Clarification is helpful, but not a panacea

Evaluation of the ACM guideline collective procurement of drugs

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Executive summary

In June 2016, the Dutch Authority for Consumers and Markets (ACM) published the guideline "Collective procurement of prescription drugs for medical specialist care (MSC)". In this guideline, the ACM describes a so-called "safe harbor" in which collective procurement is permitted. The ACM published this guideline to clarify the opportunities for collective procurement permitted within competition rules. The ACM expects that collective procurement could help procurement agents to negotiate lower prices for drugs and better conditions, which benefits patients and the insured.

The ACM decided in advance to evaluate the guideline after three years. The ACM has asked strategic consultant firm SiRM to carry out this evaluation and to investigate the effect of the guideline and possibilities for improvement or expansion of the guideline.

We conclude that clarification of competition rules is helpful, but not a panacea for lower prices of prescription drugs for MSC. We substantiate this conclusion in the following paragraphs and make recommendations on how to refine the guideline and describe possibilities for expansion. We start by introducing the different segments of prescription drugs we distinguish and conclude with a chapter that describes two other barriers to effective collective procurement not related to competition rules.

The market for prescription drugs has four segments based on their degree of price competition

The market for prescription drugs has four segments based on their degree of price competition:

1. *Monopoly* drugs – Prescription drugs for which there are no therapeutic alternatives available, mostly, but not exclusively, because of patents or regulatory protection. For these monopoly drugs, hospital procurement agents can hardly negotiate lower prices from the moment the drug is covered by health insurance. Only parties that decide on health insurance coverage and reimbursement have some negotiation power.
2. *Oligopoly* drugs – Prescription drugs for which a therapeutic alternative is available, which is not its generic variant or biosimilar. For these oligopoly drugs, price competition is only possible after prescribers decide that the drugs are interchangeable and therapeutically equivalent.
3. Drugs *in competition* – As soon as patents of prescription drugs expire, the price competition increases sharply from the moment generic variants or biosimilars enter the market. These are so-called drugs in competition.
4. *Multi-source* drugs – Price competition is strongest when multiple suppliers provide the same drug.

The guideline has some impact on the effectiveness of price negotiations of oligopoly and monopoly drugs

The guideline is well known to those involved in the procurement of prescription drugs for MSC in the Netherlands and the majority of them believe that publishing the guideline has been useful. The impact of the guideline differs per drug segment. Negotiation power of procurement agents for prescription drugs is actually based primarily on the ability to effectively shift prescribed volumes. We refer to this power as implementation power. Scale of procurement organizations, for which the guideline clarifies the opportunities permitted by competition rules, comes second.

- For *oligopoly* drugs, the guideline has led to a new dynamic in the procurement of prescription drugs as a new national procurement organization was created – the NFU / NVZ / ZN[1] procurement organization. However, the collaboration within this national procurement organization of hospitals and health insurers was complex, which reduced its effectiveness and implementation power.
- For *monopoly* drugs, the guideline contributed to lower friction costs and possibly to some price reduction, as health insurers took a (certain) position collectively in the procurement of these drugs.
- Although the guideline does relate to drugs *in competition*, it has had no impact on the procurement of these drugs. Joint procurement organizations of hospitals that purchase these drugs among others, were created several decades before the publication of the guideline in 2016. Its publication has not resulted in an increase of scale or aggregation of these procurement organizations.

ACM can further strengthen purchasing power, also for medical devices

Refining the guideline for procuring prescription drugs for MSC can further strengthen its effect on purchasing power to some extent. Expanding the safe harbor - within the limits of competition rules - can reduce the reluctance for collective procurement. The safe harbor could, for example, be expanded by describing the permitted options and topics for information sharing between parties in a procurement organization. In addition, it could be expanded by describing the permitted possibilities for stricter admission criteria for procurement organizations for the benefit of strengthening their implementation power.

In addition to prescription drugs, a guideline could also describe the opportunities for collective procurement of medical devices permitted within competition rules. The market of medical devices is less developed in the Netherlands than, for example, in Germany. A guideline could increase collaboration on procurement of devices by the attention it generates. A greater effect can be expected of a guideline in this market than the effect the current guideline has on the market of prescription drugs. Compared to the procurement market for prescription drugs in 2016, there is relatively little cooperation in the procurement of medical devices. This seems to be due, among

[1] NFU = Dutch Federation of University Medical Centers, NVZ = Dutch Hospital Association , ZN = The Federation of Health care insurers.

other things, to the fact that procurement agents of medical devices are more reluctant to procure collectively because of competition rules.

Other aspects than competition rules impede effective procurement

The disappointing results of the NFU / NVZ / ZN procurement organization for oligopoly drugs are largely due to a limited implementation power. This is in part related to the narrow definition of the safe harbor. Another major obstacle to effective procurement of oligopoly drugs is the lack of agreement on interchangeability of drugs. After all, without an agreement on this, an oligopoly market cannot be created.

The negotiation organization of health insurers for monopoly drugs is also not yet optimally equipped for price negotiations. It has little, or no information at all, on the cost-effectiveness of the drugs under negotiation. In addition, health insurers lack a legal basis to jointly refuse a drug's reimbursement that is offered at a "non-cost-effective" price.

1 Introduction and conclusion

In June 2016, the Dutch Authority for Consumers and Markets (ACM) published the "Guideline for collective procurement of drugs for specialist medical care (MSC)".[2] With this guideline, the ACM wishes to enable market participants to take more advantage of the opportunities that competition rules offer for collective procurement, by clarifying the opportunities permitted within competition rules. The ACM expects that collective procurement allows procurement agents to negotiate lower drug prices, higher discounts, and better conditions, which benefit patients and the insured. Together with the guideline, the ACM published Q&A's on its website. Text box 1 describes the purpose of an ACM guideline.

With a guideline, the ACM explains the competition rules concerning a specific topic. It clarifies the rules and opportunities permitted within competition rules. In the guideline on collective procurement of drugs for the MSC, market parties are given clarifications for compliance with the competition rules and criteria for a "safe harbor". Within this safe harbor the ACM assumes no negative effects on competition from collective procurement. In principle, collective procurement beyond the safe harbor is also possible, depending on a more specific consideration of the pros and cons in light of the competition rules. In such situations, it is up to the market participants themselves to assess the compatibility with competition rules in a self-assessment. In case of important new (legal) questions, the ACM can provide further clarification.

Text box 1 In a guideline, the ACM clarifies competition rules and opportunities permitted within competition rules

The guideline relates to the collective procurement of prescription drugs for MSC. This concerns all so-called "add-on" drugs and other drugs that fall under the "medical care that medical specialists usually provide" and are covered by the basic health insurance package under the Healthcare Insurance Act. A brief explanation of drugs in the Dutch health care system can be found in Appendix 1 Drugs in the Dutch healthcare system. The guideline describes a so-called "safe harbor" within which collective procurement is permitted. This safe harbor is defined by the following three criteria:

1. Only a limited share of the hospital / health insurance costs is harmonized.
2. Admission to the joint procurement organization is possible on the basis of objective and nondiscriminatory criteria that are known in advance.
3. The joint procurement organization does not impose (legally or factually) any unnecessary constraints on participants in terms of the contract period, purchase obligations, and resignation.

The ACM decided in advance to evaluate the guideline after three years. The ACM has asked SiRM - Strategies in Regulated Markets - to carry out this evaluation and to investigate the effect of the

[2]ACM - Guidelines on collective procurement of prescription drugs for medical specialist care (2016)

guideline and possibilities for improvement or expansion of the guideline. The full research approach and questions can be found in Appendix 2 Research approach.

We conclude that clarification of competition rules is helpful, but not a panacea for lower prices of prescription drugs for MSC.

We substantiate this conclusion in Chapter 3 and make recommendations on refining and expanding the guideline in Chapter 4. We start by introducing the different segments of prescription drugs in Chapter 2 and end in Chapter 5 with two other barriers to effective collective procurement that are not related to competition rules.

We base our conclusion on desk research and about 25 interviews with, among others, hospital pharmacists, health insurers, purchasers of medical devices and representatives of umbrella organizations of hospital and of health insurance companies. For an overview of the interviewees, see Appendix 2 Research approach.

The recommendations on refining and expanding the guideline in Chapter 4 respond to the needs of market participants. Their compatibility with competition rules, however, have not yet been assessed.

2 The market for prescription drugs has four segments based on their degree of price competition

The market for prescription drugs has four segments based on their degree of price competition. For monopoly drugs, hospital procurement agents can hardly negotiate lower prices from the moment the drug is covered by health insurance. Only parties that decide on health insurance coverage and reimbursement have some negotiation power. For oligopoly drugs, price competition is only possible after prescribers decide that the drugs are interchangeable and therapeutically equivalent. As soon as patents of prescription drugs expire, the price competition increases sharply from the moment generic variants or biosimilars enter the market– the so-called drugs in competition. Price competition is strongest when multiple suppliers provide the same drug – multi-source drugs.

In general, four drug segments are distinguished in procurement strategy and policy: monopoly drugs, oligopoly drugs, drugs in competition and multi-source drugs (Figure 1). All these segments apply to prescription drugs for MSC as well as the ACM guideline and Q&A.

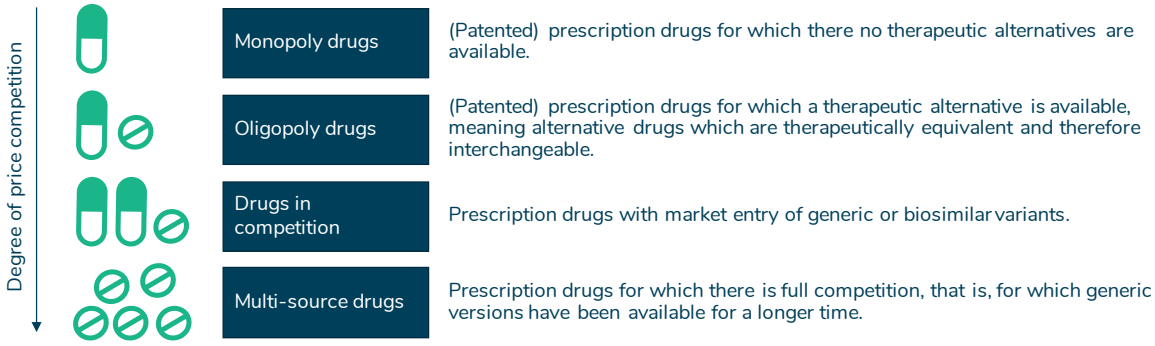


Figure 1 We distinguish four drug segments

As the number of therapeutically equivalent products increases, so does their price competition. There is virtually no price competition for monopoly drugs and a lot of price competition for multi-source drugs. The boundaries between the segments are not always clear and the same drug can be in different segments for different indications.

