

Ministry of Health, Welfare and Sport

> Return address: PO box 20350 2500 EJ The Hague

Visiting address:
Parnassusplein 5
2511 VX The Hague (Holland)
www.rijksoverheid.nl

The Speaker of the Second Chamber of the
Estates-General
PO box 20018,
NL-2500 EA THE HAGUE

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Attachment(s)
1

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Date: 10 July 2012
Subject: Investigation of Sanquin's cost allocation by
Research Agency ConQuaestor

Mr. Speaker,

With my letter of 13 July 2011 I sent you the final report entitled "Sanquin's Cost Allocation and the storage life of supplies of plasma medicinal products" by the research agency ConQuaestor. With the present letter I am sending you my views on the aforementioned report.

You will receive separately the Ministerial Plan for Blood Supplies 2012-2014, setting out the policy framework regarding blood supplies for the coming period. My views and the ministerial plan constitute the basis for Dutch blood supplies for the near future.

Background

The Blood Supplies Act (BSA) came into force in 1998 and since then there has been a single blood supply organisation. The *Stichting Sanquin Bloedvoorziening* (Sanquin) has been appointed to this task on the grounds of the BSA by the Minister of Health, Welfare and Sport. The BSA sets out the frameworks for efficient and effective blood supplies. The basic principles here are that the aim will be towards *national self-sufficiency with voluntary donations of blood without reward*.

Sanquin is a so-called hybrid organisation, comprising a public and a private branch organisation-wise. The public branch of Sanquin consists of the Bloodbank division, which is responsible for collecting blood and plasma, preparing the so-called 'short-lived' blood and intermediary products and the delivery thereof to respectively the hospitals and Sanquin's Plasma Products division. The private branch of Sanquin consists of the Plasma Products, Diagnostic and Research divisions, and two business units. The Plasma Products division produces plasma medicinal products and sells them on the open market in competition with commercial companies. The internal supply of plasma is located precisely at the border between the public and the private branch of Sanquin. The level of the price that the private branch pays the public branch for the plasma (this is the so-called internal set-off price of the plasma) is the central point in the response to the question of whether Sanquin is acting correctly in

the field of competition with the hybrid nature of the organisation and government interference.

In response to questions about the position of my predecessor in office regarding the second evaluation of the BSA, the research agency Plexus carried out an international benchmark into the prices of short-lived blood products and the prices of plasma. This investigation was completed on 20 August 2009. From the report it emerged, among other things, that the public branch of Sanquin took a loss in favour of the private branch of Sanquin on the sale of plasma to Sanquin's private division. In response to this it was decided at the time to raise the internal set-off price of plasma to the average level of the price of plasma in the benchmark from the Plexus report. In addition, it was decided to look more closely into the financial relationship between the public and private branches of Sanquin. Research agency ConQuaestor was given the task of doing this at that time.

ConQuaestor's conclusions

The ConQuaestor investigation comprises a complex study with the aim of making Sanquin's cost structure transparent. Below are the main findings of ConQuaestor:

1. *Negative margin*

With regard to the negative margin noted in the Plexus investigation, ConQuaestor comes to the conclusion that this was due to the obligatory use of Dutch, voluntary, unrewarded donations of plasma. This plasma is different from European full-blood plasma, which is available on the market and would be the most logical choice from a commercial point of view. The use of Dutch plasma arises from Sanquin's legal self-sufficiency task as well as the prioritised supply of plasma medicinal products in Holland. ConQuaestor comes to the conclusion that there was no cross-subsidisation from the public branch to the private branch of Sanquin, but that there was a loss of efficiency caused by public obligations to the private division.

2. *Distinction between Market and Government: Cohen test*

The purpose of the Cohen test is to create competitive relationships that are as fair as possible between authorities and legal persons with a public task as provider of goods or services to third parties on the one hand and private enterprises on the other. According to the requirements of the Cohen test, the total integral costs must in principle be assigned to the plasma.

