THE NATIONAL OMBUDSMAN - THE NETHERLANDS

- English translation of the summary of the report about the investigation of the National Ombudsman on the attitude of the Dutch Government towards protecting haemophiliacs against the risk of infection with the AIDS virus via the transfusion of blood products.

July 18th 1995

13. SUMMARY

At the request of the Netherlands Association of Haemophiliacs, the National Ombudsman has investigated the attitude of the Dutch Government towards protecting haemophiliacs against the risk of infection with the AIDS virus via the transfusion of blood products. The investigation focused on the attitude of the Ministry of Welfare, Health and Cultural Affairs (now: Health, Welfare and Sport) between 1982 and 1989. During the course of the investigation both the petitioner and the Minister of Health, Welfare and Sport were given the opportunity to explain their standpoints. In addition, the National Ombudsman appointed an independent expert. Additional information was obtained from the Red Cross Central Laboratory for Blood Transfusion Services (CLB) and the Netherlands Association of Haemophilia Specialists (NVHB).

The petitioner's general complaint pertained to the attitude of the Ministry of Health, Welfare and Cultural Affairs following reports, in mid-1982, of the discovery of a new virus, later known as the AIDS virus, that was transmittable via blood and blood products, and its response to early indications from the field that haemophiliacs ran the risk of being infected with this virus. This general complaint was subsequently broken down into five sections covering specific aspects of the complaint.

The report has been subdivided into a number of chapters. Prior to presenting the results of the investigation in Chapter 8, along with a thorough reconstruction of relevant events during the 1977-1989 period, the report discusses a number of topics which formed the background and framework of the National Ombudsman's investigation.
Following the introduction and three chapters, which respectively cover the decision to investigate, the formulation of the complaint and the extent of the investigation, Chapter 5 takes a look at the relevant legislative framework. In this chapter, the main point of focus is the significance of the first paragraph of Article 22 of the Dutch Constitution. Subsequently, a number of relevant

provisions stipulated in public health legislation—particularly those pertaining to the supply of blood—will be discussed. These legislative provisions will then serve as a basis for sketching the organisation of the blood supply services in the Netherlands.
Chapter 6 covers background information and includes a description of haemophilia and its treatment. Haemophilia is a hereditary disorder that affects blood clotting. Due to the absence (or limited efficacy) of specific blood-clotting factors, the blood does not coagulate or forms weak clots. People who suffer from the most common form of haemophilia, haemophilia A, have a deficiency or total lack of factor VIII. Haemophilia B is characterised by a deficiency or lack of factor IX. Haemophiliacs are treated with antihaemophilic concentrates: haemophilia A is treated with factor VIII concentrate (and, until 1991, with cryoprecipitate) and haemophilia B is treated with four-factor antihaemophilic concentrate (PPBS). Cryoprecipitate is derived from a pool of up to 16 donations, factor VIII concentrate and PPBS are derived from pools of between 2,000 and 3,000 donations. Unlike the United States, where people may be reimbursed for donating blood, donation is strictly voluntary in the Netherlands. People can donate blood at one of the 22 regional Red Cross blood banks or at the CLB. In the Netherlands, factor VIII concentrate and PPBS were produced exclusively by the CLB, while cryoprecipitate was produced by both the CLB and the blood banks.
It is estimated that 170 Dutch haemophiliacs, out of a total of 1,300, were infected with the AIDS virus between 1979 and 1985. On 31 December 1994, it was established that 55 of these patients had contracted AIDS, and that more than half of them had already died as a result of the disease.
In addition, Chapter 6 will assess the situation in a number of other countries and will take a look at the way in which the Netherlands and various other countries have developed systems of compensation for those involved.

Chapter 8A, which partly covers the results of the investigation, includes a chronological overview of facts and events pertaining to the treatment of haemophiliacs prior to the discovery of AIDS, and the development of tests for screening preparations in order to prevent the spread this disease. This will be followed by a chronological rundown on the development of the AIDS epidemic, scientific research into the cause of the disease and the discovery of the AIDS virus. Subsequently, the development and introduction of the AIDS test will be discussed. Other topics of discussion will include government prevention and information campaigns, blood donation and registration policy, and the contamination of a product supplied by the American company, Armour. The chapter will conclude with an overview of the spread of AIDS in the Netherlands. In Chapter 8B, which includes the rest of the results, each of the five specific aspects of the complaint will assessed individually.

