



RECORDED DELIVERY  
Preventative Medical Centre  
Mr R.T.H.K. Trossel  
Joost Banckertsplaats 24-29  
3012 HB ROTTERDAM

Our reference	Contact person	Extension number	The Hague
CZ-B 2721578	Mw. S.L.J. Bos	070-3406476	9 October 2006
Subject	Enclosure(s)		
Extension of order under article 7 of the Care (Quality) Act			

Dear Mr Trossel,

In my letter to you of 3 October 2006, posted on 4 October 2006, I informed you of my intention to extend the order of the Health Care Inspectorate (hereunder IGZ) of 2 October 2006. As you are aware, this decision was based on the letter from the Deputy Inspector General for Health Care of 4 October 2006 (incorrectly dated 3 October 2006). In this letter the IGZ states on page 2 under point 5 that the safety and quality of the stem cells used by the Preventative Medical Centre (hereunder PMC), which are supplied by Umair's Clinic in Pakistan, cannot be established. The IGZ explains this in subsections a to d under point 5 on page 2 of the letter of 4 October 2006.

At the hearing of 5 October 2006 you were given the opportunity to make your views on this intention known. The argument you put forward on this occasion is summarized as follows. You are of the opinion that the products used by the PMC are safe and may moreover be traced from donor to recipient. Furthermore, you argue that the laboratory that supplies the stem cells is equipped with a quality control system and that certificates of analysis for the cells have been provided. Furthermore, protocols are operated by the PMC and a plan of approach has been submitted to the IGZ, as specified during the hearing.

For the sake of completeness I refer you to the enclosed report of the hearing of 5 October 2006, a draft of which was presented to you on 6 October 2006. Your comments on the report are recorded in the final version.

I see insufficient reason to reverse the decision to extend the order, in view of the following.

Article 2 of the Care Institutions (Quality) Act stipulates that a care provider must provide safe health care. This is understood to mean health care of a good level, that is effective, appropriate and patient-oriented, and geared to the patient's needs. This legal standard is of a general nature and is to be interpreted by the care provider according to circumstances. Furthermore, it is important that in interpreting the term safe health care, consideration must be given to legal standards and, among other things, consensus guidelines, protocols, the standards of professional groups, and scientific reports. An example of such a standard is included in the Requirements Decree for Bodily Material (Decree of 5 March 2004, Dutch Bulletin of Acts and Decrees 123), based on the Safety and Quality of Bodily Materials Act. This decree establishes that an organ bank must organize its administration in such a way that information on the donor, the identity of the material, and the processing may be linked. It also stipulates that the organ bank must maintain a quality control system.

The provisions of articles 3 and 4 of the Care Institutions (Quality) Act are also relevant. These articles place specific obligations on the care provider. Article 3 of this act stipulates that the care provider must organize health care provision, provide a quality and quantity of staff and resources, and ensure a division of responsibility, such that this may reasonably be expected to result in safe health care. Pursuant to article 4 paragraph 1 of the act referred to above, the implementation of article 3 also entails the systematic monitoring, management and improvement of the quality of care. The second paragraph of article 4 states that the care provider is responsible for:

- a. systematically compiling and recording data on the quality of care;
- b. on the basis of the data referred to in a, systematically evaluating the extent to which the implementation of article 3 results in safe health care;
- c. on the basis of the evaluation referred to in b, where necessary altering the way in which article 3 is implemented.

I have concluded that on the basis of the documentation known to me, including the documents produced by you during the hearing of 5 October 2006, and in view of the matters dealt with during the hearing, the PMC has not been able to demonstrate convincingly that it meets the standard for safe health care. This conclusion is based on the following points.

1. I have determined that the PMC has not been able to produce a certificate of analysis for each delivery whereby it is clearly demonstrated that the donor cells have been tested for the usual risks, and at least for those referred to on page 3 of the IGZ's order under the heading 'Risk', and whereby there is a correlation between the batch number and the donor.