Generally, hospitals tend to purchase drugs together as price competition increases. For example, more hospitals jointly procure generic drugs (for which a lot of price competition exists) than that they jointly procure monopoly drugs (for which less to no price competition exists).[3]

In the coming paragraphs, we will further explain the degree of price competition per segment.

2.1 No price competition for monopoly drugs

For monopoly drugs, the selling power of manufacturers is high.[4] This is especially true for innovative drugs. In principle, innovative prescription drugs for MSC are automatically included in the insured package in the Netherlands if the drug meets the "standard of science and practice". There is no systematic cost-effectiveness assessment as there is for outpatient drugs: The Healthcare Institute (ZIN) makes a reimbursement decision for every new outpatient drug. For outpatient drugs there is a closed system and for inpatient drugs an "open inflow" system without a formal statement about the price or the cost effectiveness of the medication (see Appendix 1 Drugs in the Dutch healthcare system).

In order to exert some influence on prices of inpatient drugs, the Ministry of Health Welfare and Sport (VWS) established the "office of financial arrangements" in 2015.[5] A monopoly drug is placed in a so-called "waiting room" for expensive inpatient drugs if its budget impact is expected to be more than € 40 million or more than € 10 million with yearly costs per patients of at least € 50,000. As long as the drugs are in the "waiting room", they will not be reimbursed. After placement in the "waiting room", ZIN calculates their cost-effectiveness. For drugs for which manufacturers charge a price that is too high in relation to the value added by the drug, ZIN advises the Minister of VWS not to include the drug in the insured package, unless he can agree a price with the manufacturer that is in better relationship to its added value. The VWS "office of financial arrangements" will subsequently negotiate the price with the manufacturer. When they reach an agreement, the Minister of VWS decides on the inclusion of the drugs in the insured package. With the "waiting room", the Minister of VWS is the only one who has a certain degree of negotiation power regarding monopoly drugs. The Minister can refuse to include the monopoly drug in the insured package, although this has never happened so far.[6] Placement in the "waiting room" is primarily a signal to the manufacturer that serious price negotiations will take place, with delay in health insurance coverage as one of the Minister's leverages.

Health insurers also have the option of looking critically at reimbursement of new drugs under the Health Insurance Act. They are allowed to assess the "standard of science and practice" of new forms of care, i.e. whether this care can be considered effective. Health insurers do not currently use this position to refuse health insurance coverage for new drugs.[7] They do jointly - and in collaboration with the professional group / scientific association – set up criteria for quality of care

[3] Dutch Healthcare Authority (NZa) – *Monitor geneesmiddelen in de medisch-specialistische zorg* (Jan, 2019, Article in Dutch).
[4] Monopoly drugs are often drugs under patent. But also drugs for which the patent has expired, but for which no therapeutic alternatives or generic / biosimilar variants are (yet) available, are monopoly drugs.
[5] The VWS "office of financial arrangements" also participates in BeNeLuxA for the Dutch government.
[6] SiRM - Up for high-hanging fruit – Evaluation of the Dutch expensive drugs policy 2016-2018
[7] Except perhaps for drugs for which there is relatively little evidence of effectiveness.

for new drugs, for example by designating centers of expertise in the Add-on Drugs Assessment Committee (cieBAG) of the Dutch association of health insurers (ZN). Individual health insurers also make agreements with hospitals for each add-on drug, considering whether they will reimburse the drug in a specific hospital. Still, hospitals are allowed to prescribe registered drugs (off-label), even if no reimbursement agreements have been made with the health insurer.

As soon as a monopoly drug has entered the health insurance package and is reimbursed, there is virtually no price competition. The price of the manufacturer is fixed and (procurement organizations of) hospitals have limited options to negotiate prices of monopoly drugs, unless the prescribers in the hospital are so-called "key opinion leaders". These hospitals often receive discounts, for example in the form of research funding.

2.2 Price competition for oligopoly drugs only starts after a decision on interchangeability is made

A monopoly drug can be classified as an oligopoly drug if a therapeutic equivalent drug is available (Figure 1).

Patent law allows several patented drugs with a comparable mechanism of action to become available concurrently. For example, several “comparable” drugs may be available that affect the same protein (such as infliximab and adalimumab that affect TNFα and nivolumab and pembrolizumab that affect PD-1). Based on the structure of the drugs, there is a good chance that there are no (clinically relevant) differences in their effectiveness and safety.

However, there are several factors that make it difficult to create an oligopoly market and price competition:

- First, interchangeability is considered per indication and the indications of "comparable" drugs mostly differ. If "comparable" drugs are already on the market, manufacturers often try to (also) market their new drug for an indication for which the "comparable" drugs are not indicated. For example, avelumab is indicated for treatment of metastatic Merkel cell carcinoma, for which the similar drugs durvalumab and atezolizumab are not indicated. In this way manufacturers try to increase their sales market, but it also ensures that the indication areas of comparable products are not identical. Existing drugs can also be registered for new indications. This results in the situation that the patent for the first indication(s) expires, but the drug remains patented for the new indication. For example, the patent for imatinib for chronic myeloid leukemia (CML) indication has expired and generic drugs are available on the market, but only the originator is registered for the new indication gastrointestinal stromal tumors (GIST). This complicates price competition between “comparable” drugs, since often only one price for a drug is agreed upon for all indications.
- In addition, differences in the route of administration of "comparable" drugs can prevent the creation of an oligopoly market. For example, adalimumab and infliximab are both TNFα blockers, but adalimumab can be administered subcutaneously at home by patients themselves and infliximab can only be given per infusion in hospitals. For patients, a choice in

route of administration is pleasant. However, due to the difference in administration, there is hardly any price competition between these products.[8]

- Although there are (probably) no clinically relevant differences in the mechanism of action and effectiveness of "comparable" drugs, it may still be clinically useful to prescribe several of these drugs (sequentially) to patients. For example, because of differences in safety profiles or - in the case of biological drugs - because a specific immune response limits the effectiveness of the first drug but not the "comparable" drug. Price competition is limited for such oligopoly drugs, because less volume can be shifted to one preferred drug.
- Finally, an oligopoly market can only emerge once a decision has been made on the interchangeability of the drugs. However, the necessary information to make this decision is often lacking (see § 5.1.1). To obtain market authorization, it is not a requirement for manufacturers to compare their new drug with existing (comparable) drugs. A comparison with a placebo is usually enough, although this varies per indication. As a result, the evidence for establishing the interchangeability of comparable drugs is often lacking (see § 5.1.1). For example, a head-to-head prospective comparative study into the effectiveness and safety of nivolumab and pembrolizumab is missing.

Because the (timely) creation of an oligopoly market is difficult, effective price competition often does not arise until generic or biosimilar variants become available and the drug moves to the next segment, drugs in competition.[8]

2.3 Further increase in price competition for drugs in competition

Once the patents of monopoly (or oligopoly) drugs expire and as soon as generic variants or biosimilars receive a marketing authorization, competing manufacturers may also produce and trade the same drug. For chemical drugs, competing manufacturers can make a product that is identical to the original, also known as a generic variant. This is not possible for biological drugs, since they are biological products made with living cells. For biologicals, competing manufacturers market similar but not identical drugs – biosimilars.

The introduction of generic variants or biosimilars causes an increase in price competition. The fact that hospitals can choose between identical or comparable variants gives them a good negotiating position. In addition, competing manufacturers with a (usually substantially) lower price can still make a profit because they do not have to incur any costs (generic variants) or significantly less costs (biosimilars) for clinical research of their drugs.

With the addition of a biosimilar to the market, the increase in price competition is usually smaller than for generic variants, since the acceptance of biosimilars by prescribers can take more time than the acceptance of generic variants. The research and production costs of biosimilars are also higher than those for generic variants, which means that competing manufacturers often charge relatively higher prices for biosimilars than for generic variants.

[8] ACM - Sector inquiry into TNF alpha inhibitors (2019)

There are also drugs, mostly orphan drugs - such as agalsidase alpha and beta for Fabry disease and alglucosidase alfa for Pompe disease - of which patents have expired, but no generic or biosimilar variants have entered the market. These drugs are not in the "drugs in competition" segment, but remain in fact monopoly drugs (or oligopoly drugs if there is a therapeutic alternative).

2.4 Very low prices for multi-source drugs

The increase in the number of generic variants can, over time, result in a situation in which very low prices are paid for drugs. This is because procurement parties in this market segment have a strong position compared to manufacturers. In the Netherlands the debate is whether we are paying too little for some generic drugs in view of the quality and accessibility of these drugs.

In this evaluation report we do not elaborate on multi-source drugs, because the procurement power of procurement agents in this segment is already very high. The guideline is therefore not particularly aimed at this segment, although it does apply to these drugs.

3 Guideline has some impact on the effectiveness of price negotiations of oligopoly and monopoly drugs

The impact of the guideline differs per drug segment. Negotiation power of procurement agents for prescription drugs is actually based primarily on implementation power. Scale of procurement organizations, for which the guideline clarifies the opportunities permitted by competition rules, comes second. For oligopoly drugs, the guideline has led to a new dynamic in the procurement of prescription drugs as a new national procurement organization was created. However, the collaboration within this organization was complex, which reduced its effectiveness and implementation power. For monopoly drugs, the guideline contributed to lower friction costs and possibly to some price reduction, as health insurers took a (certain) position collectively in the procurement of these drugs. Although the guideline does also relate to drugs in competition, it has had no impact on the procurement of these drugs.

According to the National Health Authority (NZa) MSC prescription drugs monitor, the ACM guideline is well known to those involved in the procurement of prescription drugs for MSC.[9] According to the NZa monitor, the majority of those involved believe that the publication of the guideline has been useful. The people we interviewed shared this opinion. They state that it is a clear guideline based on a careful process in which various stakeholders were involved.

Interviewees indicate that the guideline has contributed to gaining internal and external support for joint efforts regarding the procurement of prescription drugs. It enlarged the willingness that emerged at the beginning of 2016 to jointly control spending on prescription drugs. At the same time, there was a growing willingness among prescribers to look more critically at the costs of drugs. In addition to the guideline, this willingness was induced by the Dutch expensive medicines policy "timely access to innovative drugs at socially acceptable costs", which Minister Schippers of VWS published early 2016.[10]

[9] NZa – Monitor geneesmiddelen in de medisch-specialistische zorg (Jan, 2019, Article in Dutch).
[10] SiRM - Up for high-hanging fruit – Evaluation of the Dutch expensive drugs policy 2016-2018

In this chapter we describe the impact of the publication of the guideline on the procurement of prescription drugs for MSC:

- We note that the guideline has had some impact on the effectiveness of procuring oligopoly drugs and on the price negotiation of monopoly drugs.
- The guideline has had no impact on the procurement of drugs in competition.

