

FOR 2003-09-24 nr 1202: Regulation relating to clinical trials on medicinal products for human use

Chapter 1. Introductory provision

- § 1-1. Scope
- § 1-2. Definitions
- § 1-3. Multi-centre trials
- § 1-4. Insurance of subjects
- § 1-5. Prior ethical opinion
- § 1-6. Licence from the Norwegian Data Inspectorate
- § 1-7. Further duty of notification for special studies

Chapter 2. Application for clinical trial

- § 2-1. Application for clinical trial
- § 2-2. Protocol
- § 2-3. Supplementary information about the trial
- § 2-4. Documentation of the medicinal product
- § 2-5. Manufacture and import of medicinal products for clinical testing

Chapter 3. Assessment of the trial

- § 3-1. Requirement concerning assessment and reporting of the outcome of the assessment
- § 3-2. Time periods for considering a valid request for authorisation
- § 3-3. The outcome and legal effect of a reasoned assessment

Chapter 4. Consent, information and protection of privacy

- § 4-1. Requirement of informed consent
- § 4-2. Clinical trials on persons aged under 18
- § 4-3. Trials on persons unable to or with limited capacity to give informed consent
- § 4-4. Withdrawal of consent
- § 4-5. Inspection of subject's record
- § 4-6. Duty of confidentiality in connection with inspection of patient records pursuant to § 4-5
- § 4-7. Information to subjects

Chapter 5. Requirements relating to the investigator and the trial

- § 5-1. Requirements regarding the investigator's qualifications
- § 5-2. Information rules for trials
- § 5-3. Protocol and source data etc.
- § 5-4. Labelling and dispensing of the medicinal product
- § 5-5. The investigator's duty to report adverse events
- § 5-6. The sponsor's duty of notification
- § 5-7. Duty of notification in the event of amendments to the trial
- § 5-8. Duty of notification of changes etc. in the medicinal product
- § 5-9. Annual report and final report

Chapter 6. Supervision and suspension

- § 6-1. Supervisory authority
- § 6-2. Inspection
- § 6-3. Suspension of clinical trials

Chapter 7. Entry into force

- § 7-1. Entry into force
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Regulation relating to clinical trials on medicinal products for human use

Laid down by the Norwegian Ministry of Health on 24 September 2003 pursuant to § 3 of Act no. 132 of 4 December 1992 relating to Medicines etc. (Medicines Act), cf. Delegation Decision, no. 521 of 8 June 1995. Cf. the EEA Agreement Annex II, Chap XIII no. 150 (Directive 2001/20/EC).

Chapter 1. Introductory provisions

§ 1-1. Scope

This regulation applies to clinical trial of medicinal products for human use, on both patients and healthy persons.

The regulation does not cover investigational treatment of individual patients or non-interventional trials.

Trials that entail modification of the trial person's germ line genetic identity may not be conducted.

§ 1-2. Definitions

The following definitions apply in this regulation:

