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Guidelines on collective procurement of prescription drugs for medical specialist care

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Introduction

Hospitals, health insurers and other market participants increasingly look for ways to join forces in the procurement of prescription drugs for medical specialist care. They do so against the backdrop of increasing pressure on the affordability and availability of expensive drugs in particular.

ACM observes that, in some cases, there may be some hesitation to collaborate, even if cooperation would be in the interest of patients and the insured. ACM is of the opinion that the competition rules offer a lot of room for collective procurement of drugs for medical specialist care, as it allows purchasing agents to negotiate lower drug prices, higher discounts, and better conditions, which benefit patients and the insured.

ACM wishes to enable market participants to take more advantage of the opportunities that the competition rules offer for collective procurement. These guidelines therefore define the 'safe harbour' where collective procurement of prescription drugs for medical specialist care is allowed. ACM additionally explains what the starting points are for its oversight of this form of collective procurement.

How does ACM define collective procurement of prescription drugs?

These guidelines relate to the collective procurement of prescription drugs for medical specialist care. In these guidelines, such drugs are: all so-called 'add-on' drugs, and other drugs that fall under the scope of the criterion 'medical care that medical specialists tend to offer', which is covered by the Dutch Healthcare Insurance Act (in Dutch: Zorgverzekeringswet). These guidelines do not apply to other forms of procurement collaborations by hospitals and/or health insurers, nor does it apply to collective procurement of 'pharmaceutical care'.

In these guidelines, ACM defines collective procurement as follows: collective procurement by Dutch market participants from manufacturers of drugs for specialist medical care. The procurement itself can be done by different hospitals, including the hospital pharmacists who work there, by different hospitals in collaboration with a health insurer or by multiple health insurers combined, possibly with one or more hospitals. Other parties, too, such as medical associations can be involved in the collective-procurement process.

The degree of cooperation in collective procurement may vary. It is, for example, possible to cluster the demand for specific drugs, but there can also be more directive forms of collective procurement such as a collective drug-preference policy where arrangements are made on the use of specific preferential drugs, where medically possible.

Limited risks for competition

Generally speaking, ACM believes that the possible negative effects for competition as a result of collective procurement of drugs for medical specialist care will be limited.

ACM thinks it is not likely that collective procurement of drugs for medical specialist care will create harmful effects for the drug market such as reduced innovation efforts, reductions in the selections of products, or a decrease in the quality of products. After all, the drugs are procured from drug manufacturers serving a market that is much larger than the Netherlands, and thus have ample selling opportunities outside the Netherlands. Therefore, drug manufacturers generally have a strong position vis-à-vis buyers, even if those buyers combined had a large share of the Dutch market.

ACM also considers it unlikely that, as a result of collective procurement of drugs, hospitals and health insurers will have similar costs to such an extent that it becomes easier for them to coordinate their behavior on the medical specialist care market or the health insurance market, thereby restricting competition. Even though drugs take up an increasing share of hospital budgets, the total purchasing costs of drugs still take up only a limited share of those budgets. For this reason, ACM thinks it is also unlikely that harmonization of that part of the costs would not leave enough room for effective competition.

Safe harbour for collective procurement

ACM assumes that collective procurement of drugs for medical specialist care will not have any negative effects on competition, and is therefore allowed, provided that the following three criteria are met.

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

In this context, it is not relevant whether the parties participating in the collective procurement each (or combined) have a strong position on the market for medical specialist care or the health insurance market. As long as the collective procurement itself meets the abovementioned criteria, it is allowed, even if the participating parties together take up a large share of the market. ACM does

assume, however, that all participants limit their procurement arrangement to the collective procurement of drugs for medical specialist care only.

Parties that wish to collaborate in procurement are, of course, allowed to choose a different approach, as long as this approach complies with competition rules. Collective procurement that does not comply with said criteria, too, will not necessarily have any negative effects on competition. This applies, in any case, to collective procurement by market participants that are not each other's competitors on the sales market, the market for medical specialist care or the health insurance market, respectively. A collaboration between non-competitors could, in fact, improve competition, and is, in principle, allowed.

Procurement collaborations between competitors that do not meet said criteria do not necessarily meet objections either. If their combined market share is small, it is unlikely that this collective procurement will have negative effects on competition. However, if participants combined do hold a stronger position on the market for medical specialist care or the health insurance market, a more thorough analysis of the procurement collaboration is required to test it against competition rules. Market participants will then have to investigate further whether their collaboration will have negative on competition, and, if so, whether the benefits of the collaboration outweigh those negative effects.

In addition, the following is also important. Procurement of drugs for medical specialist care takes place within the boundaries of a regulated market. Market participants operate within a multitude of boundaries established by, among other laws, the Dutch Health Insurance Act, the Dutch Medicines Act (Dutch: Geneesmiddelenwet), and the Dutch Individual Healthcare Professions Act (Dutch: Wet BIG), as well as thereto-related regulations. ACM stresses that the competition rules obviously leave intact the health care-related rights and duties that follow from said acts.