We explain these conclusions in the paragraphs below. First, we explain why scaling up alone does not contribute to more effective procurement of prescription drugs. Instead, effective procurement requires implementation power.

3.1 Implementation power is usually more important than scale, for which the ACM provides guidance

With the guideline, the ACM clarifies the opportunities for collective procurement of prescription drugs for MSC permitted within competition rules. In essence, the ACM indicates the possibilities for scaling up of the procurement process.

However, the interviews and earlier research by SiRM show that the effectiveness of the procurement of drugs, depends mainly on the *implementation power* of the procurement organization.[11] The vast majority of those interviewed indicate that *implementation power* is usually more important than *scale*, and that implementation power generally decreases as the scale increases[12] (Figure 2). However, implementation power, once in place, can in turn be leveraged by increased scale. Monopoly drugs are an exception: For these drugs there is in fact only a certain degree of bargaining power before inclusion of the drug to the basic health insurance package. This means that price negotiations have to be done on a national level.

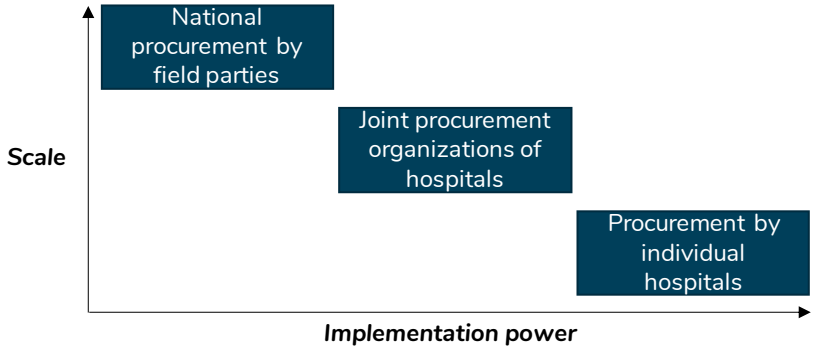


Figure 2 Implementation power generally decreases as the scale of procurement increases

In terms of *scale*, we distinguish procurement organizations at three levels:

- The individual hospital.
- A group of hospitals that collaborate regionally or nationally. Examples of the latter include *the Procurement Organization of University Medical Center Pharmacists* (iZAAZ) and *Santeon*.

[11] SiRM - Strengthening purchasing of drugs (2016)
[12] Incidentally, not all individual hospitals have more implementation power than joint purchasing organizations of hospitals, but an individual hospital that can effectively shift prescription volumes has the most implementation power.

- National collaboration of all hospitals and / or health insurers.

A procurement organization has *implementation power* if the hospital / affiliated hospitals can effectively shift prescribed volumes to a preferred drug. This implementation power is created by systematically going through five steps when purchasing a drug (group). The five steps are described in Text box 2.

1. Determining medical policy and volume
Medical specialists from the hospital / affiliated hospitals are involved in formulating medical policy for procurement. After all, they are the ones "at the helm" of the implementation of the final contract agreements.[13]

2. Issuing procurement mandate
The hospital / affiliated hospitals - preferably through the Executive Board - issues a mandate to the procurement team for the negotiations.[14]

3. Negotiating with the manufacturer
The procurement team that has received a mandate from those involved in the hospital / affiliated hospitals, conducts negotiations with the manufacturer.

4. Implement procurement policy
The agreements with the manufacturer are implemented as quickly as possible in the hospital / affiliated hospitals. This is preferably done directly via the electronic prescription system.

5. Monitoring of prescribing policy
In the hospital / affiliated hospitals, company specific benchmark information is frequently provided on compliance with the contract agreements. If contractual agreements are not met, those involved will address each other on this.

Text box 2 Implementation power is obtained by systematically going through five steps when purchasing drugs

(Procurement organizations of) hospitals that are able to go through the steps of the procurement process systematically and quickly, are best positioned to achieve good negotiating results. They formulate a single medical policy that all doctors involved support and can quickly translate agreements with the manufacturer to clinical practice. Doctors who do not adhere to the agreed prescription policy are called to account.

As the scale of the procurement organization - the number of participating hospitals - increases, the differences between participating hospitals often increase. This makes it more difficult to guarantee the above elements and decreases the implementation power of the procurement organization.

[13] For generic drugs, the choice of product lies with the pharmacist.
[14] Involved parties in the hospital / affiliated hospitals should not make any other arrangements with drug vendors after the purchasing mandate has been issued.

3.2 Guideline has led to new forces in the oligopoly market but to little negotiating results to date

The guideline has paved the way for initiatives to jointly procure oligopoly drugs on a national level. As a result, the guideline has led to new forces in the oligopoly market. However, due to the limited implementation power, which is partly related to the limited definition of the safe harbor, the effectiveness of the national procurement organization of the Dutch Federation of University Medical Centers (NFU), the Dutch Hospital Association (NVZ) and The Federation of Health care insurers (ZN) is disappointing.

3.2.1 Guideline has paved the way for the national NFU / NVZ / ZN procurement organization for oligopoly drugs

The guideline has paved the way for the formation of the national procurement organization for oligopoly drugs between the NFU, NVZ and ZN. The guideline provided comfort for a procurement organization of hemophilia treatment centers, but this collective procurement would probably have taken place without the guideline as well.

The guideline was an important incentive for the formation of NFU / NVZ / ZN procurement organization

The publication of the guideline was an important incentive for hospitals and health insurers to form a procurement organization for oligopoly drugs at industry level with the umbrella organizations NFU, NVZ and ZN. This procurement organization would probably not have existed without the guideline. The publication of the VWS expensive medicines policy also played an important role.[15] Healthcare insurers, in particular, had reservations about jointly procuring drugs on a national level before the publication. They are more focused on compliance. They are (also) audited on this topic by the NZa and De Nederlandsche Bank. Moreover, the public is more critical of health insurers.

In 2018, the procurement organization ran a pilot with the drug cluster of tyrosine kinase inhibitors (TKIs) for the treatment of Chronic Myeloid Leukemia (CML). All hospitals with patients in the CML cluster and all insurers participated in the pilot. The Haemato Oncology Foundation for Adults in the Netherlands (HOVON) played an important role in the formation of the procurement organization because they made statements about the interchangeability of TKIs in order to create an opportunity for joint procurement of oligopoly drugs in hemato-oncology.

In Appendix 3 National procurement and negotiation organization, we present a schematic representation of this national procurement organization.

[15] SiRM - Up for high-hanging fruit – Evaluation of the Dutch expensive drugs policy 2016-2018

Guideline has provided comfort to the procurement organization of the hemophilia treatment center

At the end of 2016, national joint procurement of coagulation factors took place by procurement organization iZAAZ together with several general hospitals.[16] It involved a total of eight hemophilia treatment centers[17] in the Netherlands, including six UMCs.

The guideline played a less important role for this procurement organization than for the national NFU / NVZ / ZN procurement organization. The collective procurement by hemophilia treatment centers would probably have taken place jointly without the guideline as well. The iZAAZ - an existing procurement organization - was the initiator of the procurement collaboration. Therefore, no procurement organization had to be established. Nevertheless, the guideline provided comfort to the participants. The guideline also provided clarity to the manufacturers about the permitted scope for national joint procurement.

3.2.2 Negotiating results of pilot NFU / NVZ / ZN procurement organization were disappointing due to insufficient implementation power

The results of the two national procurement organizations differ greatly. We explain this below and describe the reasons for this difference.

The NFU / NVZ / ZN procurement organization did not (yet) lead to more effective procurement

Based on interviews it turns out that the CML pilot of the NFU / NVZ / ZN procurement organization has been unsuccessful in terms of negotiating results. Some interviewees even indicated that the previously decentralized negotiations yielded better results than the negotiations by this national procurement organization.

According to the interviewees, possible reasons for the disappointing results are:

- Manufacturers were reluctant to submit a tender because the mandate, as issued by HOVON, was not in line with the active treatment guideline at the time.
- The NFU / NVZ / ZN procurement organization did not yet have a track record, so the implementation power still had to be demonstrated to the manufacturers. The Association Innovative Medicines (VIG) states that there was a great deal of uncertainty about the tender among applicants, e.g. regarding which hospitals participated, how many patients were involved and what the precise selection criteria were. The period in which manufacturers had to respond was also limited and unclear, according to the VIG. Because of this lack of clarity, manufacturers may have been less inclined to make a competitive offer.
- The NFU / NVZ / ZN procurement organization indicates that manufacturers offered higher discounts to hospitals that did not participate in the procurement organization in order to make national procurement more difficult.

[16] Dutch Association of Haemophilia Patients (NVHP) – Evaluation of the joint purchasing coagulation factors (2018, Article in Dutch)
[17] Erasmus MC (Rotterdam), Van Creveldkliniek UMC Utrecht (Utrecht), LUMC (Leiden), HagaZiekenhuis (Den Haag), AMC (Amsterdam), UMCG (Groningen), Maxima Medisch Centrum (Eindhoven/Veldhoven) and Maastricht UMC (Maastricht).

In addition to the "external" reasons described above, the disappointing results of the NFU / NVZ / ZN procurement organization pilot seem to be the result of divergent interests and a low level of implementation power of the procurement organization itself. The sense of ownership of the individual participants for the joint result may also have decreased as the number of participating parties in the procurement organization increased.

In principle, all hospitals and health care insurers participate in the procurement organization via their umbrella organization. In addition, scientific associations play an important role in determining medical policy. The participating parties have different roles, tasks and responsibilities in the health care system. This means that their interests in the procurement of prescription drugs differ. The negotiated discounts are an example: Should the outcome of the negotiation - the discounts minus the costs incurred - flow back to the health insurer and therefore the premium payer entirely? Or are hospitals allowed to keep part of the negotiation result and use it for (pharmaceutical) care? And how can the scientific association convince its members of interchangeability? What interests do doctors have for transferring their patients to a the drug that won the tender? This discussion led to a complex distribution formula for the discounts.[18]

Partly due to the divergent interests, the implementation power of the national procurement organization was limited. The experiences from the pilot show that the five steps of the purchasing process were not systematically and promptly followed (see Text box 2):

- The volume to be purchased was found to be difficult to extract from the hospital systems (step 1).
- It took a long time for all participating hospitals to issue a procurement mandate (step 2).
- Implementing the purchasing policy agreed with the manufacturer - that is, switching volume to the preferred drug - was difficult (step 4).
- The monitoring of the prescription policy was not possible (in time) for most participating hospitals (step 5).