- a) *clinical trial*: any systematic investigation of medicinal products for human use for the purpose of acquiring or testing knowledge of the effects or influence of the products on physiological function, interactions, adverse reactions, absorption, distribution, metabolism and secretion, or to study their therapeutic value;
- b) *non-interventional trial*: a study where one or more medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. A therapeutic strategy for each individual patient is not decided in advance by a trial protocol, but falls within current practice, and the prescription of the medicinal products is clearly separated from the decision to include the patient in the study. Additional diagnostic or monitoring procedures for patients shall not be necessary and epidemiological methods shall be used to analyse the collected data;
- c) *subject*: an individual who participates in a clinical trial as either a recipient of the investigational medicinal product or a member of a control group;
- d) *investigator*: doctor or dentist who conducts a clinical trial;
- e) *principal investigator*: the investigator who leads the trial at the individual trial site;
- f) *national coordinating investigator*: the investigator in Norway who coordinates the Norwegian sites taking part in a multi-centre trial;
- g) *sponsor*: an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial, and that signs the application;
- h) *monitor*: the person who shall ensure that the trial is conducted, recorded and reported in accordance with the protocol, standard operational procedures, applicable guidelines for good clinical trial practice, Norwegian legislation generally, and to ensure that the trial has the agreed progression;
- i) *Contract research organisation (CRO)*: a person or an organisation (commercial, academic or other) engaged by the sponsor to perform one or more of sponsor's trial-related duties and functions;
- j) *IEC*: Independent regional committee for medical research ethics, which is established in each of Norway's five health regions according to guidelines laid down by the Ministry of Education and Research (MER). MER appoints the members of the committees;
- k) *good clinical practice*: a standard for the design, management, conduct, monitoring, auditing, recording and reporting of clinical trials, which also ensures that data and the reported results are credible and accurate, and that the rights, integrity and confidentiality of the subjects are protected;
- l) *protocol*: a document that describes the objective(s), design, methodology, statistical considerations and organisation of the trial;
- m) *protocol amendment*: a written description of one or more changes in, or a formal clarification of the protocol;
- n) *investigator's brochure*: a compilation of the clinical and preclinical data on the investigational

medicinal product or products which are relevant to the study of the product or products in human subjects;

- o) *inspection*: the act by a competent authority of conducting a review of documents, facilities, patient records, quality assurance arrangements and any aid regarded by the authorities as relating to the clinical trial, and that may be located at the site of the trial, at the sponsor's and/or CRO's facilities, or at other establishments that the authorities see fit to inspect;
- p) *informed consent*: a process where a subject voluntarily confirms his or her participation in a particular trial, after having been duly informed of all aspects of the trial that are relevant to the subject's decision regarding participation;
- q) *multi-centre trial*: clinical trial conducted at several centres at the same time and according to the same protocol;
- r) *medicinal product*: a substance, drug or formulation etc. as specified in § 2 of Act no. 132 of 4 December 1992 relating to Medicines etc.;
- s) *investigational medicinal product*: a pharmaceutical form of an active substance or placebo that is tested or used as a reference in a clinical trial, including products already with a marketing authorisation, formulated or packaged in a way different from the authorised form, or used for an non approved indication or to gain further information about the marketed form;
- t) *adverse event*: an untoward medical occurrence in a subject to whom a medicinal product has been administered, and which does not necessarily have a direct relationship with this treatment;
- u) *adverse reaction*: an adverse event in a subject who has received a medicinal product in a clinical trial where a causal relationship between the occurrence and the product that is being tested is regarded as probable or possible;
- v) *serious adverse event or serious adverse reaction*: harmful and unintended response or effect that at any dose results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect;
- w) *unexpected adverse reaction*: an adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. investigator's brochure for an unauthorised medicinal product or a summary of product characteristics¹ (SPC)).

¹ See § 4-10 and following and § 6-8 of the Medicinal Products Regulation.

§ 1-3. Multi-centre trials

Multi-centre trials shall have a national coordinating investigator in Norway.

§ 1-4. Insurance of subjects

The sponsor shall ensure that the subjects who participate in trials are satisfactorily insured against any injury that might occur during the trial (cf. Act no. 104 of 23 December 1988 relating to Product Liability).

§ 1-5. Prior ethical opinion

All clinical trials shall be considered by the Independent Regional Ethics Committee (IEC) before commencement. The notification to the IEC shall be drawn up in conformity with the IEC's mandate. No trials may commence before a positive opinion of the notification has been given by the IEC.

In forming its opinion pursuant to the first paragraph, the IEC shall consider the following:

- a) the relevance and design of the clinical trial,
- b) that the presumed risk and inconveniences are weighed up against the benefits to the individual subject and to other present and future patients,
- c) protocol,
- d) investigator's qualifications,
- e) investigator's brochure,
- f) the suitability of the trial site,

- g) the relevance and completeness of the informed consent form and the information process in connection with the obtaining of informed consent (cf. § 4-1),
- h) justification for research on persons who are unable to give informed consent (cf. § 4-2 and § 4-3),
- i) provisions concerning indemnity or compensation in the event of the injury or death of a subject as a result of a clinical trial,
- j) insurance or compensation to cover the liability of the investigator and the sponsor,
- k) the amount of, and the detailed rules for payment of any fee or compensation to investigators and subjects,
- l) relevant clauses in any intended agreement between the sponsor and trial site,
- m) arrangements for the recruitment of subjects.