Chapter 8C contains a number of general issues pertaining to the government's attitude and actions.

The following may be concluded on the basis of the investigation.
Owing to a lack of sufficient donor blood in the Netherlands, factor VIII preparations (which had not been heat-inactivated) were imported from the United States as of 1977 (at the latest). In the summer of 1981, the first reports of a new disease, later known as AIDS, started to reach the Netherlands. As of early 1983, there was growing conviction that the disease was in all probability being caused by a virus. However, it was not until the end of 1983 or early 1984 that this became a point of fact. By which time sufficient scientific proof had been gathered to report that the virus could be transmitted via blood products. In 1985, a method of testing blood samples for the presence of HIV antibodies became available. The CLB started using this test in April 1985. The blood banks did so in June of the same year. During the course of 1983 and 1984, a number of articles were published on the (possible) efficacy of heat as a way of inactivating the AIDS virus. By the end of 1984/1985, sufficient proof had been gathered that heat-inactivation was indeed effective. In August 1984, the CLB decided to start inactivating blood products using heat.
The CLB started supplying heat-inactivated factor VIII concentrate in June 1985. Heat-inactivated PPBS became available in July 1985, while heat-inactivated cryoprecipitate became available in December 1985. In May 1983, Hyland introduced a heat-inactivated factor VIII product. As of June 1983, the Factorate preparation, produced by Armour, was also heat-inactivated. In early 1986, the first consultations were held on the development of regulations for the preparation of factor VIII products. These consultations led to the drafting of the Norm Registration Document (NRD) in June 1986. In spite of the fact that consensus was reached on the date of implementation—18 June 1987—it was not until 1 January 1988 that the NRD was implemented. From that date on, blood banks producing cryoprecipitate were also compelled to inactivate their products using heat.

Having presented the findings of the investigation, the National Ombudsman's assessment will be presented in Chapter 9.
Prior to assessing the five specific aspects of the complaint, the National Ombudsman had to establish the role of the government and, more specifically, the role of the Minister/Secretary of State for Public Health. This role was to a great extent determined by the structure of 'the field', and the manner and extent to which 'the field' executed its tasks. With regard to health care for haemophiliacs, it may therefore be concluded that the government and 'the field' had a shared responsibility. The government moreover, had an additional responsibility owing to the fact that it had a

number of specific instruments at its disposal, which, at least in part, only it could apply. The manner in which the government implements one or more of these instruments, is dependent, *inter alia*, on the gravity of the threat to public health and on the extent of the assurances that 'the field' has reacted to this threat promptly and adequately. In the case of diseases with an epidemiological character, such as AIDS, it is imperative that the government should be actively involved in combating the disease.

A variety of extenuating circumstances have a bearing on the assessment of the role played by the government in this case. These circumstances include the fact that there was insufficient blood plasma in the Netherlands to meet domestic needs. Furthermore, the organisational structure of the blood transfusion services became a point of debate, and, when the possibility of excluding people from risk groups as donors was discussed, it became clear that homosexual men saw exclusion as a form of discrimination. It also bears mentioning that, in order to give a fair assessment, it was clear that the circumstances would have to be viewed in the context of the information that was then available. We therefore had to reconstruct what information was, or may be assumed to have been, available to the government at a specific point in time. Considering the available knowledge and the prevailing circumstances, and keeping in mind the issues discussed above, we subsequently had to establish what sort of reaction might reasonably have been expected from the government.