Rules of thumb for the assessment of collective procurement

Market participants can use the following rules of thumb to assess whether a specific procurement collaboration falls within the safe harbour.

- 1. The total costs of the collectively purchased drugs cannot comprise more than a limited share of the hospital costs.** It is important that collective procurement does not lead to participants sharing costs to a high degree in order to safeguard that collective procurement does not facilitate coordination of the behavior of participants on the market for medical specialist care or the health insurance market. If the total costs of the collectively purchased drugs comprise less than 15 percent of the turnover of each of the hospitals participating in the collaboration, ACM assumes that the collective procurement will not have any negative effects on competition. A threshold of 5 percent applies to health insurers, with the total costs of claims for the basic health insurance as the starting point. Participants are advised to monitor the trend of the costs of the collectively purchased drugs in order to be able to detect on time if the costs exceed that threshold.

2. **Admission to the joint purchasing organization is sufficiently safeguarded.** In order to avoid anti-competitive exclusion, it is important that the admission process for joining the joint purchasing organization is based on objective and non-discriminatory criteria that are known in advance. This does not mean that joint purchasing organizations must accept all potential participants, or that they are not allowed to set admission criteria, for example concerning minimum purchase obligations or monitoring drug consumption. Such requirements may be necessary for a well-functioning joint purchasing organization. However, this does mean that joint purchasing organizations, in order to be able to remain in the safety zone, cannot reject potential participants without having objective and non-discriminatory criteria that are known in advance.
3. **The flexibility of the joint purchasing organization is sufficiently safeguarded.** It is critical that the joint purchasing organization is sufficiently flexible in order to retain the incentive for parties involved to pursue an efficient procurement policy. Participants should be allowed to arrange the procurement (or a part thereof) differently, without disregarding any contractual obligations that have been made, of course. Any restrictions imposed on participants, for example concerning purchase obligations or purchasing outside the purchasing organization, should not go beyond what is necessary for a well-functioning joint purchasing organization. Also, the joint purchasing organization should not make participants commit to a specific contract longer than what is necessary for being able to negotiate effectively with a drug manufacturer. 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.

Furthermore, the following is also important, in a more general sense. In order to safeguard that the procurement policy remains limited to the collective procurement of prescription drugs, it is critical that the information exchange between the participants of the joint purchasing organization should not go beyond what is necessary for the collective procurement, and that there are sufficient safeguards that prevent the direct exchange of commercially-sensitive information between participants. This will, for example, be the case if the joint purchasing organization is positioned independently, and all information required for the procurement, including information for monitoring, is only shared with the joint purchasing organization, and not among participants.

The procurement collaboration cannot have an anticompetitive objective either. Competitors are not allowed to make price-fixing agreements or to share markets, either the market for medical specialist care or the health care insurance market. This means, for instance, that hospitals that procure collectively are not allowed to make mutual arrangements about their bids regarding the reimbursement of drugs in the negotiations with health insurers. Similarly, health insurers that collectively procure drugs are not allowed to make mutual arrangements about how much of the negotiated discount they will pass on to their clients. They need to draw up their own commercial strategies. Participants of a joint purchasing organization consisting of hospitals and with one or more health insurers are, however, allowed to make arrangements about the distribution of the realized purchasing discounts among themselves (using a formula).

It is also conceivable that hospitals and health insurers that collaborate make arrangements that contain elements that go beyond procurement of drugs from drugs manufacturers, and may, for example, relate to the market of medical specialist care and the health insurance market. Such arrangements, for instance on the level of drug reimbursement, on subsequent calculations or on selective procurement fall outside the scope of these guidelines. In such situations, it is up to the participants themselves to assess whether such arrangements are compatible with the competition rules.

ACM's starting points for oversight of collective procurement

It is good that hospitals, health insurers and other parties together are looking for ways to make their purchasing policies more effective, and to negotiate better conditions.

The competition rules offer enough room for such efforts. As long as the collective procurement of prescription drugs for medical specialist care meets the criteria of the safe harbour, ACM sees no reason for further action.

Outside the safe harbour, ACM will only intervene if the collective procurement has negative effects on competition, and if the cost savings or other benefits of the collective procurement do not offset these anticompetitive effects. If ACM receives indications about or establishes that a joint purchasing organization may have harmful effects, it can further investigate whether or not competition rules are infringed.

Conclusion

Developments in collective procurement of prescription drugs for medical specialist care occur at great speed. With these guidelines, ACM wishes to provide hospitals, health insurers and other parties involved the clarity they need in order to be able to collaborate in the collective procurement of drugs for medical specialist care. ACM thus wishes to offer room for market initiatives. Furthermore, ACM assumes that the procurement benefits achieved by hospitals and health insurers through collective procurement are passed on to patients and the insured.

ACM expects that, with these initiatives, purchasing parties are able to strengthen their positions on the drug market, and, in this way, help realize an affordable and durable health care system.

ACM will evaluate this approach after three years.