The IEC shall have a maximum of 60 days from the date of receipt of a valid application pursuant to the first paragraph to submit its reasoned opinion.

A reasoned opinion of a clinical trial that involves gene therapy, somatic cell therapy or any medicinal product that contains genetically modified organisms shall be submitted within 60 days. This time period may be extended once by 30 days. The processing period of 90 days may be extended by a further 90 days if a group or committee has to be consulted.

There is no maximum time period for giving an opinion on a trial that involves xenogenic cell therapy.

Within the period of consideration of the application for an opinion, the IEC may once request supplementary information. The time limit is suspended until the supplementary information has been received.

Amendments as described in § 5-7, first paragraph, shall be examined by IEC before they are implemented. A reasoned opinion shall be submitted a maximum of 35 days after receipt of valid notification. If the opinion is unfavourable, the amendment may not be implemented.

The provisions in § 5-7 third paragraph *litra b* and § 5-7 fourth paragraph are similarly applicable to the IEC.

§ 1-6. Licence from the Norwegian Data Inspectorate

The sponsor shall arrange for the licence required pursuant to § 33 of Act no. 31 of 14 April 2000 relating to the processing of personal data (Personal Data Act).

§ 1-7. Further duty of notification for special studies

Clinical trials that involve gene therapy or the use of genetically modified organisms as medicinal products shall also be approved pursuant to Act no. 56 of 5 August 1994 relating to biotechnology.

Clinical trials of medicinal products that consist of or contain genetically modified organisms may involve the deliberate release of the organism, and shall be approved in advance pursuant to Act no. 38 of 2 April 1993 relating to the production and use of genetically modified organisms (the Gene Technology Act).

Chapter 2. Application for clinical trial

§ 2-1. Application for clinical trial

Applications for clinical trials shall be sent to the Norwegian Medicines Agency (hereinafter referred to as 'the NoMA') by the sponsor. The application shall contain:

- a) the information on the stipulated application form,
- b) a protocol, cf. § 2-2,
- c) supplementary information about the trial, cf. § 2-3,
- d) documentation of the medicinal product, cf. § 2-4,
- e) copy of the notification to the IEC, cf. § 1-5,
- f) copy of the written information it is planned giving patients or trial subjects, cf. § 1-4, and
- g) copy of confirmation of fee paid.

Under special circumstances, the NoMA may grant exemption from the requirements in the first paragraph relating to the contents of the application.

The application shall be signed by the sponsor.

The NoMA shall provide detailed guidelines as to how the application is to be formulated, and what documentation is to be provided.

Multi-centre trials are regarded as one trial. In these cases, one valid application signed by the sponsor shall be submitted.

§ 2-2. Protocol

The protocol shall contain the following:

- a) general administrative information,
- b) background to and objective(s) of the trial,
- c) type of trial,
- d) inclusion and exclusion criteria,
- e) treatment programme,
- f) registration of efficacy and evaluation of safety,
- g) choice of method and statistical grounds for the number of subjects and assessment of results,
- h) direct access to source documentation,
- i) verification of data quality and procedures,
- j) ethical considerations,
- k) data handling and storage,
- l) financing and insurance coverage and
- m) plan for publication of results (publication plan).

It shall also be specified whether the trial forms part of an international study.

§ 2-3. Supplementary information about the trial

In addition to the information provided in the protocol, the NoMA shall be informed of:

- a) principal investigator's professional qualifications for the trial in question,
- b) plan for termination of earlier treatment, if relevant,
- c) follow-up of subjects after the trial,
- d) plan for information to personnel concerned,
- e) preparedness in the event of complications,
- f) plan for handling medicinal products,
- g) review of which listings that will be kept for subjects in the trial, and overview of case record forms,
- h) insurance of subjects,
- i) labelling of the medicinal product packaging, and
- j) the place of the trial in the product manufacturer's overall plan for development of the product in question.

