care services and thus benefit patients.

Examples of services that the agreement can cover, if this is legally permissible:

- Aggregate information (anonymous) disclosed by medical quality registers to a supplier in unprocessed form.
- Anonymised/aggregate analysis results from medical quality registers, if relevant collated with data from other health registers, other national quality registers or other registers, based on a concrete enquiry from a supplier. The analysis could be a way of assessing the effects, safety or cost-efficiency of a product. This will allow suppliers to fulfil monitoring requirements imposed by Norwegian or European authorities.

- Research cooperation with an agreement between the provider and a university/university college under which scientists carry out research where medical quality registers are used for research purposes.
- Disclosure of statistics/anonymised data for the suppliers' development of products and services, for example new innovations, decision support and monitoring tools for the main goal of improving health and care services.
- Statistics from medical quality registers to map patient base, costs and how effective existing methods are in a new product's development phase. Statistics can also be prepared to determine whether it is possible to conduct a clinical study.
- Personal information from medical quality registers collated with other registers and biobanks can be used as a basis for defining new needs in the health and care sector, for example new pharmaceuticals, products and services.

3.1 Enquiries concerning disclosure and use of data from medical quality registers

Initiatives to cooperation on the use of data from a medical quality register can come from the register's steering group/advisory board, a researcher or a supplier. Regardless of who took the initiative, cooperation must be formalised at an early stage in the form of contracts, and the quality register's data controller is responsible for ensuring that any agreements are signed.

The agreement shall be entered into between the quality register's data controller and the industrial supplier. The data controller for a medical quality register can refuse to disclose data if reasonable grounds exist to refuse cooperation or disclosure of data. Moreover, there must be a legal basis for disclosure of data and processing by the recipient.

All cooperation must be approved by the steering group of the medical quality register in question and the body acting as the data controller, and must comply with the individual medical quality register's statutes.

When cooperation takes the form of a service, the agreement must contain information about the service and the consideration for the service. Terms and conditions for access to register data, publication policy and any intellectual property rights must be set out in the agreement. It must not be possible for the supplier to influence the interpretation of analyses and the compilation of final reports and publications derived from the register. All disclosure of data from medical quality registers requires the advance approval of the public bodies required by law.

In connection with cooperation on the development of a product, service or innovation and research studies, the agreement must be supplemented with a project outline containing information about how the project is to be implemented and evaluated. The different parties' contributions to the project in the form of resources such as financial and material contributions and working hours must also be regulated in a separate agreement for the project.

The agreement must be registered with the medical quality register's data controller. A copy should also be sent to the Norwegian Advisory Unit for Medical Quality Registries for purposes of overview and sharing of experience gained from agreements entered into. The cooperation should also be presented on the website of the medical quality register in question or, if the register does not have its own website, on the website of the Norwegian Advisory Unit for Medical Quality Registries.

3.2 Disagreement between the parties

Cooperation is to take place in such a manner that full credibility and independence is retained between the parties. The cooperation will not entail any obligation or expectation to prescribe or use an enterprise's products.

3.3 Non-exclusivity

In cases where more than one supplier is active in the same market, all suppliers shall be offered the same opportunities for cooperation with medical quality registers.

Questions regarding analyses, compilation and disclosure of medical quality register data cannot be reserved for one stakeholder. Registered data must therefore be available to all parties that wish to use the data within the purpose of the register and that can present a valid approval for the requested use.

Decisions to disclose information must otherwise comply with the governing documents in force at all times at the data controller institution and must be in accordance with license conditions, the register's statutes, consents and applicable laws and regulations.

LMI, MedTek Norge and the Norwegian Advisory Unit for Medical Quality Registries issue information material that explain in more detail the rules that apply in relation to the disclosure of data from medical quality registers.

3.2 Financial consideration for the purchase of services from medical quality registers

The parties agree that industrial suppliers' cooperation with quality registers is to be based on the purchase of services. Direct sponsoring of quality registers by suppliers must not take place.

Financial consideration for the purchase of services from medical quality registers can include remuneration for work relating to retrieval of data, data quality work, statistical analysis and compiling reports.

The consideration shall be based on cost price and shall be the same for everyone who requests the disclosure of data from a medical quality register, regardless of whether the party is a public body or a private enterprise.

The consideration shall be paid to the body acting as the data controller, which will divide it between those who provide the service in accordance with the agreement and, if relevant, the project plan. Accounts must be kept of all costs.