An exception to this principle is permitted if the calculation method of the cost price is arbitrary. In those cases, a market price can be used for the calculation. ConQuaestor comes to the conclusion that, using the Cohen standard, the adoption of the market price for supplying plasma to the private branch of Sanquin is permitted because the cost price of plasma is difficult to determine clearly.

However, ConQuaestor is of the opinion that the market prices adopted by Sanquin on the basis of the Plexus report are too low in comparison with current market prices.

3. *Price-raising effect of products with exploitation shortfall*

The Bloodbank supplies a number of products whose production costs are higher than the revenues and which thus have an exploitation shortfall. However, because the Bloodbank covers all costs with the revenues from all products in the budget, the products with an exploitation shortfall have a price-raising effect on the products that have no exploitation shortfall.

According to ConQuaestor, the following products have an exploitation shortfall, based on an activity-based cost calculation:

- Umbilical-cord plasma: €0.9 million
- Bone bank: €0.3 million
- Aphaeresis plasma: €11.7 million
- Full-blood plasma: €17.5 million.

4. *Utility functions of Sanquin and cost-allocation*

When determining a level playing field as aimed at by the Cohen test, Sanquin's legal tasks and social responsibilities play an important role. These tasks and obligations hinder Sanquin in its commercial opportunities, which in principle means that there is no level playing field vis-à-vis commercial parties.

ConQuaestor describes Sanquin's legal and social responsibilities and, where possible, the costs arising therefrom. In addition, ConQuaestor gives a description of the cost allocation to the end-products and the method of determining the price. In addition, ConQuaestor pleads for changing the system of subsequent calculation (T-2 system), because it only sets off part of the profits or losses made.

My position

I have considered my position on the report in the light of the public tasks and special utility functions that Sanquin exercises. In addition, when adopting my position I took into consideration the shelf-life of the blood and plasma supplies in the longer term.

Modifying the organisational structure of Sanquin: separating the assets of the public and private branches

Although the principle of the free movement of goods and services applies to the trade in plasma medicinal products, the policy of the Ministry of HWS regarding blood and blood products, just as for tissues and solid organs, has always been directed towards maintaining our own (plasma) supplies for Holland. In the past, a choice was deliberately made for the hybrid construction of Sanquin. The principles of that choice at the time were: (financial) security and continuity concerning the availability of plasma medicinal products, maintenance of knowledge and effective business management by Sanquin (including by sharing R&D and overhead costs). In addition, the fact that the requisite infrastructure was already present played a role in the choosing a hybrid structure for Sanquin.

Because the aforementioned principles still apply and it can be seen from the ConQuaestor investigation that the present system can be maintained over the long term if the private branch of Sanquin considers a further increase in scale, I see no reason to make changes in the hybrid structure of Sanquin. However, I am aware that the current structure does run risks. To be precise, all of Sanquin's activities take place within the *Stichting Sanquin Bloodvoorziening* and there is no legal separation between the various asset components of Sanquin. This means that the entire capital of the *Stichting* ['Foundation'] is exposed to risk for both the Bloodbank and the private activities. Administratively speaking, the assets and liabilities of the bloodbanks and the private activities are however separated and thus transparent.

I believe it is undesirable that at the moment the entire capital of the Foundation is exposed to risk for both the bloodbank and the private activities. I will therefore be asking Sanquin to take measures to ensure that the equity capital of the bloodbank is not risk-bearing for the private activities and vice-versa.

Cohen test

During the investigation, ConQuaestor focussed attention on the so-called Cohen test, which gives frameworks and rules of conduct for fair competition. The Cohen test relates to all organisations that carry out a public task under a government decision and have a temporary or permanent, exclusive or special position to do that in terms of rights to market access or to financial resources. Sanquin falls within that scope, because Sanquin organisationally consists of a public branch, which deals with blood supplies for the so-called short-lived blood products, and a private branch, which produces medications prepared from plasma and sells them on an open market in competition with commercial companies. The purpose of the Cohen test is to create competitive relationships that are as fair as possible between authorities and legal persons with a public task as provider of goods or services to third parties on the one hand and private enterprises on the other.