§ 2-4. Documentation of the medicinal product

A summary of the documentation regarding the chemical, pharmaceutical, toxicological, pharmacological (animal and human) and clinical properties shall be appended to the application. The scope of the documentation shall be appropriate to the current phase of the trial. An earlier phase should normally be concluded before the next phase is initiated.

When special reasons indicate the need, the NoMA may require that further information be submitted.

§ 2-5. Manufacture and import of medicinal products for clinical testing

Manufacture, including import, of medicinal products from countries outside the EEA, requires authorisation from the NoMA.

Manufacture shall proceed in accordance with the provisions in Regulation no. 635 of 30 June 1995 on the Manufacture and Importation of Medicinal Products.

Chapter 3. Assessment of the trial

§ 3-1. Requirement concerning assessment and reporting of the outcome of the assessment

The NoMA's assessment is based on the application and information provided pursuant to Chapter 2, and shall comprise an assessment of the product's quality, safety and assumed efficacy, the scientific standard, research methods, clinical relevance and quality assurance.

If the NoMA's assessment is unfavourable, the sponsor may amend the contents of the request once in order to take account of the ground(s) for non-acceptance. If the application is not amended accordingly, it shall be considered rejected, and the clinical trial may not commence.

§ 3-2. Time periods for considering a valid request for authorisation

A reasoned assessment shall be available 60 days at the latest after the submission of a valid request for authorisation pursuant to Chapter 2.

An assessment of a clinical trial that involves gene therapy, somatic cell therapy or any medicinal product that contains genetically modified organisms shall be submitted within 60 days. This time limit may be extended once by 30 days. The 90-day period may be extended by a further 90 days if a group or committee has to be consulted.

There shall be no maximum period for the assessment of a clinical trial that involves xenogenic cell therapy.

§ 3-3. The outcome and legal effect of a reasoned assessment

If the NoMA has not delivered its assessment within the time limit as specified in § 3-2, the trial may commence, provided that IEC has delivered a positive reasoned opinion.

A clinical trial may not commence without a written response from the NoMA if the trial concerns:

- a) a medicinal product without marketing authorisation as referred to in Part A of the Annex to Council Regulation (EEA) No. 2309/93
- b) a medicinal product in which the active substance is a biological product of animal or human origin,
- c) a medicinal product that contains biological components of animal or human origin, or the manufacturing of which requires such components,
- d) a medicinal product for gene therapy, somatic cell therapy, including xenogenic cell therapy, or
- e) a medicinal product that contains genetically modified organisms.

The NoMA can refuse to allow the trial to commence

- a) for reasons of patient safety,
- b) when the trial has not been planned in accordance with applicable rules, or
- c) if the NoMA finds it necessary for other special reasons.

Chapter 4. Consent, information and protection of privacy

§ 4-1. Requirement of informed consent

The subject's informed consent to take part in the trial shall be obtained before procedures relating to the trial commence.

The consent shall be obtained after the investigator, or the person who has managed the information process on behalf of the investigator, has given advance oral and written information about the trial. There must be written confirmation from the person managing the information process that the information has been provided.

The informed consent form shall contain information about:

- a) who is sponsoring the trial,
- b) who is responsible for conducting the trial,
- c) the objective(s) and execution of the trial,
- d) possible risk and inconvenience,
- e) possible alternatives to the trial treatment,
- f) termination of previous treatment, if relevant,
- g) that a proprietary medicinal product without marketing authorisation or a placebo may be involved in the trial,
- h) any follow-up treatment,
- i) insurance of subjects,
- j) contact point where the subject can obtain more information,
- k) that consent may be withdrawn at any time and the effects of this, cf. § 4-4,
- l) that Norwegian and foreign authorities etc. have the right of inspection of the patient records.

