General Purchasing Conditions Healthcare (GPCH)

Module Pharmaceuticals

General Purchasing Conditions in Healthcare (GPCH) from the Dutch Hospital Association (NVZ), Association of the Care for People with Disabilities in the Netherlands (VGN), ActiZ, organization of healthcare entrepreneurs, Dutch Mental Health Care (GGZ), Dutch Procurement Association (Nevi), Intrakoop, the healthcare purchase cooperative, Purchase Alliance Hospitals (IAZ), Santeon, Purchase Cooperation Friesian Hospitals (IFZ), mProve and Zorgservice XL. This Module Pharmaceuticals may be declared applicable to agreements to be concluded between institutions affiliated to the aforementioned sector associations and suppliers, together with the "General Purchasing Conditions Healthcare", which were filed with the District Court of The Hague on 14 November 2022, under file number 2022/33. The Module Pharmaceuticals was filed with the District Court of The Hague on 11 September 2024, under file number 21/2024.

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Article 1 Additional or Revised Definitions for the Module Pharmaceuticals

AIP: Pharmacy Purchase Price excluding VAT, which serves as the basis for the maximum price of pharmaceuticals.
DHPC: Direct Healthcare Professionals Communications.
Distribution Arrangement: A set of agreements among the manufacturer, wholesaler, and Client regarding logistics and associated rates.
FMD: Falsified Medicines Directive.
G-Standaard: A database that facilitates the prescribing, dispensing, ordering, billing, and reimbursement of healthcare products. It contains relevant information about healthcare products available at pharmacies and Clients, including pharmaceuticals, medical devices, and self-care products. All public pharmacists, hospital pharmacists, outpatient pharmacists, general practitioners, pharmacy-holding general practitioners, medical specialists, and health insurers in the Netherlands utilize the G-Standaard.
Deficiency: The failure of the Products to meet the guarantees specified in Article 12.1 of GPCH or the failure of the Services provided by the Supplier to fulfil the obligations outlined in the Agreement.
Auxiliary Materials: Non-medical device materials such as supporting aids, tools, drawings, models, administration aids, and dosing aids, as well as software and other tools (including but not limited to e-learning modules) for the correct use of the Product.
IGJ: The Dutch Health and Youth Care Inspectorate.
Supplier: The counterparty of the Client, whose role can vary and can coexist in different forms, including:
a. As a manufacturer defined in the Dutch Medicines Act (Geneesmiddelenwet, GnW), hereafter referred to as the 'Medicines Act', recognized as a direct counterparty with whom the Client and Supplier establish direct agreements and maintain contractual relationships.
b. As a wholesaler defined in the Medicines Act, with the role of either 1. a direct counterparty, establishing direct agreements and maintaining contractual relationships, or 2. acting as a distribution channel for the manufacturer under an Agreement between the Client and manufacturer, with operational execution carried out through the wholesaler. The Agreement will specify the agreements made in this regard to ensure proper operational execution.
c. As a supplying pharmacy defined in the Medicines Act, serving as a direct counterparty, where direct agreements are made and contractual relationships are maintained.
NZa: The Dutch Healthcare Authority.
SmPC: Summary of Product Characteristics.
WGP: Medicines Price Act.

Article 2 General Provisions

2.1 The definitions from the GPCH 2022 (specifically, the general section) are applicable unless stated otherwise in this module.

2.2 The provisions of the GPCH 2022 apply unless explicitly modified in this module.

2.3 The Agreement will detail the Supplier's role and specify the role assigned to each part of the assortment. If the Agreement does not clarify the Supplier's role, it will be understood as role a, which is that of the manufacturer.

2.4 If the Product is delivered through a Distribution Arrangement via a wholesaler, the Supplier, acting as a wholesaler in the manufacturer's distribution channel, will ensure that the agreements with the manufacturer align with those made between the Client and the Supplier as outlined in the Agreement, including the GPCH 2022 and this module.

Article 3 Deviations from GPCH 2022

Article 4.1 of the GPCH 2022 is amended to:
The Client is authorised to modify the scope and nature of the Performance to be delivered in consultation with the Supplier within a reasonable timeframe unless such modifications result in consequences that make it unreasonable to expect the Supplier to comply without negotiation. The Supplier will promptly inform the Client in writing following notification of the change. The Supplier will then propose new conditions, if feasible, which the Client can reasonably accept or reject.

Article 5.1 of the GPCH 2022 is amended to:
The Ministry of Health, Welfare and Sport (VWS) sets the maximum prices (AIP) for prescription-required and registered medicines twice a year (in April and October) in accordance with the WGP. These prices are listed in the G-Standaard. The Supplier may agree to different purchase prices or discounts. The agreed-upon prices can never exceed the maximum prices stated in the G-Standaard; indexing for medicine prices is not applicable.

