

Patient information letter for MS quality registry

Dear Sir/Madam,

You have multiple sclerosis (MS) and are being treated for its symptoms. Neurologists in the Netherlands are continuously searching for the best treatment methods.

In the Netherlands, the Netherlands Society of Neurology (Nederlandse Vereniging voor Neurologie, 'NVN'), the National Association of MS Nurses (Landelijke Vereniging van Multiple Sclerose Verpleegkundigen, 'LVMS') and the MS Society Netherlands (Multiple Sclerose Vereniging Nederland, 'MSVN') have formed a partnership with the aim of analysing and further improving the care given to patients with multiple sclerosis.

This is only possible with good insight into the effects of existing treatments. What works well, what works better? Obtaining and making a comparison of treatment data are essential for that insight. The Neurology Registry Foundation (Stichting Registratie Neurologie, 'SRN') has been set up for that purpose.

We would like to ask your consent to store your data, including medical data relating to MS, in a new, central registry. These data are protected by medical confidentiality and are subject to statutory privacy rules. The organisations involved in maintaining the registry have made agreements with one another to ensure your personal data are handled with due care. The SRN has appointed certified data administrator Healthcare Information Service (Stichting Informatie Voorziening Zorg, 'IVZ') to process the collected data and store them in a database.

Why the need for this registry?

The complexity of MS means that a standard treatment is not available. A variety of different medicines can be prescribed. Recording these different medicines and their effects in a registration system facilitates our understanding of the effect on you as an individual patient as well as the group of people with MS. Collecting and analysing this information will improve insight into the quality of the care that is provided. By participating in this registry you are therefore making a contribution toward better treatment options, for you as well as other MS patients. The data are also used for scientific research aimed at improving the quality of care.

Your personal and medical data

It is important that your name, gender, date of birth, Citizen Service Number (BSN) and email address are registered to enable the correct processing of your medical data and allow feedback to be provided to the doctor treating you. These personally identifiable data will be replaced with a code by IVZ before they are recorded in the database, so that it is not possible to connect the patient to the data that are stored. This is known as 'pseudonymisation'. Your coded data may be shared with trusted research partners in the Netherlands as well as other countries, for example in order to compare the data from different registries.

It is important that your email address is registered so that you can be contacted and asked to fill in a short questionnaire that is then shared with the doctor treating you. The questionnaire includes a number of questions about the quality of life experienced by you in relation to your health. The data are stored for a maximum period of 15 years.

Your data are compared with the treatment data of other MS patients and this comparison is then shared with the medical specialist treating you. The medical specialist treating you is the only person who can access your personal data. The comparison made by the computer is undertaken using coded data. This means that the individual concerned cannot be identified through the processing operation. The medical specialist may be informed however that the information being shared concerns his/her patient.

Confidentiality and your rights

All the persons involved in this registry are obliged to maintain confidentiality. Your data will be safely stored. Storage and processing of the data meet the statutory safety and due care requirements and there is strict monitoring of compliance with those requirements. If additional research is to be undertaken, you will once again be asked for your consent in that regard. We may contact you in the future in this connection.

In very exceptional circumstances, the coding may be disabled by the lead developer at IVZ, to enable identification of a particular individual from the data. This is only permissible in the event that it is necessary for the individual patient to be contacted for medical reasons and only after the hospital where the patient concerned is being treated has given explicit consent for coded data to be used to identify a particular individual. Should a security-related incident occur (also referred to as a 'data breach'), this will be reported to the Dutch Data Protection Authority (Autoriteit Persoonsgegevens).

You have the right at all times to know which data relating to you are being processed, to access those data and, if your data are incorrect, to have them rectified. You also have the right at all times, and without giving any reason, to withdraw from the registry and to have your data deleted/removed from the database. In case you withdraw from the registry, your data will not be used in future analyses. Your data can not be withdrawn from previous analyses. You can arrange withdrawn from the registry with the doctor treating you.

Each year, a report will be drawn up setting out the overall results of the registry and the analysis of the data. This report will not contain any patient information and will be made available to the National Health Care Institute (Zorginstituut Nederland, part of the Ministry of Health, Welfare and Sport).

Participation in this registry is voluntary. That means that the process is free of charge for you, but also that you do not receive any fee for participation. The same also applies to the neurologist and the other care providers involved, such as MS nurses. The doctor treating you can give you further information on the new registry.