I note that every method for calculating the cost price of plasma is arbitrary. For this reason, the market price will be the deciding factor in determining what the private division pays for the plasma supplied.

The Competition Law amended on 24 March 2011 prescribes that the integral costs must be allocated when establishing set-off prices for products that must be supplied by a State enterprise to a private organisation. ConQuaestor states that with the amended Competition Law, Sanquin should charge the integral cost price for the internal plasma price to the private branch of Sanquin. However, I am of the opinion that the Competition Law does not apply to Sanquin as regards the determination of the integral cost price because Sanquin does not come under the definition of a State enterprise. The adoption of a market price for the internal set-off price for plasma is in my opinion also permitted under the amended Competition Law.

ConQuaestor comes to the conclusion that the present internal set-off price, which is based on the Plexus investigation, is too low. In order to determine the level of the plasma price, ConQuaestor investigated what price Sanquin would have had to pay for plasma if Sanquin was not ordered to use Dutch plasma and would therefore have had to buy the plasma on the world market. The cheapest plasma with the requisite quality in which there is a demonstrable trade is, according to ConQuaestor, European full-blood plasma. According to ConQuaestor, the market price for such plasma is between €80 and €90 per unit. A set-off price of €85 for the plasma that Sanquin's public branch supplies to its private branch is the closest to a commercial situation, according to ConQuaestor.

Sanquin is of the opinion that it is not the market price but the market value of Dutch plasma that should be taken as the starting-point.

For this reason, Sanquin proposes maintaining the current set-off price, which at the time was determined on the basis of the Plexus investigation, as compensation for a possibly lower income, caused by the prioritised supply for the Dutch market.

However, I believe that a set-off method based on market price, instead of market value, results in an internal set-off price that is more verifiable and transparent. For this reason, I would like to go along with ConQuaestor's finding and take €85 as the starting-point for the internal set-off price of plasma.

Elsewhere in this exposition of my viewpoint I deal with the question of whether compensation for the prioritised supply on the Dutch market should be paid.

When determining a level playing field as aimed at by the Cohen test, account must be taken of Sanquin's legal tasks and social responsibilities. These tasks and obligations after all hinder Sanquin in its commercial opportunities, which in principle means that there is no level playing field vis-à-vis commercial parties. ConQuaestor describes Sanquin's legal and social responsibilities and, where possible, the costs arising therefrom.

Given the fact that the private branch of Sanquin also performs public tasks, which in principle means that there can be no question of a level playing field, I find it in principle reasonable that Sanquin should be compensated for those activities. According to ConQuaestor, the public tasks concern the obligatory use of Dutch plasma, the manufacture of (plasma-)orphan medicinal products, the prioritised supply of plasma medicinal products and public R&D activities.

ConQuaestor indicates that it can give no indication of the costs relating to the prioritised supply of plasma medicinal products in Holland. It is in fact not possible to establish afterwards what price might have been obtained elsewhere for a plasma medication supplied in Holland. Verifiable data from which one might conclude whether Sanquin suffered a loss of income and the eventual extent of that loss are not available. Having said that, I note that Sanquin cannot be considered for compensation for loss of income at the moment.

With regard to orphan medicinal products, these are also put on the market by other commercial manufacturers. Until 31 December 2011, they were paid for via the NZA policy rule for expensive and orphan medicinal products. As from 1 January 2012, orphan medicinal products are funded via DBC/-health care products. Because Sanquin suffers no disadvantage compared to other orphan medication manufacturers, I do not think it reasonable to compensate Sanquin for the production of orphan medicinal products.

However, I do want to compensate Sanquin for the costs of the public R&D activities which are borne by the private branch. This is because the financing of these activities by the private branch puts Sanquin at a disadvantage compared with commercial parties. Sanquin has indicated that there are shortfalls in the public R&D activities from the year 2013 onwards due to all the obligations imposed, in addition to the contribution for R&D already processed into the blood prices.