The first of the five sections of the complaint pertains to the ministry's purported negligence in failing to (promptly) gather information in the field concerning the possibility of AIDS infection via blood products, and its failure to formulate relevant policy on the basis of this information. With regard to the gathering of information in the field, it was established that the NVHB had already initiated research into the possibility of HIV infection among haemophiliacs in early 1982. The government therefore decided that it was unnecessary to launch research programmes of its own. The National Ombudsman's investigation also revealed that the government was both promptly and adequately informed of the results of the ongoing research programmes. With regard to the formulation of policy, the petitioner argued that, on the basis of the available information, the government should have taken action on two occasions during the 1983-1985 period. The first instance primarily involved HIV infection resulting from the use of American products that had not been heat-inactivated. In this case, the National Ombudsman concludes—and will elaborate on this viewpoint in the second section of the complaint—that the government was actively involved in finding solutions to the problems at hand. However, in view of the fact that 'the field' had taken charge of the problem and had advised medical practitioners and patients to revert to Dutch antihaemophilic concentrates, the

government concluded that there was insufficient pretext for intervention.
The second instance involved the formulation of policy in reaction to reports of HIV infection via Dutch antihaemophilic concentrates that had not been heat-inactivated. In this case, the National Ombudsman concludes that by the end of 1984/beginning of 1985 there was sufficient proof that the heating of antihaemophilic concentrates could be effectively used to inactivate the AIDS virus. At that time, heat-inactivation was already being used in the production of American factor VIII concentrates. Moreover, in late 1984 there were indications that it was unwise to assume that plasma from Dutch donors was not infected with the AIDS virus. This information, which was available prior to the introduction of the AIDS test and heat-inactivation in the Netherlands, warranted an in-depth discussion as to whether it was prudent to treat (continue treating) haemophiliacs with concentrates that had not been heat-inactivated. However, there are no reports of any discussion of this kind, and apparently 'the field' did not react to the warning signals. We therefore conclude that in late 1984/early 1985, the government should have initiated a broad public discussion of the risks involved in using Dutch antihaemophilic concentrates that had not been heat-inactivated, and, at the same time, should have considered the possibility of temporarily reverting to heat-inactivated products from abroad. There may even have been sufficient pretext for the government to prohibit the use of all concentrates that had not been heat-inactivated, thus excluding all risks.

The second section of the complaint involves the fact that the ministry failed to prohibit the import of non-purified American antihaemophilic concentrates in late 1982/early 1983. The National Ombudsman's investigation revealed that in 1983 it had become clear that the risk of AIDS infection was higher for people using factor VIII concentrate, than for those using cryoprecipitate. The fact that American donors were paid for donating blood, coupled with the fact that AIDS was relatively widespread in the United States, increased the probability that American non-heat-inactivated factor VIII concentrates posed a greater threat of infection than non-heat-inactivated Dutch products.
In February 1983, the government announced that it intended to prohibit the import of antihaemophilic concentrates from abroad. This intention is testimony to the alertness of the government. However, the petitioner and the NVHB immediately informed the Secretary of State for Health, Welfare and Cultural Affairs that they wished to discuss the issue first. The petitioner subsequently submitted a written memorandum arguing that, and why, an import stop was undesirable at that time. In this memorandum, the petitioner indicated that the NVHB had already advised against using imported concentrates. In view of the aforesaid, and particularly in light of the fact that the NVHB had already published guidelines indicating

that they were well aware of the risks involved in using imported concentrates in 1983, the National Ombudsman concludes that it was understandable that the government refrained from imposing an import stop at that time.

The third section of the complaint pertains to the ministry's negligence in failing to promptly compel Dutch producers to switch to heat-inactivated antihaemophilic concentrates.

In early 1986, 'the field' initiated consultations on the development of regulations for the preparation of factor VIII concentrates. This led to the drafting of the NRD by the Government Control Laboratory in June 1985. In this document, virus inactivation by means of heat treatment was made compulsory. In addition, the parties involved agreed on a one-year transitional period, ending in June 1987; the NRD was set to be implemented on 18 June 1987. In light of the aforesaid, and in view of the fact that there was sufficient proof of the efficacy of heat-inactivation at the end of 1984/beginning of 1985, one might well ask whether the government—in an effort to exclude all risks—might not have been better advised to give the blood banks the option, at a much earlier date, of either heat-inactivating cryoprecipitate or temporarily discontinuing production of this concentrate. Whatever the case may be, the ministry may rightly be accused of negligence in the drafting of the NRD and in its implementation, which came into effect on 1 January 1988 following a six-month delay.
With regard to the concentrates used in the treatment of haemophilia B, the investigation revealed that the first heat-inactivated PPBS was made available by the CLB on 22 July 1985. In view of the fact that the CLB was the sole producer of this concentrate in the Netherlands, the government rightly decided that it was unnecessary to impose strict regulations enforcing the use of heat-inactivation in the production of said concentrates.