In connection with the third paragraph of *litra l*, subjects shall be informed that consent to take part in the trial is also consent to Norwegian and foreign government supervisory authorities from countries for which market authorisation for the product is being applied for, monitors and representatives of the sponsor's quality assurance unit, having the right of inspection of the data in the subject's records (cf. § 4-5).

The subject shall confirm that informed consent has been given. The consent shall preferably be given in writing. Oral consent shall be attested to by an independent witness.

§ 4-2. *Clinical trials on persons aged under 18*

Trials on persons aged under 18 may be conducted on the basis of informed consent from parents or others with parental responsibility if the following conditions are regarded as fulfilled;

- a) the person consenting has received written and oral information about the trial in accordance with § 4-1,
- b) the consent is presumed to express the will of the minor,
- c) the minor has received information about the trial, risk and benefits, adapted according to the capacity of understanding of the minor concerned,
- d) the trial can be expected to be of direct benefit to the patient group,
- e) the trial is crucial for verifying data obtained through clinical trial or other investigative methods on persons able to give informed consent,
- f) the trial either directly concerns a clinical condition from which the minor suffers, or the trial is of such a nature that it can only be conducted on minors,
- g) relevant guidelines from the European Medicines Evaluation Agency (EMA) are complied with,
- h) the trial is designed to minimise pain, discomfort, fear and any other risk in relation to the disease,
- i) the protocol has been endorsed by the IEC, which has expertise in paediatrics or has taken advice on clinical, ethical and psychosocial issues in the field of paediatrics, and
- j) the interests of the subject always prevail over those of science and society.

The view of subjects aged under 18 shall count as an increasingly important deciding factor, in pace with his or her age and maturity.

All use of inducements for minor subjects is prohibited, except compensation in connection with participation in the trial.

§ 4-3. *Trials on persons unable to or with limited capacity to give informed consent*

Trials on incapacitated persons or adults who are unable to give consent because of inadequate mental powers, an illness or other reasons, may take place after informed consent has been obtained from his or her legal representative, if the following conditions are regarded as fulfilled:

- a) the person consenting has received written and oral information about the study in accordance with § 4-1,
- b) the consent is assumed to express the subject's will, and the subject does not oppose himself or herself to the trial,
- c) the subject has received information about the trial, risk and benefits, adapted according to the capacity for understanding of the person concerned,
- d) there is reason to believe that the results of the trial will directly benefit the health of the subject,
- e) the trial is essential for validating data obtained through clinical trials or other research methods on persons able to give informed consent, and relates directly to a life-threatening or debilitating clinical condition from which the subject suffers, or the information cannot be obtained on the basis of consent given pursuant to § 4-1 and § 4-2,
- f) the trial only entails minimal risk and distress for the subject,
- g) the interests of the subject always prevail over those of science and society,
- h) the trial is designed to minimise pain, discomfort, fear and any other risk in relation to the disease, and
- i) the protocol has been endorsed by the IEC, which has expertise in the disease and patient group in question, or has taken advice on clinical, ethical and psychosocial questions relating to the disease and patient population in question.

§ 4-4. *Withdrawal of consent*

Consent to take part in a clinical trial pursuant to § 4-1, 4-2 or 4-3 may be withdrawn at any time. In the event of such withdrawal, participation in the trial will cease immediately. Patient data that has been collected up to the time of withdrawal of the consent will be included in the trial data, but no further data shall be collected.

§ 4-5. *Inspection of subject's record*

Norwegian and foreign government supervisory authorities from countries for which marketing authorisation is being applied for the product, monitors and the sponsor's quality assurance personnel, have the right to inspect data in the subject's record, under an oath of confidentiality, when the purpose is to verify the quality of the trial data. The right of inspection applies only to data in the subject's record which are necessary for quality assurance.

Inspection pursuant to the first paragraph does not imply the right to copy confidential subject's data. Record data may only be collected in anonymised form.