Even though the pilot of the NFU / NVZ / ZN procurement organization was not very successful in terms of the outcome of the negotiation, the intensive collaboration between hospitals and health insurers did lead to a joint sense of responsibility in controlling the spending on prescription drugs for MSC. The procurement organization has also helped place the subject on the national agenda. And finally, the parties have learned a lot from the pilot. They have gained experience with scaling up, which among other things has resulted in more attention being paid to the implementation power of procurement.

Based on the experiences from the pilot, the NFU / NVZ / ZN procurement organization is now considering another way to organize cooperation:

- The procurement mandate is collected at national level, based on a statement on interchangeability by scientific associations.

[18] Incidentally, a few interviewees indicated that there was a lack of clarity about whether parties could make agreements about the mutual distribution of discounts. However, the guideline is fairly clear on this: "Participants in a joint purchasing organization of hospitals with one or more health insurers may make agreements about the mutual distribution of the purchasing benefits achieved (using a formula)."

- Procurement itself takes place through (decentralized) procurement organizations of hospitals - iZAAZ, Santeon and regional procurement organizations.

The procurement organization of hemophilia treatment centers has indicated good results

The procurement organization of hemophilia treatment centers declared that it has been able to negotiate considerably lower prices with manufacturers of coagulation factors. These good results can largely be attributed to the market entry of a considerably lower-priced product. In addition, the number of participating centers was clear and the interchangeability of the coagulation factors was widely accepted among prescribers, both for new and existing patients. Previously, hemophilia treatment centers had purchased coagulation factors separately, and the different factor VIII and factor IX coagulants were not purchased as interchangeable drugs.

If the guideline had not been published, the centers would probably also have procured together and negotiated low prices. The guideline did, however, offer comfort (see § 3.2.1).

3.2.3 Narrow definition of safe harbor also reduces the implementation power of NFU / NVZ / ZN procurement organization

The experiences of the NFU / NVZ / ZN procurement organization with the CML pilot are to a large extent influenced by the juridical search that the parties have gone through. The " juridical uncertainty" has considerably reduced the implementation power of the procurement organization. One interviewee also indicated that the juridical assessments, or the prospect thereof, have led to a loss of creativity among parties in the field.

Parties have devoted a great deal of time and money to the juridical interpretation of the guideline and of the safe harbor, for the planning and designing of the procurement organization.[19] For example, a great deal of attention has been paid to drawing up a distribution formula that all participating parties supported and that passed the test for enough remaining competitiveness (‘competition test’). Health insurers in particular believe it is important that all joint activities explicitly pass the competition test. For that reason, the NFU / NVZ / ZN procurement organization has carried out several “self-assessments”. These have been time-consuming and have led to high legal costs during the setting up of the procurement organization.

The ACM has defined the safe harbor relatively narrow. In addition, the parties are inclined to formalize the collaboration slightly more “safe” than possible within the safe harbor, in order to avoid any juridical risks (Figure 3).

[19] In addition, the users of the guideline felt that the Q&A, which was published simultaneously with the guideline on the ACM website, had a less important status than the guideline itself.

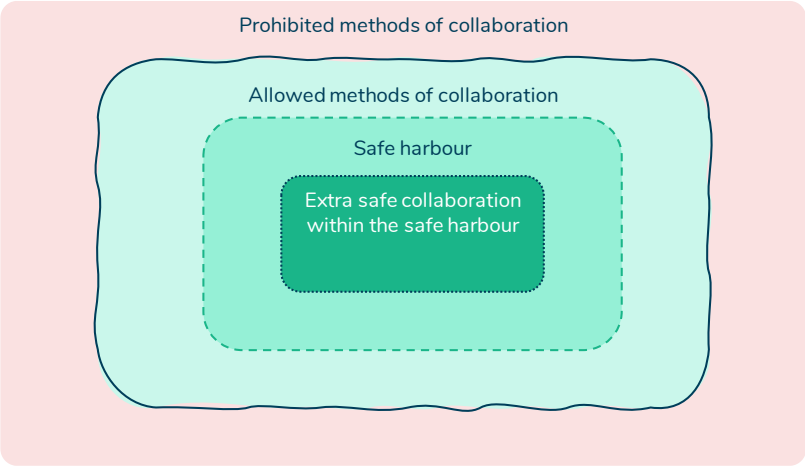


Figure 3 The safe harbor is defined relatively tightly and parties are inclined to seek extra safety within it

There are also ways of collaborating outside the safe harbor. The ACM also describes this in the guideline. But, because it means parties must self-assess compatibility with competition rules, they prefer to stay well within the safe harbor. On the one hand, this is because (self-) assessments are time consuming and lead to high legal costs. And on the other hand, even if parties invest in a juridical analysis, they are inclined to avoid risks and tend to play it safe.

The disadvantage of the focus on a safe harbor with a relatively narrow definition is that collaborating parties do not use the full space available within competition rules. This way, the safe harbor can hinder innovation of collaboration structures.

Desk research and interviews indicate that the safe harbor is defined (too) narrowly with regard to the possibilities for information exchange and admission criteria for procurement organizations. We will explain these two points in more detail below.

Text about information exchange within safe harbor seems to call for unnecessary restraint

Interviewees indicate that it is unclear what information one may exchange in preparation of negotiations with manufacturers and to monitor implementation of agreements. For example, are health insurers allowed to share information about prices and volumes of “add-on” drugs from claims data? Can hospitals mutually and confidentially share their results of earlier price agreements between each other?

The text in the guideline, and especially the in-depth text in the Q&A on information exchange, requires collaborating parties to show great restraint (see Table 1). SiRM wonders whether such caution is necessary since the costs of the group of drugs on which information is exchanged only represent a very limited part of the total costs of hospitals and health insurers and fall within the limits of the safe harbor.

Text guideline	Text Q&A
To ensure that the procurement arrangement is limited to joint procurement of drugs, it is important that the exchange of information between the participants in the procurement organization does not go beyond what is necessary for collective procurement and that there are sufficient guarantees to prevent the direct exchange of competition-sensitive information between the participating parties.	One possibility to limit the risks to competition is, for example, to position the procurement organization independently and only communicate the information needed for procurement, including information on volumes and information needed for monitoring of an agreed preference policy, to the procurement organization and not to share it among the participants. If negotiations with drug manufacturers are conducted by representatives employed by (one of) the participating parties, then these representatives must at least be bound by strict confidentiality obligations.

Table 1 The in-depth text in the Q&A about information exchange seems to be a limiting the extent of the safe harbor

The safe harbor condition about admission to joint procurement organizations may impede implementation power

Interviewees indicate that the second condition of the safe harbor "Admission to the joint procurement organization is possible on the basis of objective and non-discriminatory criteria that are known in advance" impedes the formation of an effective procurement organization.

In the Q&A, the ACM further explains objective and non-discriminatory criteria:

> *"Access to a procurement organization is objective if the criteria for admission contribute to the purpose of the procurement organization. A procurement organization therefore does not have to accept every potential participant and may set requirements for participation. Such requirements may be necessary for the proper functioning of the procurement organization. Those requirements must then be applied without discrimination. Restricting the procurement organization to a certain region, in order to limit participation to market parties in a certain geographical area, is not an objective criterion. Also, requiring the participant to belong to a certain category of hospital - general, university medical center - is not an objective criterion. In principle, every hospital must be able to participate in a procurement organization if that hospital meets the objective requirements that are necessary for the proper functioning of the procurement organization."*

A procurement organization only has implementation power if the affiliated hospitals can effectively shift prescription volumes to a preferred drug. The explanation of "objective and non-discriminatory" criteria in the Q&A does not seem to provide enough maneuvering space to deny access to parties that will dilute implementation power. Moreover, the existing decentralized procurement organizations - iZAAZ, Santeon and the regional procurement organizations - often do not meet this access criterion. On the contrary, they define their procurement organizations by category of hospital or by geographical area in order to form a procurement organization with implementation power.

3.3 Guideline has contributed to lower friction costs and possibly some price reduction of monopoly drugs

For monopoly drugs, there is virtually no price competition. Only the decision for inclusion in the basic health insurance package creates leverage for price negotiations (see § 2.1). Nonetheless, we observe that partly due to the guideline, the ZN negotiation organization has taken a certain position in the price negotiation of monopoly drugs. Without the publication of the guideline, the formation of the ZN negotiation organization would probably not have taken place or would have been slowed down.

Interviewees indicate that the guideline has paved the way for joint national price negotiations by health insurers about monopoly drugs outside the scope of the VWS "office of financial arrangements". The negotiations take place through the ZN negotiation organization. Up to and including 2018, the organization negotiated on prices of nine monopoly drugs.[20] In Appendix 3 National procurement and negotiation organization, we present a schematic representation of this national negotiation organization.

The negotiation power of the ZN negotiation organization remains limited because it concerns monopoly drugs. But the ZN negotiation organization has taken a certain position:

- Through the negotiation organization, health insurers agree that a declaration code, for hospitals to claim the drug costs, will be created for the drug under negotiation as soon as:
  - quality criteria are agreed upon (see § 2.1)
  - a price agreement has been reached with the manufacturer.
- The negotiating organization can offer manufacturers smooth access in exchange for a discount, by offering uniform reimbursement conditions to prescribing hospitals.

The ZN negotiation organization states that it has succeeded in negotiating substantial discounts on the prices of monopoly drugs. Other interviewees state that discounts have been reached of only a few percent. We estimate that manufacturers of monopoly drugs are willing to give discounts, because the friction costs they incur upon introduction are lowered by the smooth access that the ZN negotiation organization offers. Other reasons for manufacturers to give discounts on their drugs could include the incipience of an oligopoly situation in the foreseeable future or that there is still relatively little evidence of the effectiveness of the drug concerned. There is no real insight into the negotiated discounts. There is little public information about discount rates for monopoly drugs and certainly not at product level.[21] Manufacturers are willing to give a higher discount if this discount does not become public knowledge. This is (partly) caused by the fact that various European countries base their maximum prices on (public) prices in neighboring countries.

Just like the NFU / NVZ / ZN procurement organization for oligopoly drugs, the ZN negotiation organization for monopoly drugs spends a substantial amount of time and money on the juridical interpretation of the guideline (see also § 3.2.3). ZN has also carried out "self-assessments" for this

[20] ZN – Overzicht gezamenlijke afspraken 30-01-2019 (Article in Dutch).
[21] The office of financial arrangements periodically reports discounts at an aggregated level.

negotiation organization, mainly to determine the possibilities for the negotiation organization to offer uniform reimbursement conditions to prescribing hospitals and the way in which this is permitted within competition law.

3.4 Guideline had no impact on procurement of drugs in competition

Although the guideline is relevant for the procurement of drugs in competition, it has had no impact on procurement in this segment.