3.3 Fees and gifts

Employees affiliated to a medical quality register must not, either on their own behalf or that of others, accept gifts, commission, services or other benefits that are capable of improperly influencing their actions, case preparations or decisions. However, this does not apply to gifts of an insignificant value such as advertising material, flowers etc., unless such gifts fall under the scope of the sentence above. The assessment will be based on the regulations issued pursuant to the Health Personnel Act Section 9 third paragraph.

The term 'gifts' covers not only physical objects, but also other benefits, for example in the form of personal discounts when purchasing goods and services. Fees to personnel affiliated to a medical quality register for assignments such as participation in advisory boards, lectures, consultancy activities etc. must be approved by the register's data controller.

Medical quality register employees are expected not to take paid assignments/employment linked to the supplier industry without the approval of their employer. The responsibility for ensuring clearance of such activities rests with the individual medical quality register employee.

3.4 Use of names and trademarks in advertising etc.

The parties agree that neither party is permitted to use the other party's name, trademark, distinguishing marks etc. in press releases, advertisements, marketing etc. without obtaining written permission to do so.

3.5 Courses, conferences, meetings etc.

Invitations to employees affiliated to medical quality registers concerning courses, conferences, meetings etc. are to be addressed to the register's data controller, and any supplier contact persons at the RHAs and health trusts must also be named and/or be informed about such invitations. Invitations must always state who organises and pays for an activity.

Employees affiliated to medical quality registers can take part in such activities with the approval of the register's data controller. The responsibility for ensuring clearance of such activities rests with the employee affiliated to the medical quality register.

The data controller shall have an overview over and be able to document approved activities.

Travel expenses of employees affiliated to the medical quality register in connection with professional activities shall be covered by the data controller. This provision does not apply to short-distance travel where shared transport is practical.

3.6 Competence-raising measures

Cooperation on competence-raising measures should be motivated by knowledge and expertise. Competence-raising cooperation between medical quality registers and suppliers should be transparent and characterised by integrity and honesty.

Courses, conferences, meetings etc. under the auspices of the data controller for medical quality registers must be held without financial or practical contributions from industrial enterprises.

Suppliers can give talks or send a speaker to internal courses under the auspices of the data controller by invitation. A medical quality register can organise meetings, courses, conferences etc. with suppliers as co-organisers. In such cases, the cooperation must be based on professional and not financial considerations. It must be clearly stated in all programmes, invitations etc. to such events that it is co-hosted by an industrial enterprise, and also that the event has been approved by the data controller.

No agreements are to be entered into for support for courses that constitute credit-conferring or approved further and continuing education.

4. Implementation, follow-up and termination

4.1 Compliance and follow-up

The parties agree that compliance with this agreement is a joint responsibility. The parties will inform affected members about this agreement and recommend and make active efforts to ensure that affected members comply with the agreement.

The parties undertake to make the agreement known in their respective enterprises and member organisations. The parties have a mutual responsibility for ensuring that employees and enterprises/RHAs/health trusts comply with the agreement and will inform each other of any breaches and measures implemented to prevent new breaches.

The agreement has been entered into as a preliminary attempt to prepare guidelines for interaction between medical quality registers, the Association of the Pharmaceutical Industry in Norway (LMI) and Medtek Norge – the Norwegian Association for Health and Welfare Technology. The practical aspects of this cooperation should be determined in dialogue characterised by mutual trust between the parties involved, and positive experience should be highlighted.

The parties will endeavour to prepare support material describing expedient work methods for service specification. The parties will gather experience of the cooperation and evaluate whether the agreement has fulfilled its purpose, and revise the agreement if necessary. The parties will review the agreement within two years of its entry into force.

LMI, MedTek Norge and the Norwegian Advisory Unit for Medical Quality Registries will hold an annual contact meeting to maintain and develop the cooperation established through this agreement.

The further follow-up will aim to ensure that this agreement is as far as possible adapted and harmonised with other cooperation agreements entered into concerning the same matters.

4.2 Sanctions

The parties agree that any sanctions for breaches of the agreement shall be dealt with through the parties' internal sanction systems.

Each of the parties may demand that breaches of the agreement be made publicly known.

4.3 Entry into force and duration

This agreement enters into force when signed by the parties and runs until it is terminated by one or all parties or until another agreement is entered into.

Each of the parties may terminate the agreement at three – 3 – months' notice.

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