Regarding the certificates of analysis for the stem cell batches RLS 133 and RLS 173 produced during the hearing of 5 October 2006, I observe the following. The certificate for lot number RLS 133 states the same 14 test results as the certificate previously sent to the IGZ for lot number RLS 132. Two extra tests have been added to the certificate of analysis for lot number RLS 173, whereby it does contain all the necessary test data as previously indicated by the IGZ, but it is neither dated nor signed. The document is therefore not authorized. For this reason I deem it to be invalid. The laboratory's working method does not follow a Standard Operating Procedure or other protocol, on the basis of which tests on

umbilical cord blood from which stem cells are obtained for the treatment of patients must be carried out according to a set standard.

2. The ISO 9001:2000 certificate of 9 February 2004 from Swisso, as produced during the hearing of 5 October 2006, states that the quality control system of Citi-lab in Pakistan meets the relevant ISO standard. The certificate refers to 'clinical, pathological and diagnostic services'. It is not clear whether the activities of Umair's Clinic are covered by the same certificate. Even if this were the case, it is not apparent from the import-export certificate from the Pakistani authorities of 31 May 2006 that it relates to stem cells from umbilical cord blood intended for the treatment of patients. During the hearing of 5 October 2006 you explained this by observing that at the end of May 2006 the export of stem cells was not in question. In view of this I consider it implausible that at the time of the certification by Swisso in 2004 work was indeed taking place using stem cells. I also therefore cannot reasonably consider the certificate produced to be adequate for reliable conclusions to be drawn regarding the quality of the acquisition, processing and storage of the stem cells in Umair's Clinic.

3. During the hearing a declaration by Dr Umair Ahmed was also produced, in which he states the following: "It is certified that the Blood Components that are being manufactured and sent are for human use, are non-infectious and non destructive in nature." I cannot reasonably attach any significance to this document because its validity is not indisputable; in view of the fact that the declaration is made by the doctor himself and not by an institution, its validity cannot be guaranteed. The suitability for human use of the stem cells used by the PMC is therefore not certain.

4. On 22 September 2006 the PMC sent the IGZ a plan of approach and on 27 September 2006 a letter detailing a set of eight procedures. The plan of approach insufficiently guarantees the origin, suitability and safety of the products used by the PMC. It contains under point 10 only the intention to have an auditor carry out a supply audit. The scope of the audit is not established and the results are not yet known. I note that the protocols are not supplied with standard references such as date, authorization and protocol holder. Moreover, the procedure described in the protocols significantly differs from that which is usual in stem cell therapy as applied in Dutch hospitals. Apart from the administration of stem cells, in particular the unusual procedure consists of the administration of several products of which the effectiveness has not been scientifically proven, such as cells or cell extracts from animal placentas, the vitamin preparation Gerovital, and RNA. This creates additional risks for the PMC's patients.

In view of the above, pursuant to article 7 paragraph 4 of the Care Institutions (Quality) Act, I hereby extend the order to discontinue the application of stem cell therapy. If you fail to comply with the extended order, administrative enforcement will be applied or a financial penalty will be imposed.

This extension of the IGZ's order is valid until such time as it has been adequately demonstrated that the PMC is able to provide safe health care as referred to above. This may be regarded as being the case when at least the following documents have been produced:

- a. a verifiable certificate from a recognized certifying body regarding the quality control system of the stem cell bank and the laboratory that processes the stem cells used by the PMC;
- b. a certificate of analysis for each delivery whereby it is clearly demonstrated that the donor cells have been tested for the usual risks, and at least for those referred to on page 3 of the IGZ's order under the heading 'Risk', and whereby there is a correlation between the batch number and the donor.

An interested party may object to this decision pursuant to article 7:1 of the Dutch Administrative Law Act. A written objection may be submitted to the Ministry of Health, Welfare and Sport, attn. Legislation and Legal Affairs Directorate, PO Box 20350, 2500 EJ The Hague, Netherlands. The term within which an objection may be submitted is six weeks. This term commences from one day after the date of the decision. The objection must be signed by the person submitting it, must include his or her address and the date, and must specify the disputed decision, for example by stating the case number, reference number and date, or by enclosing a copy of the decision and the grounds for objection.

The Minister of Health, Welfare and Sport  
p.p. the Curative Care Director  
M.J. Boereboom

Enclosures:

1. the report of the hearing of 5 October 2006
2. the three documents produced during the hearing of 5 October 2006