The interviews show that procurement organizations of hospitals did not and do not experience reticence based on competition rules when jointly procuring drugs in a competition. Procurement organizations of hospitals that focus on joint procurement of drugs have existed for several decades before the publication of the guideline in 2016. For example, iZAAZ was established in the early 1990s. The main type of drugs that they procure has shifted over the past few years: they started with cheaper prescription drugs for MSC, and after the transfer of specialist drugs from the outpatient to the inpatient budget, their focus shifted to procuring the more expensive "add-on" drugs (see Appendix 1 Drugs in the Dutch healthcare system). This may include drugs in competition, but also oligopoly and monopoly drugs.

Publication of the guideline has not resulted in a further upscaling of the procurement of drugs in competition. In recent years, there has been some concentration of regional procurement organizations, but according to those involved this was not related to the publication of the guideline. This concentration mainly took place for the purpose of further professionalization of the procurement organizations.

The fact that no significant further increase in scale has taken place, seems to indicate that purchasers of individual hospitals or groups of hospitals see no advantage in a (further) increase in scale for procuring drugs in competition. Interviewees indicate that (also) for the procurement of drugs in competition, implementation power is more important than scale (see § 3.1). In addition, when setting up the NFU / NVZ / ZN procurement organization, health insurers made the choice not to procure drugs in competition via this national procurement organization. They see procurement of drugs in competition as a competitive market.

There are two national procurement organizations that purchase prescription drugs for MSC for groups of hospitals: one for the UMCs (iZAAZ) and one for the Santeon hospitals. In addition, there are currently eight regional procurement organizations of hospitals. For an overview see Table 2. Approximately 90% of the hospitals are affiliated with one or more procurement organizations.[22]

[22] NZa – Monitor geneesmiddelen in de medisch-specialistische zorg (Jan, 2019, Article in Dutch).

Scale of organization	Name procurement organization
National joint procurement organization of hospitals	*Procurement Organization of University Medical Center Pharmacists (iZAAZ)* *Santeon*
Regional joint procurement organization of hospitals	*Apotheek Haagse Ziekenhuizen (AHZ)* *Inkoopcombinatie Zuid Oost Nederland (ICZON)* *Inkoopgroep IJmond Midden Nederland* *Inkoopsamenwerking Friese Ziekenhuizen (IFZ)* *Inkoopvereniging Ziekenhuisapotheken Oost- en Noord Nederland (IZON)* *Ziekenhuisapotheek Midden-Brabant (ZAMB)* *Ziekenhuisapotheek Noord Oost Brabant (ZANOB)* *Ziekenhuisapothekers Rijnmond inkoopgroep (ZRIG)*

Table 2 There are two national joint procurement organizations and eight regional procurement organizations of hospitals that purchase prescription drugs for MSC.

The existing procurement organizations claim to receive substantial discounts on drugs in competition, mostly as a result of increased competition due to expiring patents. With the arrival and increased acceptance of biosimilars, prices for biological drugs have dropped. For example, the introduction of biosimilars for different TNFα blockers resulted in a significant price decrease for these agents. The introduction of the etanercept biosimilar resulted in a decrease in the average price of 60%, the introduction of the infliximab biosimilar to a 70% price decrease and the introduction of the adalimumab biosimilar to a price decrease of more than 80%.[23] However, for most drugs in competition it is difficult to compare the results of various (procurement organizations of) hospitals, because there is hardly any public information about discount percentages.

[23] ACM - Sector inquiry into TNF alpha inhibitors (2019); Financieel Dagblad - *Prijzenslag farmabedrijven levert €180 mln op* (2018, article in Dutch)

4 ACM can further strengthen purchasing power, also for medical devices

Refining the guideline for joint procurement of prescription drugs for MSC can further strengthen its effect on purchasing power to some extent. Expanding the safe harbor – within the limits of competition rules – can reduce the reluctance for collective procurement. The safe harbor could be expanded by describing the permitted options and topics for information sharing between parties and permitted possibilities for stricter admission criteria for procurement organizations. In addition to prescription drugs, a guideline could also describe the opportunities for collective procurement of medical devices permitted within competition rules. A guideline could increase collaboration on procurement of devices by the attention it generates.

In chapter 3 we conclude that the guideline had some impact on the effectiveness of procuring oligopoly drugs and price negotiation of monopoly drugs. Although implementation power for oligopoly drugs is more important than scale, and price competition for monopoly drugs is by definition low, the guideline can be further refined to improve the effectiveness of collective procurement and price negotiation. In this chapter, we state recommendations that respond to the needs of market participants. **Their compatibility with competition rules have not yet been assessed.**

In addition, we expect that more clarification of competition rules for collective procurement of medical devices can contribute to more effective procurement in this market. This can be done by expanding the guideline or composing a new guideline or document. A few interviews indicated that expansion into markets other than medical devices seems to be less useful. For example, several interviewees indicated that clarification of the possibilities for collaboration in procurement of ICT and / or facility services is less needed. For these suppliers, healthcare is usually only one of the sectors in which they are active. They are therefore less concerned with procurement organizations that purchase on behalf of multiple hospitals. As a result hospitals are less hesitant to joint procurement.

There seems to be little request among market participants for clarification of opportunities within competition rules for international collaboration in the field of procurement and / or price negotiation. Only one of the interviewees saw concrete benefits. Other interviewees indicate that

sufficient implementation power will be very difficult to achieve with *international* joint procurement or price negotiation.

4.1 Expanding the safe harbor can slightly improve negotiation power

Based on the interviews, we note that expansion of the safe harbor can increase the effectiveness of the joint procurement and joint price negotiation of prescription drugs for MSC. The ACM has defined the safe harbor quite narrow (see § 3.2.3). We recommend the ACM to expand the safe harbor and make it as large as possible within competition rules. This will allow market participants to initiate more effective ways of collaboration, even those that avoid juridical risks or find the associated legal costs too high.

Expansion of the safe harbor can be achieved, for example, by describing the permitted space for collaboration mapped by previous collaborations and "self-assessments", for instance by adding cases to the guideline as an appendix. This contributes to better use of the possibilities for collaboration by market participants within competition rules. In addition, it would be good to include the Q&A information in the guideline, instead of posting it separately on the website.

Interviewees indicate that expanding the safe harbor is particularly desirable in the area of information exchange within procurement organizations. And secondly by allowing procurement organizations more strict admission criteria. We explain these points in more detail in the sections below.

Although the possibilities of offering prescribing hospitals uniform reimbursement conditions are not apparent from the guideline for the ZN negotiation organization (see § 3.3), the negotiation organization currently has no desire for the ACM to describe these elements more explicitly in the guideline. They fear that a more explicit description may become a barrier instead of creating more maneuvering space.

4.1.1 Effectiveness of joint procurement and joint price negotiation can be improved by clarifying the possibilities of information exchange

The text in the guideline, and especially the in-depth text in the Q&A, on information exchange requires collaborating parties to exercise great caution. We advise the ACM not to include the in-depth Q&A text on information exchange, as shown in Table 1, in the guideline. After all, the safe harbor allows for collaboration on procurement of drugs that represent a limited share of the costs. This also includes information exchange about these drugs. We recommend to include in the guideline which information may be exchanged for the preparation of negotiations and for monitoring the contract agreements (see § 3.2.3).[24] For example, information about prices and volumes of add-on drugs. This reduces the uncertainty about which information participants in a procurement organization are allowed to exchange. After all, insufficient exchange of information reduces the effectiveness of procurement.

[24] Incidentally, the NFU / NVZ / ZN purchasing organization or the ZN negotiation organization can still make stricter agreements about confidentiality and similar topics if the negotiations with the manufacturer demand this.

4.1.2 The possibility of applying stricter admission criteria can improve the implementation power of procurement organizations

The unsuccessful negotiation results of the NFU / NVZ / ZN procurement organization seem to be primarily due to the participation of many and different types of parties in the procurement organization for oligopoly drugs (see § 3.2.2). The multitude of participating parties reduces the implementation power of the procurement organization, because the interests of the parties differ and the implementation is complex.

Refusing applicants to a joint procurement organization is seen as impossible or at least complicated within the safe harbor (see § 3.2.3). We advise the ACM to pay more explicit attention to implementation power of procurement organizations. Scale is subordinate to implementation power for oligopoly drugs. In the Q&A, the ACM already indicates that a procurement organization does not have to accept every applicant and that a procurement organization may set requirements for participation. We recommend the ACM to include more examples of these requirements in the guideline. Procurement organizations should be able to refuse participants if they are unable to systematically and timely follow the five steps of an effective purchasing process (see § 3.1).

In addition to the possibility of applying stricter admission criteria, the interviewees indicated that in some cases the maximum contract duration to which the ACM refers is perceived as being too short. The guideline states the following on contract duration:

> *" ACM assumes that a maximum contract period of three years is reasonable, provided that the criteria leave enough room for any adjustments in the case of significant market developments."*

For the joint procurement of coagulation factors (see § 3.2.1), a contract duration of four years was agreed instead of three years. This longer contract period was chosen because the patient association involved considered it important that patients should not have to switch medication too frequently.[25] We recommend the ACM to include in the guideline that deviation from the maximum contract duration is possible if this is desirable from a patient perspective. Another consideration is whether a drug will become preferent only for new patients or also for existing patients, that is if existing patients will also switch to the preferred drug. The ACM could also include this in the guideline.

4.2 Defining competition frameworks for collective procurement of medical devices can strengthen purchasing power

Although the impact of the guideline on the effectiveness of the procurement of prescription drugs for MSC is currently limited (see Chapter 3), a greater effect can be expected from clarifying the possibilities for collective procurement of medical devices within competition rules. Compared to the 2016 procurement market for drugs for MSC, relatively little collaboration is taking place on

[25] Dutch Association of Haemophilia Patients (NVHP) – Evaluation of the joint purchasing coagulation factors (2018, Article in Dutch)

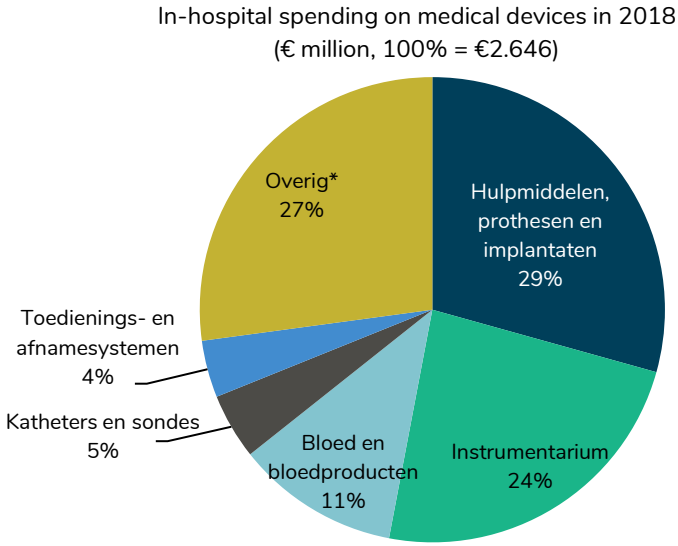
the procurement of medical devices. Additionally, purchasers of medical devices appear to be more reluctant to procure jointly due to competition rules. Publication of a guideline clarifying the possibilities for joint procurement of medical devices could speed up joint procurement of medical devices with the attention it generates.