Article 5.2 of the GPCH 2022 is amended to:
Prices are quoted in Euro (€), exclusive of VAT, and are based on the delivery condition of 'delivered duty paid' (D.D.P.) as per Incoterms® 2020, at the specified place of delivery. The price of the medicine includes only the costs of the Product. Any additional charges may be billed separately and only if there is mutual agreement between the Parties. The Parties will make every effort to deliver or receive as many Products as possible in the same order to minimise the Supplier's shipping costs and reduce environmental impact.

Articles 7.3 to 7.11 of the GPCH 2022 apply unless overridden by European legislation or the Medicines Act, including the FMD.

Article 8.1 of the GPCH 2022 is amended to:
The Product must be adequately packaged and labelled in accordance with applicable European and national laws and regulations, including the FMD, as well as any additional requirements set by the Client, ensuring that the Product reaches the Client in good condition and preservation.

Article 8.2 of the GPCH 2022 is amended to:
The Supplier is responsible for any damage resulting from improper packaging. The Supplier will handle the collection or return of the damaged Products and will coordinate, in consultation with the Client, to provide a new (undamaged) delivery of the Product within a reasonable timeframe, as short as possible, without incurring additional costs for the Client. If the Client deems the situation urgent, the Supplier will expedite delivery without any extra charges for the Client.

Article 8.7 of the GPCH 2022 is amended to:
If the Supplier processes or destroys packaging materials at the Client's request, this will be done at the Supplier's cost and risk, in compliance with the provisions of the GDPR regarding personal data protection.

Article 9 of the GPCH 2022 is amended to:
Ownership of the Product and its Components will transfer upon delivery and, if applicable, after completing an acceptance procedure. In cases where Products are part of advanced therapies involving co-creation between the Supplier and the Client, the transfer of ownership will be detailed separately.

Article 11.1 of the GPCH 2022 does not apply if the Product is delivered through a Distribution Arrangement via a wholesaler for the Products delivered under that arrangement.

Article 12.1, 5th subparagraph of the GPCH 2022, does not apply to the Supplier in its capacity as a wholesaler.

Article 12.2 of the GPCH 2022 is amended to:
In the event of a Safety Notification or Recall, the Supplier must inform the Client and the IGJ in writing according to the DHPC once it has been internally confirmed that a Safety Notification or Recall is warranted. The Supplier is responsible for maintaining an adequate and careful internal procedure for Safety Notifications or Recalls, which will be shared with the Client in the manner specified by the Client.

Article 12.5 of the GPCH 2022 does not apply to the Supplier in its capacity as a wholesaler.

Article 13 of the GPCH 2022 does not apply if the Product is governed by the Medicines Act, which outlines the required documentation and how it should be provided.

Articles 13.5 and 13.6 of the GPCH 2022 do not apply to the Supplier in its capacity as a wholesaler.

Article 16 of the GPCH 2022 does not apply except in the case of radiopharmaceuticals, where quality control is specified in the SmPC as established by the manufacturer.

Article 17.2 of the GPCH 2022 is applicable as long as it does not contradict the Medicines Act.

Articles 25 and 26 of the GPCH 2022 do not apply to the Supplier in its capacity as a wholesaler.

Article 27.2 of the GPCH 2022 is amended to:
The Supplier must replenish the stock of Products by the next working day after the Client has indicated through an Order that it has started using or intends to use Products from the Supplier. If Products on Consignment are nearing their expiration date, the Supplier will replace them with Products that have a reasonable shelf life, incurring no additional costs for the Client.

Article 4 Articles of the GPCH 2022 that are not applicable

The following articles of the GPCH 2022 do not apply when using this Module Pharmaceuticals:

- Article 8.5;
- Article 15;
- Article 22, which is included in this module as Article 5;
- Article 25;
- Article 26.

Article 5 Termination

5.1 In the case of an indefinite contract, either Party may terminate the Agreement at any time. The Supplier has a notice period of at least twelve months, while the Client must observe a notice period of at least four months. The Client will not be liable for any damages to the Supplier due to this termination.

5.2 Termination must be communicated in writing and will be promptly confirmed by the receiving Party.

5.3 Additionally, either Party may terminate the Agreement (in addition to legal options) if:

- new options for the same application (such as generics or biosimilars) are introduced to the market, leading to significantly lower prices;
- there are changes in Dutch laws or regulations, rulings from Dutch courts, self-regulatory bodies, the IGJ, the NZa, or other government institutions, or if new or revised policy guidelines are issued by the IGJ, NZa, or other government institutions that create a situation where the Parties can no longer reasonably comply with the terms of the Agreement.