The contribution already processed into the blood prices proceeds in accordance with agreements made earlier in 2013 amounting to €12.7 million. If think that this last amount (true, to be indexed from the start of 2013) is the maximum that can be paid to public R&D. Because there is at the moment an ongoing research programme and friction costs involved in reducing it, I am nevertheless prepared to compensate the costs exceeding the amount during a transitional period until 2015 at the latest. The compensation will be found in the cutback of the existing reserve destined for R&D within the equity capital.

Nevertheless, Sanquin remains permitted at its own initiative to invest funds obtained from the private branch in public objectives such as R&D, so long as this does not endanger the viability of the supply of plasma medicinal products. However, there will be no compensation for this, partly because this is then done at its own initiative and given the framework outlined for it.

All in all, I think that the market price for plasma as ConQuaestor has established it does more justice to a market situation than the market price that emerges from the Plexus investigation and which is currently adopted by Sanquin. So I set the internal set-off price for plasma at €85 for a period of three years.

On account of the discussions over the level of the internal set-off price for plasma, I am inclined towards a system whereby the internal set-off price is set periodically on the basis of market prices. The periodical testing will take place by researching the market price and the eventual compensation every three years.

Equity capital

To prevent arguments over the level of Sanquin's equity capital, it is important to set a norm for this. I want to use that norm in the annual testing of Sanquin's budget. Setting a norm does not mean that if the equity capital deviates from it, it will be skimmed off or supplemented directly. In this regard, the liquidity position will be examined annually. Moreover, there will only be external financing for investments if Sanquin's financing needs justify it.

When setting a norm, I looked at the norms that the Guarantee Fund for the Health Sector adopts. The Fund is based on a percentage of 10-15% of income. Given the continuing developments in the market, there is increasing demand to raise that norm to 25%. Sanquin has the characteristics of a pharmaceutical company and because it works with human material is vulnerable to a failure in products. On the other hand Sanquin has a guaranteed cashflow for the fixed costs. A cautious norm off 25% of income for the equity capital is therefore a good basis.

The equity capital of the Sanquin Bloodbank is currently €80 million. Of this, €12 million is invested in a special reserve for Research, which I discuss elsewhere in this outline of my position. The remaining €68 million constitutes the general reserve. Based on the income in 2012, the norm for the equity capital comes out at about €49 million.

At the moment, Sanquin has made the equity capital profitable by financing the investments from it. At the present time I do not think it desirable to cream off the equity capital and thus force Sanquin to refinance the investments.

I am inclined to a situation in which Sanquin borrows on the capital market for investments in the bloodbank which cannot be financed from the requisite equity capital. Thus we would have a situation comparable to that of the hospitals. The financing of Sanquin's investments will then not be paid in advance by the hospitals, but processed afterwards into the blood prices, as is usual in business economics. Based on the current investments, that will be the case at the start of 2016.

As can be seen from the foregoing, capital constituted unnecessarily can be creamed off at the time of budget approval. For this reason, the current form of subsequent calculation (t-2 system) remains in operation. However, further transparency requirements will be imposed on the subsequent calculation.

Tissue business

The Bloodbank supplies a number of products whose production costs are higher than the revenues. Because the Bloodbank covers all the costs with the revenues from all products in the budget however, those products have, with a so-called exploitation shortfall, a price-raising effect on the products for which there is no exploitation shortfall. It emerges from the ConQuaestor report that the tissue business that Sanquin conducts has an exploitation shortfall:

- Umbilical cord bloodbank: €0.9 million
- Bonebank: €0.3 million.

I am of the opinion that Sanquin's tissue business should not influence the exploitation balance of the bloodbanks. This means that that business must either be placed within Sanquin's private divisions, or conducted – covering costs – within the bloodbank divisions, or should be discontinued. In any case, this means that as per 1 January 2013 no exploitation shortfall for the bonebank can be charged against the bloodbank any more.

With regard to the umbilical-cord bloodbank, I intend later this year to take a position on how we must deal further with the umbilical-cord bloodbank in Holland.