Procurement of medical devices can be greatly professionalized. Collaboration in procurement, such as is being done on a large scale in the United States and Germany, can be of help. UMCs and a number of procurement organizations that we interviewed, indicate that they think a guideline for joint procurement of medical devices will be useful. Health insurers also expect that a guideline could help strengthen procurement of medical devices. We explain this further in the paragraphs below.

However, also this guideline will not be a panacea. Fear of violating the competition rules is certainly not the only obstacle to effective procurement of medical devices. Receiving a mandate from doctors for preferred medical devices is very difficult. The industry is actively present in hospitals, influencing doctors in their choices for a specific implant, prosthesis or consumable. If the hospital, the participating hospitals in a procurement organization, or the scientific association, are unable to collectively build up knowledge in order to agree on a shared medical policy with clear preferential products, then the procurement organization has no serious position in the negotiations with manufacturers. Here too, implementation power is probably more important than scale.

4.2.1 Markets for medical devices do not seem to work well enough yet

Intrakoop estimated the inpatient part of the market for medical devices in 2018 at around € 2.6 billion, of which more than half could be attributed to “Devices, prostheses and implants” (29%) and “Instruments” (24%), followed by “Blood and blood products” (11%), “Catheters and probes” (5%) and “Administration and collection systems” (4%). Intrakoop based its estimates on ledgers from 2018 of 118 members (hospitals and care institutions), extrapolated to a national level based on the annual reports of the remaining Dutch healthcare institutions (Figure 4).



*Other expenses include the following items “Other treatment and treatment support costs”, “Adhesive material”, “Other costs not specific to research”, “Bandage and plaster cast”, “Medical gases”, ”Therapy costs”, “Gloves”, ”Dental supplies“ and ”Anesthetics”

Figure 4 In 2018, the inpatient part of the medical device market was approximately € 2.6 billion, of which more than half was attributable to "Medical devices, prostheses and implants" and "Instruments".

According to several researchers, the medical devices market in the Netherlands does not seem to work well. Moreover, considerably less collaboration takes place in procurement of medical devices in the Netherlands than, for example, in the USA and Germany.

High margins due to insufficient professional procurement

According to Gupta Strategists, the profit margins of medical device companies are around 15 to 20%.[26] Ecorys states that prices and margins are not transparent, but that for some prostheses and implants it has been found that prices in the Netherlands are 30 to 40% higher than in Germany.[27] According to Ecorys, improvement of the procurement process can contribute to controlling costs. The process is now fragmented, the professionalism of procurement departments is inconsistent, the incentives in organizations do not always reward better purchasing and the relationship between doctor and manufacturer hinders switching between suppliers. Intrakoop also expects hospitals to be able to purchase medical devices more competitively, i.a. by procuring more jointly.[28] Intrakoop, for example, estimated that hospitals can purchase orthopedic implants 10% to 20% cheaper, partially through more joint procurement.

Demand side is less strongly organized in the Netherlands than elsewhere

In general, Ecorys concludes that the demand side of the market for medical devices in the Netherlands is not very strong.[27] Although hospitals cluster procurement, the emphasis is mainly

[26] Gupta Strategists – Profits in the Dutch healthcare sector (2017).
[27] Ecorys - Sector Study Medical Devices (2011)
[28] Intrakoop – Marktanalyse orthopedische implantaten (2017) and Intrakoop – Marktanalyse cardiologie (2017) (Articles in Dutch).

on procurement for facility services. In other countries such as the US and Germany, there is much more joint procurement of medical devices by hospitals.

- Purchasing volume is highly clustered in the United States and Germany. This is done by Group Purchasing Organizations (GPOs) often owned by hospitals.[29] O'Brian et al. state that the GPOs lead to 10 to 18% decreased spending on procurement due to lower prices, obtained due to a stronger negotiating position and lower transaction costs. Almost all hospitals in the US purchase through a GPO. Approximately three-quarters of the (non-labor) procurement of hospitals go through a GPO.[30] Six large GPOs together provide around 90% of procurement services.
- According to the website zukunft-krankenhaus-einkauf.de[31], the seven largest German GPOs bought in 2017 for € 11 billion on behalf of 5,472 healthcare providers. Almost all German hospitals are affiliated with a GPO (Einkaufsgemeinschaft). A few GPOs are connected to large hospital chains.

4.2.2 UMCs and several procurement organizations see the need for further clarification of the possibilities for collective procurement, for internal and external stakeholders

According to several interviewees, there is room to professionalize the procurement of medical devices. They indicate that scaling up through collective procurement plays an important role in this. Organizations such as *iZAAZ*, *InkoopAlliantie Ziekenhuizen (IAZ)*, *Santeon*, *Zorgservice XL*, *Friese ziekenhuizen* and *Intrakoop* are already working on joint procurement of medical devices, but still at a modest level. (Some of) these organizations also interact with each other, especially concerning methods and procurement strategies. But these organizations do not procure medical devices together. According to iZAAZ, IAZ and Intrakoop, publication of a guideline can speed up further collaboration on the procurement of medical devices with the attention it generates. Santeon indicates that it has no specific need for a guideline.

Procurement agents experience that the existing suppliers of medical devices sometimes frustrate the procurement process. Suppliers of medical devices frequently alert procurement agents that they don't comply with legal provisions, among which the competition rules. It would be helpful for procurement agents to have a guideline to refute the objections of suppliers and to convince colleagues, who are less skilled legally, not to believe any opportunistic reasoning.

For UMCs, collective procurement of medical devices is more difficult than for general hospitals. They are not allowed to privately procure but must comply with European procurement legislation. In particular, they experience the "proportionality" criterion from European procurement legislation as an obstacle to procuring medical devices. In practice, this appears to be open to interpretations, even though much has already been explained in the Proportionality Guide.[32] The collective procurement of ICDs and pacemakers by UMCs and two hospitals, for example, is much delayed by several summary proceedings from manufacturers.[33]

[29] O'Brian, Dan; Leibowitz, Jon; Anello, Russel – Group Purchasing Organizations (2017).
[30] United States Government Accountability Office - Group Purchasing Organizations (2010).
[31] Krojer, Stefan - Wer ist der König unter den Einkaufsgemeinschaften? (2019).
[32] Pianoo Dutch Public Procurement Expertise Centre - Proportionality Guide (2016)
[33] Zorgvisie - Rechter: 'Ziekenhuizen mogen samen medische hulpmiddelen inkopen' (2019, article in Dutch).

One of the objections was:

> *"Furthermore, Medtronic objects to the fact that thirteen contracts were merged in the tender. The UMCs therefore operate as a single power block and abuse their large market share by imposing unreasonable and unlawful conditions on suppliers. Merging is not necessary and the UMCs have not given reasons why this was necessary, which they are obliged to do on the basis of Article 1.5 of the Public Procurement Act. "*[34]

The judge decided in favor of the hospitals, but the proceeding claimed a lot of attention, time and money. A clear guideline about the scope for collective procurement may have prevented the proceeding.

A general hospital also indicated that a guideline for collective procurement of medical devices would be useful, especially to enable more exchange of information between procuring hospitals. They would like to learn from each other and, to the extent permitted by competition rules, exchange information on realized prices. Possible violation of competition rules, and the fear of it, is mentioned as one of the obstacles hindering closer cooperation.

4.2.3 Health insurers expect a guideline to incentivize collective procurement of medical devices

At present, health insurers are mainly concerned with the procurement of outpatient medical devices. Their expenditure is directly visible to insurers in claims data, and they can make the use of a non-preferred product unattractive for the insured. Health insurers do this, for example, for colostomy and incontinence material.[35] Health insurers have little or no involvement in the procurement of inpatient medical devices. Their costs are reimbursed within Diagnosis Treatment Combinations (DBC) rates together with costs of diagnostics and treatment. Hospitals are primarily responsible for procurement of inpatient medical devices.

Health insurers are currently reluctant to collaborate in procurement of medical devices. A few of the interviewed health insurers do see a possible role for themselves in this. They mention two categories:

- outpatient devices of which the supplier has a monopoly position, and
- medical devices that are first prescribed in the hospital and then used outside the hospital.

A guideline could create room for national price negotiations about monopoly medical devices by health insurers

Health insurers could jointly negotiate the prices of outpatient monopoly devices at a national level, comparable to the ZN negotiation organization for monopoly drugs. Just as with drugs, a guideline can help realize such a collaboration. An example of a monopoly medical device is a glucose meter for diabetes patients that no longer needs a finger prick to measure glucose levels. In the coming years, health insurers expect even more monopoly medical devices with high overall costs.

[34] Court ruling Den Haag – Kort geding ECLI:NL:RBDHA:2019:7772 (in Dutch)
[35] Court ruling Zeeland-West-Brabant - Bettercare BV tegen CZ, ECLI:NL:RBZWB:2016:3891 (2016, in Dutch).

With a guideline, health insurers could work with hospitals to procure medical devices that are used in the hospital and outside the hospital

In addition, health insurers could work together with hospitals to purchase medical devices that are initially prescribed in the hospital and then used outside of the hospital. A guideline for joint procurement of medical devices can help to put this on the agenda and make it more effective.

Some medical devices are first used in the hospital and then outside of the hospital. In response, manufacturers give hospitals big discounts or even supply medical devices for free, while requesting high prices from health insurers for outpatient use. For joint procurement of these medical devices, it is important that *all* health insurers in the relevant hospital region work together with the hospital. As such, hospitals do not have to offer different medical devices per health insurer. Health insurers will have to convince / compensate hospitals for such a joint purchase. After all, the manufacturer probably won't give the same discounts as the hospital is currently receiving, because in the case of joint procurement the discount also applies to the much longer use outside the hospital.

An example of such a device is a CPAP. This device keeps the airways open, allowing the patient to breathe well. It is first prescribed in the hospital followed by longer outpatient use, while the data the device generates are used in the treatment at the hospital. Such combinations of prescription and data use in the hospital, and using a medical device at home will probably become more important in the future.