When the right of inspection has been granted, it shall be noted in the subject's record.¹

1 See Regulation no. 1385 of 21 December 2000 concerning patient records.

§ 4-6. *Duty of confidentiality in connection with inspection of patient records pursuant to § 4-5.*

Persons granted access to subject's records pursuant to § 4-5 shall observe confidentiality with respect to the data to which they gain access. The NoMA may require written confirmation of knowledge of the duty of confidentiality.

§ 4-7. *Information to subjects*

If, in the course of or after the trial, information of major importance that concerns the subjects should emerge, they shall be informed of it by the investigator.

Chapter 5. Requirements relating to the investigator and the trial

§ 5-1. *Requirements regarding the investigator's qualifications*

The investigator shall have the necessary professional qualifications to conduct the clinical trial in question, cf. § 1-2 litra d and § 2-3 litra a.

§ 5-2. *International rules for trials*

Clinical trials shall take place in compliance with the Helsinki Declaration and subsequent revisions thereof.

Trials shall also be conducted in compliance with the European guidelines for GCP¹, the EU Directive for the implementation of GCP in the conduct of clinical trials² and Annex 13 to the EU guidelines for GMP.³

- 1 See Note for guidance on Good Clinical Practice (CPMP/ICH/135/95).
- 2 See Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (Commission Directive 2001/20/EC).
- 3 See Annex 13 to Principles and guidelines for good manufacturing practice for medicinal products for human use (Commission Directive 91/365/EEC).

§ 5-3. Protocol and source data etc.

Trials shall take place in accordance with the protocol (cf. § 2-2). All equipment shall be available during the trial on the premises of the investigator in question.

It shall be ensured that source data is available at the trial site for at least 15 years after the final report is available.

All procedures and all records, located with all those who are or have been involved in the conduct of a trial, shall be available for at least 15 years after the final report is available.

§ 5-4. Labelling and dispensing of the medicinal product

The following information shall appear on the packaging of the medicinal products used in the trial:

- a) name, address and telephone number of the sponsor, CRO or investigator (main contact for information about the product, the trial and unblinding),
- b) the pharmaceutical form of the medicinal product,
- c) means of administration,
- d) dose,
- e) the name of or code for the medicinal products, and for open trials the strength/potency,
- f) batch number and/or ID number, to identify contents and packaging procedure,
- g) trial code,
- h) subjects' identification number/trial number,
- i) name of principal investigator,
- j) technical instructions for use (if necessary, reference may be made to a brochure or other explanatory document which is intended for the subject or other user),
- k) conditions for storage, and
- l) expiry date in clear text (month/year).

In addition, medicinal product packages shall be labelled

- a) "For clinical trial", and
- b) "Keep out of the reach of children", except when the medicinal product is being used in trials where the product is not taken home to the subject

Labelling shall be in Norwegian.

The medicinal products shall be dispensed from a pharmacy or the Pharmaceutical Department of the hospital, and be stored and handled in collaboration with these institutions.

The NoMA may on application grant exemption from the requirements in this provision.

§ 5-5. The investigator's duty to report adverse events

The investigator shall immediately report to the sponsor all serious adverse events that are not described in the protocol, in the investigator's brochure and/or in the SPC. The immediate reports shall be followed up with more detailed written reports. Immediate and follow-up reports shall be identified by means of unique codes.

The investigator shall report to the sponsor adverse events and/or abnormal laboratory test values defined as critical in the protocol.

In the event of reported deaths, the investigator has a duty to supply the sponsor, the NoMA and the IEC with the supplementary information that is requested.

§ 5-6. The sponsor's duty of notification

The sponsor shall ensure that all suspected adverse reactions that are fatal or life-threatening, and which are unexpected, are reported to the NoMA and to the IEC, immediately and no later than seven days after the sponsor has learned of the event. Relevant follow-up information shall be reported within a further eight days.

The sponsor shall ensure that suspected adverse reactions that are serious and unexpected are reported to the NoMA and to the IEC within 15 days of the sponsor after knowledge of the event.