The fourth section of the complaint pertains to the ministry's negligence in that it waited until early 1988 before prohibiting the sale of heat-inactivated factor VIII concentrates produced by the American company, Armour. Even though the Academic Medical Centre (AMC) had already reported in early 1986 that these products had led to HIV infection. In this instance, the National Ombudsman concludes that the government, owing to its responsibilities in the field of public health, should have been aware of developments in this field and of any events or reports that might have warranted direct intervention on its part. In other words, the government was duty bound to actively gather and interpret all relevant scientific information. The National Ombudsman's investigation revealed that the ministry was neither aware of the article on seroconversion published in The Lancet, nor of an abstract pertaining to this seroconversion. The ministry may therefore be accused of negligence, because, on the

grounds of the reported seroconversion, the ministry should have checked whether the Armour product in question was still available on the market and, if this was indeed the case, it should have assessed whether there was sufficient reason to prohibit its sale.
Furthermore, the investigation revealed that, as of June 1983, there was an extended period of uncertainty as to the clinical efficacy of the factor VIII concentrate imported by Tramedico. In view of the fact that an import permit had yet to be granted for this product, the ministry had sufficient reason—certainly considering its supervisory duties—to prohibit the import of this product.

The fifth section of the complaint pertains to the petitioner's claim that the ministry failed to promptly and adequately inform medical practitioners, haemophiliacs and donors of new developments.
With regard to the medical community, which includes haemophilia specialists, the National Ombudsman concludes that this group could or should have kept abreast of developments in their field via the usual professional channels. However, the government has a duty to inform the medical community in acute situations or in situations where doubts arise as to whether the information will reach the medical community on time. In this instance, the Chief Health Inspector sent out circulars to the entire medical community on a number of occasions, directly informing them of the latest developments relating to AIDS. The National Ombudsman found no examples of situations in which the government had neglected its duty to inform the medical fraternity of significant new developments.
With regard to patients, the minister has rightly argued that it was the duty of the medical community to inform their patients of new developments. It also bears mentioning that the government indirectly contributed to the provision of information to haemophiliacs by subsidising information campaigns and projects run by the petitioner.
With regard to donors, the minister has rightly argued that it was the duty of the blood banks to inform their donors of new developments. Here again it must be said that the government took adequate action, by actively contributing to campaigns which aimed to convince people from risk groups that they should refrain from donating blood, and by subsidising such campaigns.

All things considered, the National Ombudsman concludes that, in principle, the role played by the government is supplementary to the activities initiated in 'the field'. However, in this case there were situations/moments—especially those in which 'the field' failed to take action—which should arguably have prompted government intervention. On the grounds of our investigation, we must conclude that the government did not entirely fulfil its duties in this regard. In reference to various sections of the petitioner's complaint, we conclude that on a number of occasions the government failed to keep

abreast of new developments/reports and/or either failed to promptly react to the changing state of affairs or adopted an overly passive stance.

The question of a possible causal link between the shortcomings of the Dutch government prior to 1 January 1988, and certain cases of HIV infection among haemophiliacs during this period, is beyond the scope of the investigation requested by the Netherlands Association of Haemophiliacs. The same applies to the question of whether the government, regardless of its possible liability for damages in individual cases of HIV infection, is partly to blame for the consequences of risks run by haemophiliacs during the period in question, and the question of whether it should have done more in this regard than it has until now. The answers to these questions are a matter of political debate.

Translators' notes:

- For the following names of organisations in the text we have used:
  * Nederlandse Vereniging van Hemofilie-Behandelaren = Netherlands Association of Haemophilia Specialists
  * Rijks Controle Laboratorium = Government Control Laboratory