5 Other aspects than competition rules impede purchasing power

The disappointing results of the NFU / NVZ / ZN procurement organization for oligopoly drugs are largely due to limited implementation power. This is in part related to the narrow definition of the safe harbor. Another major obstacle to effective procurement of oligopoly drugs is the lack of agreement on interchangeability. After all, without an agreement on this, an oligopoly market cannot be created. The ZN negotiation organization for monopoly drugs is also not yet optimally equipped for price negotiations. It has little or no information on the cost-effectiveness of the drugs under negotiation. In addition, health insurers lack a legal basis to jointly refuse a drug's reimbursement that is offered at a "non-cost-effective" price.

In Chapter 3 we conclude that the guideline has had some impact on the effectiveness of price negotiations of oligopoly and monopoly drugs. We note that the juridical interpretation of the guideline reduced the implementation power of the NFU / NVZ / ZN procurement organization and the ZN negotiation organization. In Chapter 4 we therefore recommend refinement of the guideline by expansion of the safe harbor.

However, the guideline with the narrow safe harbor are not the only reasons for the low purchasing power of the NFU / NVZ / ZN procurement organization and the ZN negotiation organization. They can optimize their internal organizations to increase their implementation power. Furthermore, there are two important "external" non-competition barriers that impede effective procurement:

- Lack of agreement on the interchangeability of prescription drugs prevents the creation of an oligopoly market.
- Lack of information on the cost-effectiveness of the drug and lack of a legal basis for refusing drug reimbursement, limits the negotiation power of health insurers for monopoly drugs.

We explain these barriers in this chapter. We do not make specific recommendations to the ACM to resolve these barriers, because they do not fall within the ACM's direct sphere of influence. The ACM could however play a role in putting these topics on the agenda.

5.1 Failure to reach agreement on interchangeability prevents creation of oligopoly markets

An oligopoly market arises when drugs with different active substances or routes of administration are interchangeable for a specific indication (see § 2.2). A statement on interchangeability - by a party with support among prescribers - is needed to create an oligopoly market.

Currently these statements are rarely made because of failure to reach agreement on interchangeability. Firstly, because "comparable" drugs often differ in indication and routes of administration (see § 2.2). In addition, because prescribers have insufficient information about the interchangeability of “comparable” drugs. Finally, scientific associations are insufficiently equipped to make timely statements about interchangeability. Systematically establishing interchangeability on a national level could accelerate the emergence of oligopoly markets. We will explain these elements in more detail in the following paragraphs.

5.1.1 Information about interchangeability of (monopoly) drugs with the same indication to create an oligopoly market is usually not (timely) available

Information is needed to assess the (degree of) interchangeability of (monopoly) drugs with the same indication. This information is usually not available or comes too late. As a result, prescribers find it difficult to determine whether two (or more) drugs are therapeutically equivalent and therefore interchangeable, so that no oligopoly market can be created for (monopoly) drugs with the same indication.

Information about interchangeability of (monopoly) drugs with the same indication ideally comes from prospective, “*head-to-head*” comparative studies. However, these studies are rarely initiated. First, because researchers experience (financial) obstacles in setting up and financing the necessary infrastructure for measuring and collecting patient data combined with a high administrative burden.[36] Secondly, because manufacturers have little interest in comparing one of their drugs with a “comparable” drug of a competitor. In order to obtain market authorization, manufacturers are not required to compare their new drug with existing (comparable) drugs. A comparison with a placebo is usually sufficient. For example, a prospective head-to-head comparative study into the effectiveness and safety of nivolumab and pembrolizumab is missing.

Hospital information systems and registries are other sources of information on the interchangeability of (monopoly) drugs with the same indication. However, these information systems are often not designed to assess interchangeability of different drugs. The dozens of patient, disease and treatment registries set up in recent decades, usually focus on treatment outcome of just one drug or a group of drugs. Furthermore, part of these registries are financed by manufacturers. This makes it difficult to compare different (therapeutic) treatments based on hospital information systems and registries.

[36] SiRM - Up for high-hanging fruit – Evaluation of the Dutch expensive drugs policy 2016-2018

5.1.2 Scientific associations are insufficiently equipped to make timely statements about interchangeability

Scientific associations would be the appropriate parties to make statements about therapeutic equivalence and interchangeability of drugs, for example in treatment guidelines. For example, the Haemato Oncology Foundation for Adults in the Netherlands (HOVON) made a statement in a news report about the interchangeability of CML products for the pilot of the NFU / NVZ / ZN procurement organization.[37] Publication of this statement in a news report however left room for discussion, as the treatment guideline in force had not (yet) been amended.

It appears however that most scientific associations have difficulty making timely statements about interchangeability of drugs. The larger and more diverse the members of the association, the more effort it takes to reach agreement on interchangeability. For example: the statement of interchangeability within the CML cluster was made possible by a "key opinion leader" with authority in a thoroughly organized scientific association.

The difficulty in making timely statements is primarily due to the lack of information about interchangeability (§ 5.1.1). But also due to differences in the interpretation of scientific research. Moreover, prescribers mainly consider their own experiences with the drugs in question. Furthermore, (financial) interests of prescribers, departments and hospitals can prevent prescribers from making statements about interchangeability. A more practical reason is that scientific associations often have insufficient manpower to make timely statements about interchangeability. They usually come together at a low frequency, for example every six months. This low frequency makes it difficult to make timely statements when new drugs with high overall costs are increasingly coming onto the market.

Interviewees indicate that in the absence of a national statement, a statement about interchangeability can also be made by prescribers in an individual hospital or in a procurement organization of hospitals. The disadvantage of this is that the oligopoly market in that case (at first) is only created for a limited part of the Netherlands.

5.1.3 Systematically establishing interchangeability on a national level could accelerate the emergence of oligopoly markets

For oligopoly drugs, increasing scale to a national level when establishing interchangeability can be beneficial. Statements on interchangeability are often based on national and / or international information. Therefore, it would be more efficient to make these statements at the national level. This could speed up the decision-making process and could go hand-in-hand with the formulation of a joint medical policy at a national level (step 1 in the purchasing process, § 3.1).

A statement of a scientific association about interchangeability on a national level, reinforces the purchasing power of procurement agents. ZIN could systematically make these statements for inpatient drugs, just as they do for outpatient drugs. A statement on interchangeability is needed to create an oligopoly market with (a certain degree of) price competition. Subsequently, the

[37] See coverage on the HOVON website

statement needs to be supported by prescribers in hospitals. After all, they are the ones who will eventually have to prescribe the agreed upon preference drug.

5.2 Lack of information and a legal basis to refuse monopoly drug reimbursement limits negotiation power of ZN

The VWS “office of financial arrangements” only negotiates prices of inpatient drugs that have more than € 40 million total budget impact or cost more than € 10 million and at least € 50,000 per patient per year.[38] New inpatient monopoly drugs that are outside this scope automatically enter the basic health insurance package for MSC.

For several years, the ZN negotiation organization has been negotiating prices for these new inpatient monopoly drugs. However, their negotiating power remains limited because they lack information on the cost-effectiveness of monopoly drugs. Moreover they lack sufficient legal basis to jointly refuse reimbursement of a monopoly drug that is offered for a "non-cost-effective" price.[39] Independent cost-effectiveness analysis and a legal basis for a “waiting room” for decentralized negotiations, can reinforce the position of the ZN negotiation organization. We explain these points in more detail below.

5.2.1 ZN negotiation organization has almost no information on the cost-effectiveness of new inpatient drugs

For price negotiations, information on cost-effectiveness of a drug is important, certainly if the procurement agent feels that a drug is offered too expensive in relation to the value it adds. The cost-effectiveness of outpatient drugs, eligible for reimbursement, is systematically assessed by ZIN. Similarly, ZIN assesses cost-effectiveness of inpatient drugs with high budget impact (“waiting room” drugs), so that the VWS “office of financial arrangements” can use cost-effectiveness information in their price negotiations (§ 2.1).

ZIN does not assess cost-effectiveness for inpatient drugs with lower budget impact. Scientific associations, such as the NVMO or HOVON, occasionally make statements about effectiveness, but not about cost-effectiveness. The ZN negotiation organization therefore has little or no independently determined information about the cost-effectiveness of the drugs under negotiation. This information is however important to facilitate a firm discussion on the price of a drug in relation to its value, with the aim of reimbursing (only) drugs at socially acceptable costs.

5.2.2 Health insurers have insufficient legal basis to jointly refuse reimbursement of non-cost-effective drugs

As described in § 2.1, health insurers have the option of looking critically at reimbursement of new drugs under the Health Insurance Act. They are allowed to assess the “standard of science and practice” of new forms of care, including inpatient prescription drugs. This concerns the

[38] Scope of the budget impact criteria of the “waiting room” for expensive inpatient drugs.
[39] That is, when the costs per Quality Adjusted Life Year (QALY) won are higher than € 80,000 (limit used by ZIN for diseases with a high disease burden).

effectiveness of the drugs. However they lack a legal basis for jointly refusing reimbursement of non-cost-effective drugs. Yet, ZIN does apply cost-effectiveness (thresholds) when assessing outpatient drugs for inclusion in the outpatient Drugs Reimbursement System (GVS). And the VWS “office of financial arrangements” uses the cost-effectiveness analyses of ZIN for the negotiation of drugs in the “waiting room”. The roles of ZIN and the “office of financial arrangements” are defined by law.

5.2.3 Independent cost-effectiveness analyses and legal definition of a “waiting room” for decentralized negotiations can strengthen the position of ZN negotiation organization

Independent cost-effectiveness analyses, by ZIN or possibly other parties, would contribute to the negotiation power of the ZN negotiation organization.

In addition, the position of the ZN negotiation organization would be strengthened if a legal basis was created for joint application of cost-effectiveness thresholds in the reimbursement of inpatient drugs. A "waiting room for decentralized negotiations" has been topic of discussion for several years.[40] The NFU, NVZ and ZN together with VWS, currently investigate how the negotiation power of market participants with respect to drugs can be strengthened. The "waiting room for decentralized negotiations" is one of the options looked at.[41]

[40] VWS - *Visie op geneesmiddelen: Nieuwe geneesmiddelen snel bij de patiënt tegen aanvaardbare kosten* (jan 2016, in Dutch); NVZ, NFU, Netherlands Patients Federation, ZKN, FMS, ZN, V&VN en VWS - *Bestuurlijk akkoord medisch-specialistische zorg* 2019 - 2022 (2018, in Dutch).
[41] VWS – *Toelichting op actielijnen uitbreiding IPAM* (juli 2019, in Dutch).

Appendix 1 Drugs in the Dutch healthcare system

In this appendix we briefly describe the relevant background of the Dutch healthcare system with specific attention to medical specialist care (MSC) and drugs.

The Dutch are compulsorily insured for the basic package for MSC. Every year, they purchase a policy from one of the health insurers. There are approximately four large and six smaller health insurers who all work nationwide. The health insurers purchase care from hospitals on behalf of their policyholders.