Efficiency

ConQuaestor describes in the report the efficiency of the Dutch blood-supply system. In addition, ConQuaestor indicates what basic points can be investigated further in order to make possible cost-savings in the future. In this regard, ConQuaestor bases its opinions partly on the findings of the Plexus investigation. ConQuaestor comes to the conclusion that the efficiency of Sanquin's public branch has increased over the last ten years. In spite of the increased efficiency of the public branch, the prices of short-lived blood products supplied to hospitals has risen due to such things as quality measures and inflation. In the report, ConQuaestor illustrates a number of possible efficiency measures that could lead to further improvements in the efficiency of the public branch.

ConQuaestor mentions the following measures:

- Assessing the added value of the range of blood products

The vast majority of the Bloodbank sales remains limited to a small number of products. The Bloodbank offers a wide range of blood products, of which the hospitals purchase relatively few. It is a frequently-occurring phenomenon in business economics that products with a low share of sales cause a relatively large proportion of the costs. ConQuaestor indicates that the number of products (and thus the costs) could probably be reduced after assessment of the added value of the various products.

- Investigating the level of service to donors

Good service to donors is very important, because without the efforts of many voluntary donors there would be no blood supply! ConQuaestor opines that the significantly lower cost price of plasma among commercial providers of plasma medicinal products, who also pay compensation for expenses to donors, compared to the cost of apheresis plasma from Sanquin is an indication that there are ways to make savings. ConQuaestor indicates that research could be done into the differences between countries that have a voluntary donation system and into the differences with the commercial providers of plasma medicinal products.

- Reducing research

The Plexus benchmark has shown that Sanquin incurs more costs for research than the other organisations investigated. ConQuaestor believes that if the countries investigated in the Plexus investigation can have a blood supply without the amount of research conducted by Sanquin, it would appear that all that research is not strictly necessary. However, ConQuaestor did not investigate the value of the various forms of Sanquin's research, the policy consequences of reducing (areas of) research and the differences as regards content with the countries in the Plexus benchmark. ConQuaestor concludes only that it is probably possible to save on costs in the field of research, but not whether this really leads to a gain in efficiency.

- Assessing the usefulness and necessity of a number of tests

In Holland, a relatively large number of tests are conducted in order to ensure the safety of blood products, compared to other countries. In the report, ConQuaestor indicates that it is probably possible to reduce the number of tests to the level of other countries without thereby endangering the safety of the recipients of blood products.

- Reducing indirect costs

In the report, ConQuaestor refers to the Plexus investigation into Sanquin's indirect costs. In particular, the Plexus investigation has demonstrated that such things as the costs of accommodation and ICT at Sanquin are high compared with the other organisations in the benchmark.

With regard to the efficiency of Sanquin's Bloodbank, I would like to impose objectives, partly within the framework of the objectives for the government service agency, Sanquin. These objectives will contribute 6% structurally to the public budget for the year 2012. These objectives will be entered into the budget for 2013 up to and including 2016, in tranches of 1.5% per year. Nominally, this amounts to objectives of €11.6 million, in yearly tranches of €2.9 million. Because Sanquin already realised an objective of €1.5 million in 2012, €1.5 million can be deducted from the 2013 tranche. I expect to build in a stimulus towards efficiency with the objectives. Sanquin can then determine itself where the cost savings will be made. As a pre-condition in this regard, the quality of the blood supply and the willingness of donors must not be affected and the existing arrangements for compensating donors' travel expenses must remain in their present form.

With regard to the safety tests currently deployed by Sanquin, I think that the number of safety tests should be reduced, so long as the safety of the recipients of blood products is not endangered. I will therefore ask Sanquin to conduct research into the usefulness and necessity of the safety measures, and to compare them with comparable countries, the aim being to see whether the safety tests currently conducted by Sanquin are still efficient and contribute to greater safety and quality of the blood supply.

My position on the matter is the result of a period of research into the costs of the Dutch blood supplies. The functioning and quality of the blood supply have never come under discussion in the past few years. For this reason, I can confidently say that the blood supplies are in good hands with Sanquin, as they were in the past.

Respectfully yours,
The Minister of Health, Welfare and Sport,

[signature]

Dr. E.I. Schippers (Ms.)