Rijksinkoopsamenwerking
Ministerie van Binnenlandse Zaken en Koninkrijksrelaties

Procurement
Information notice

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General information Market Consultation and Contracting Authority	
Title	Supply of Medicinal Cannabis to the Netherlands
Contracting Authority	Ministry of Health, Welfare and Sport CIBG Agency (Office of Medicinal Cannabis)
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QUESTION 1.	Section 2.1 indicates an expected volume range of 350 to 750 kg over a period of at least eighteen months. Cultivation is planned per cultivar and per harvest cycle, so an aggregate figure cannot readily be converted into a capacity commitment. Can the Contracting Authority provide an indicative breakdown of that volume per variety, or the historical distribution of demand across the five varieties listed in Table 2.1?
Source	Section 2.1; page 5.
Answer	Based on the information gathered in this Market Consultation, we might write a request for a Tender. If we request certain varieties, in flower form or granulated form, the expected volumes, shelf life, packaging sizes, presentations and other requirements will be mentioned in the Tender documents.

QUESTION 2.	Table 2.1 states that all types are available in 5 gram containers and 400 gram laminated bags. Can the Contracting Authority confirm whether these specific configurations are a requirement of the Contract, or whether alternative primary packaging is acceptable provided it is validated, compliant with the applicable European Pharmacopoeia requirements and suitable for the intended shelf life? As with the granulated presentation, packaging formats specific to the current Dutch programme are not held in general stock by other EU suppliers.
Source	Section 2.1; page 5. Section 3.2; page 8.
Answer	See the answer to question 1.

QUESTION 3.	Section 3.1 describes the current situation, in which the OMC QA team reviews the batch documentation, issues the Certificate of Analysis and approves the batch, while the future process is described as including full release of medicinal cannabis in accordance with GMP by the supplier. Can the Contracting Authority clarify what is meant by full release in this context, specifically whether it expects certification by a Qualified Person as defined in Directive 2001/83/EC, or release by the responsible or competent person designated under the national legislation applicable to the manufacturing site?
Source	Section 3.1; page 7.
Answer	By 'full release' we mean the release by the responsible or competent person designated under the national legislation applicable to the manufacturing site, which may differ per country.

QUESTION 4.	Section 3.2 requires at least three medicinal cannabis varieties, similar to Bedrocan, Bediol and Bedrolite. According to Table 2.1, two of those three are currently supplied as granulate. a) Can the Contracting Authority confirm whether the granulated presentation is itself a requirement of the Contract, or whether the requirement relates to the variety characteristics, in which case dried flower tops (flos) of a comparable variety would be acceptable for all varieties? b) If the granulated presentation is a requirement, can the Contracting Authority explain the underlying reason for it, for example pharmacy handling, dosing accuracy, intended route of administration or patient preference, so that suppliers can assess whether an alternative meets the same need?
Source	Section 3.2; page 8. Section 2.1 (Table 2.1); page 5.
Answer	See the answer to question 1.

QUESTION 5.	Granulate, being comminuted cannabis flower, is not a presentation for which a dedicated European Pharmacopoeia monograph exists, and Table 2.1 additionally describes Bedrobinol as OMC grade rather than EP grade. Can the Contracting Authority indicate which specification it considers applicable in each of these two cases, and how compliance with the requirements cited in section 3.2 is to be demonstrated for a presentation or a grade that falls outside the cited monographs?
Source	Section 3.2; page 8. Section 2.1 (Table 2.1); page 5.
Answer	See the answer to question 1.

QUESTION 6.	Section 3.2 states that the OMC wishes to receive the products from general stock, with preferably no custom work or production on request. Outside the Netherlands, granulate is not a presentation held in general stock by EU medicinal cannabis suppliers, as it is specific to the current Dutch programme, and supplying it would require dedicated comminution, process validation and a separate stability programme. How does the Contracting Authority weigh the granulated presentation against its stated preference for supply from general stock?
Source	Section 3.2; page 8.
Answer	See the answer to question 1.

QUESTION 7.	Comminution increases the exposed surface area of the herbal material, which affects terpene loss, cannabinoid oxidation and microbiological control, so stability data generated on flos cannot be extrapolated to a granulated presentation. Can the Contracting Authority indicate which stability data package it would consider acceptable for a granulated presentation, for example real time data or accelerated data supported by a real time commitment, and separately what minimum remaining shelf life it would require at the moment of delivery to the Dutch distributor?
Source	Section 3.2; page 8. Section 3.3; page 8.
Answer	See the answer to question 1.

QUESTION 8.	a) If the granulated presentation is retained within scope, would the Contracting Authority consider a phased introduction, in which the flos presentations are supplied from the start of the framework agreement and the granulated presentations follow at a later agreed date once process validation and the supporting stability studies are complete? b) Relatedly, would a supplier offering a subset of the varieties, for example the flos presentations only, be considered to meet the scope as currently described?
Source	Section 3.2; page 8. Section 3.3; page 8.
Answer	See the answer to question 1.

QUESTION 9.	Section 3.2 states that the OMC shall ensure that the relevant exemptions required under the applicable Dutch Opium Act will be obtained. Can the Contracting Authority describe how import and export licensing is expected to operate in practice under the Contract, in particular whether licences are issued per shipment, what lead time the OMC applies for issuing the Dutch import licence, and how this interacts with the delivery times expected from the supplier?
Source	Section 3.2; page 8. Section 1.1; page 3.
Answer	Only the OMC can import and export medicinal cannabis; if we place an order we will provide an import authorization together with it at the same time.

QUESTION 10.	Section 3.2 requires activities to be carried out in accordance with EU GMP and GDP and applicable local legislation. Medicinal cannabis manufacture is not harmonised at EU level, and a number of Member States authorise cannabis manufacturing sites under dedicated national medicinal cannabis legislation rather than under Directive 2001/83/EC. Those national regimes nonetheless apply the same standard. The executive orders concerned adopt the European Commission's good manufacturing practice guidelines, »The Rules Governing Medicinal Products in the European Community, Volume 4«, by direct reference; they set qualification criteria for the designated responsible person that correspond to Article 49 of Directive 2001/83/EC, including the same degree disciplines, the same basic subjects and the same minimum practical experience; and they require that person to attest, on release of each individual batch, that the batch has been manufactured in accordance with those requirements, and to record that attestation in a register retained and available to the competent authority, corresponding to Article 51. Because the authorisation is granted under national cannabis legislation rather than under the pharmaceutical directives, however, the resulting GMP certificate is issued in a national format and is not entered in the EudraGMDP database, which covers certificates issued under the pharmaceutical legislation. Can the Contracting Authority confirm that a manufacturing authorisation and GMP certificate of this kind satisfy the requirement in section 3.2, and indicate which documentary evidence it will accept and how it intends to verify it? We would be glad to provide the specific legislative references directly to the Contracting Authority on request.
Source	Section 3.2; page 8.
Answer	Based on the information gathered in this Market Consultation, we might write a request for a Tender. The requirements and certifications or other documentary evidence will be mentioned in the Tender documents.