Drugs are either used inpatient or outpatient. Approximately two-thirds of the expenditure on drugs concern outpatient drugs, and a third are inpatient drugs.[42]

Outpatient prescription drugs

For outpatient drugs, an explicit decision is made as to whether or not they are allowed in the insured package. The Healthcare Institute (ZIN) advises the Minister of Health, Welfare and Sport (VWS) on the inclusion of outpatient drugs in the insured coverage and the Minister takes the final decision. Outpatient drugs can then be provided by pharmacies. Doctors prescribe the active ingredient. Health insurers agree with pharmacies on the type, variety and brand of medications they are allowed to offer. This means that for generic drugs the price is often leading.

As part of its advice, ZIN also makes a statement about the cost-effectiveness of outpatient drugs. For drugs for which manufacturers charge a price that is too high in relation to the value added by the drug, ZIN advises the Minister of VWS not to include the drug in the insured package, unless he can agree a price with the manufacturer that is in better relationship to its added value. The VWS "office of financial arrangements" will subsequently negotiate the price with the manufacturer. When they reach an agreement, the Minister decides to include it in the insured package. The results of the negotiations are not made public as manufacturers are willing to give more discounts for a confidential price agreement. Coincidentally, a budget has been agreed for the expenditure on out-of-hospital drugs at national level.

Inpatient prescription drugs / drugs for MSC

Inpatient drugs are included in the insured coverage if they meet the "standard of science and practice". It is therefore in principle an "open inflow" system without a formal statement about the price or the cost effectiveness of the medication. The exception to this is the so-called "waiting room" for expensive drugs (see § 2.1). Drugs that do not fall into the "waiting room" are bought by hospitals from manufacturers. Hospitals negotiate discounts, for example in the form of free extra products with an order, a discount on the invoice, fee for data, fee for service or research fees. The guideline of the ACM indicates that hospitals may cooperate for this purchase, even at a national

[42] Zorginstituut - Zorginstituut geeft inzicht in ontwikkeling uitgaven geneesmiddelen (2018, in Dutch)

level. Health insurers are also allowed to negotiate prices, with actual procurement taking place between hospitals and manufacturers.

Expenses for inpatient drugs fall under the budget for MSC. Health insurers purchase these drugs from hospitals. Sometimes expenditure on drugs is charged to the hospital budget, sometimes the hospital has an open volume agreement with the health insurer and the hospital is reimbursed for all its expenses. There are two ways of reimbursement:

- Cheaper inpatient drugs that have little impact on the rates of Diagnosis Treatment Combinations (DBC) in are reimbursed from the standard DBC rates. The costs for these drugs are then reimbursed at an (integral) rate with the costs of diagnostics and treatment. These drugs often fall under the fourth segment, multi-source drugs (Figure 1).
- More expensive inpatient drugs are not reimbursed by DBCs, but separate “add-on” rates apply. These drugs often fall into the top three segments, monopoly, oligopoly and drugs in competition (Figure 1).

Transfer of specialist drugs from the outpatient to inpatient budget

In 2010, the acting Minister of VWS decided to transfer part of the outpatient drugs from the outpatient funding system to the inpatient funding system of the MSC. The reason for the adjustment was that for certain specialist drugs the claim- and funding system was ambiguous. In addition, according to the Minister, the situation at the time offered insufficient guarantees for efficient medication use and sufficient price competition.

TNFα blockers and similar biologicals were transferred in 2012. Oral oncolytics and the growth hormone somatropin followed in 2013, fertility hormones in 2014 and more than 30, mostly older, oncolytics in 2015. A specific (add-on) payment title was created for each drug with separate rates.

As a result of this transfer, the type of drug that (procurement organizations of) hospitals mainly purchased shifted over the past few years. Before the transfer, they jointly purchased cheaper prescription drugs for MSC. After the transfer their focus shifted to procurement of the more expensive drugs that were reimbursed with “add-ons”.

Appendix 2 Research approach

In this evaluation report we provide answers to the research questions of the ACM. We base this report on information obtained through desk research and interviews. In case of conflicting input or input that was only given by a single interviewee, we weighted the input based on our professionalism and decided on whether, and how, this input was included in the report.

Research questions

The ACM has formulated the following research questions for the evaluation of the guideline:

1. Is the target audience familiar with the guideline and the Q&A's, is the room for collaboration that the guideline offers (in particular the “safe harbor”) clear and are the principles of the ACM for oversight of joint procurement clear?
2. What effect has the guideline had?
    a. Has the reluctancy to collaborate in procuring prescription drugs for MSC decreased?
    b. Has more and / or different collaboration been sought when procuring these drugs? For example, the collaboration between NFU, NVZ and ZN.
    c. What results - in terms of more negotiating options and possibly better negotiations results – has the collective procurement as stated under b led to?
3. What opportunities for improvement, containment and / or expansion of the guideline are there? Consider also potential expansion of the geographical scope - of the guideline - and of the scope in products and / or services. Best practices from other countries can play a role in answering this question.

Desk research

We used various public sources for desk research, such as monitors from NZa and reports from research agencies. In the evaluation report we refer to these sources in footnotes.

Interviews

The evaluation report is mainly based on information obtained in interviews with various stakeholders in collective procurement of prescription drugs, as well as those involved in collective procurement of medical devices (Table 3).

Stakeholder type	Name	Organization
Expert	Chiel Bos, Piet de Bekker	Platform inkoopkracht dure geneesmiddelen
	Peter de Braal	ZN
	Mark Van Houdenhoven	Sint Maartenskliniek
	Lonneke Timmers	Zorginstituut
Procurement organization medical devices	Paul Dalhuisen	Santeon
	Petri Heitkönig-Verberkt*	CWZ / Santeon

Stakeholder type	Name	Organization
	Gerwin Meijer	NFU Inkoopsamenwerking
	Frida van den Maagdenberg*	Amsterdam UMC
	Marco Plasier	InkoopAlliantie Ziekenhuizen
	Mario van de Sande	Intrakoop
Procurement organization drugs	Liesbeth van Dijk	VieCuri / ICZON
	Yuhan Kho	CWZ / Santeon
	Eric van Roon, Sander Zielhuis	MCL
	Tim Visser	Martini Ziekenhuis / Santeon
	Juliëtte Zwaveling	LUMC / iZAAZ
Umbrella organizations	Caspar van Loosen	NVZA
	Kor Noorlag, Harrie Kemna, Gabriëlle ten Broeke, Bart Cramers	NVZ
	Jan Oltvoort	VIG
	Peter Roos, Edith Meijwaard	NFU / iZAAZ
	Anneke Prenger, René van Duuren, Frank van den Berg	ZN
Health insurers	Erik Blaauw	ONVZ
	Alexander Bybau, Gerard Adelaar	Zilveren Kruis
	Henk Eleveld	Menzis
	Mark van Kralingen	CZ
	Maarten Loof	VGZ
	Nelly Pijnenburg	CZ
Prescriber	Nicole Blijlevens	HOVON
Patient association	Pauline Evers*	NFK
Government	Marina van den Bosch-Vos, Rob Haeck	VWS

* Only written input received.

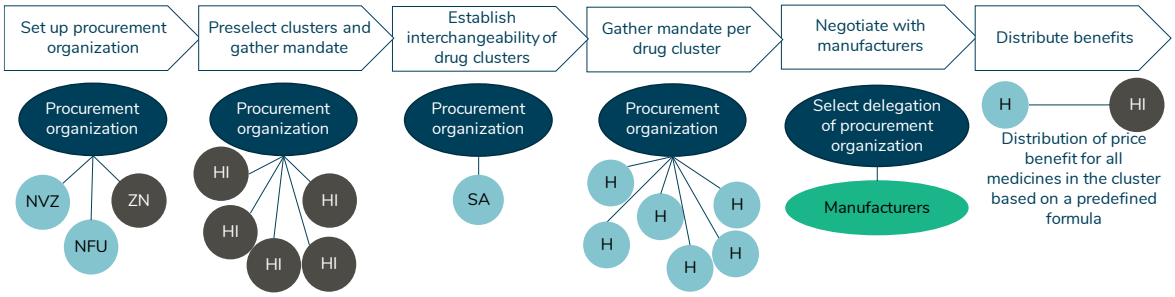
Table 3 List of persons interviewed

Appendix 3 National procurement and negotiation organization

In this appendix, we describe the designs of the NVZ / NFU / ZN procurement organization and the ZN negotiation organizations that were created after the publication of the guideline.

National procurement organization - oligopoly drugs

General hospitals (as represented by umbrella organization NVZ), academic hospitals (NFU) and health insurers (ZN) take part in the national procurement for oligopoly drugs. The umbrella organizations are responsible for the management of the project. Figure 5 describes the various steps of the procurement process that are followed. The procurement organization is currently working on a new design of the procurement organization.

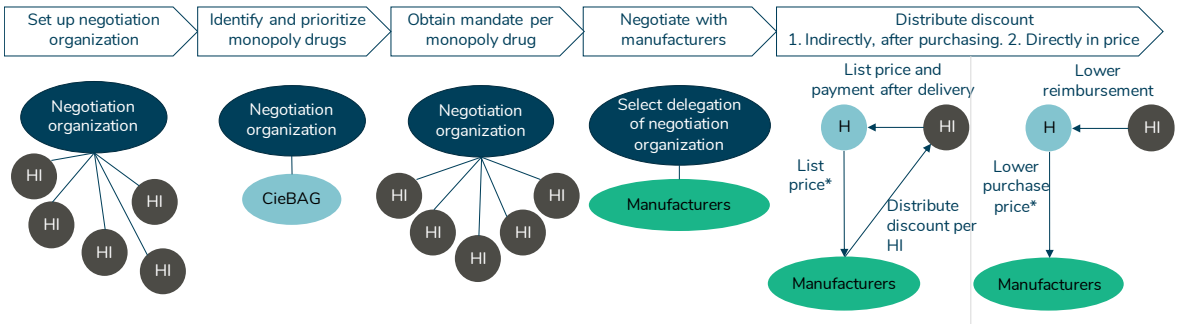


NFU = Dutch Federation of University Medical Centers; NVZ = Dutch Hospital Association; ZN = Federation of Health care insurers; HI = Health care insurer; H = hospital; SA = scientific association.

Figure 5 Schematic representation of the NVZ / NFU / ZN procurement organization for oligopoly drugs

National negotiation organization - monopoly drugs

Only health insurers participate in the national price negotiation organization for monopoly drugs, with ZN being responsible for the management of the organization. Figure 6 describes the various steps of the price negotiation process



*Hospitals have room to negotiate additional discounts with manufacturers.
HI = Health care insurer; H = hospital; CieBAG = ZN Add-on Drugs Assessment Committee

Figure 6 Schematic representation of the ZN negotiation organization for monopoly drugs