The sponsor shall inform all investigators of the trial substance in question of suspected adverse reactions that are serious and unexpected.

An account of any interruption in treatment or any breaking of the treatment code, the investigator's assessment of the causal relationship, and consequences for further testing shall accompany the notification of suspected adverse reactions pursuant to the first and second paragraphs.

The NoMA may require that individual reports of adverse events described in collective reports should also be submitted.

The sponsor shall keep detailed records of all adverse events that are reported to him by the investigator. The records shall be submitted to the NoMA on request.

§ 5-7. Duty of notification in the event of amendments to the trial

The sponsor shall inform the NoMA if it is desirable to make substantial amendments to the protocol:

- a) that may have an impact on the safety of the subjects, or
- b) that may change the interpretation of the scientific documentation, or
- c) that are of significance from any other point of view.

The information pursuant to the first paragraph shall be provided in writing, and shall contain grounds for the amendment. The amendments shall be considered by the NoMA before they are implemented, cf. § 3-1 – 3-3.

The sponsor shall inform the NoMA if:

- a) the trial does not commence according to plan, or
- b) if the trial is interrupted before it is completed. The information shall be provided in writing within 15 days and contain grounds for the interruption.

If the changes in the trial or medicinal product may have an impact on the safety of the subject, the sponsor and the investigator shall immediately ensure that the subject does not suffer injury. The sponsor shall immediately inform the NoMA of the changes and the action that has been taken.

§ 5-8. Duty of notification of changes etc. in the medicinal product

All substantial amendments to the documentation for the medicinal product shall be reported to the NoMA, including:

- a) all changes in chemical and pharmaceutical documentation,
- b) all changes in pharmacological (animal/human), toxicological and clinical documentation that may be assumed to be of significance for the further progress of the trial.

Reports pursuant to the first paragraph shall be processed according to the rules in § 3-1 to § 3-3.

§ 5-9. Annual report and final report

For long-term trials, the sponsor shall submit annual reports to the Norwegian Medicines Authority and the REC. The report shall contain:

- a) information about the trial status,
- b) a report listing all suspected serious adverse reactions that have occurred in the period to which the report applies, and
- c) information about the safety of the subjects.

In the case of multi-centre trials, a report shall also be submitted once a year listing all suspected serious adverse reactions that have occurred in the period to which the report applies.

The sponsor undertakes to notify the NoMA and the IEC that the trial has ended a maximum of 90 days after the end of the trial.

The sponsor shall submit a final report to the NoMA one year at the latest after the end of the trial. This time limit may be extended by the NoMA on application.

The final report shall be drawn up in compliance with the currently applicable guidelines.

Chapter 6. Supervision and suspension

§ 6-1. Supervisory authority

The NoMA exercises supervision to verify compliance with the provisions of this regulation.

The Norwegian Board of Health supervises the health service provided in connection with trials, cf. Act no. 15 of 30 March 1984 relating to government supervision of the health service. The NoMA shall at the request of the Norwegian Board of Health provide information as to which doctors/dentists are engaged in trials, and about conducted and planned inspections.

§ 6-2. Inspection

As part of the supervision, the NoMA may conduct inspections of the premises of all those who are or have been involved in the conduct of the trial. This applies to all stages of a trial, and also after the end of a trial.

Inspections may be conducted without prejudice to statutory confidentiality (cf. § 28 second paragraph of Act no. 132 of 4 December 1992 relating to medicines etc.)

Foreign government supervisory authorities shall inform the NoMA in advance of inspections of trials that are to be conducted in Norway.

§ 6-3. Suspension of clinical trials

A clinical trial that has commenced may be suspended at any time by the NoMA in the interests of patient safety, when the trial is not taking place in compliance with currently applicable provisions, or if the NoMA finds it necessary for other special reasons.

Chapter 7. Entry into force

§ 7-1. Entry into force

This regulation shall enter into force on 1 May 2004.

At the same time, Regulation no. 742 of 18 June 1999 relating to clinical trial of medicinal products shall be repealed.