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Planning

Prior Information Notice - Licence Variation for Anastrozole

NHS England

F01: Prior information notice

Prior information only

Notice identifier: 2021/S 000-022199

Procurement identifier (OCID): ocds-h6vhtk-02de26

Published 7 September 2021, 7:14pm

Section I: Contracting authority

I.1) Name and addresses

NHS England

Quarry House

Leeds

LS2 7UE

Contact

Liz Fleetwood

Email

liz.fleetwood1@nhs.net

Country

United Kingdom

NUTS code

UKE - Yorkshire and the Humber

Internet address(es)

Main address

<https://www.england.nhs.uk/>

Buyer's address

<https://www.england.nhs.uk/>

I.3) Communication

Additional information can be obtained from the above-mentioned address

Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at

<http://health.atamis.co.uk>

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

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II.1.2) Main CPV code

- 33600000 - Pharmaceutical products

II.1.3) Type of contract

Supplies

II.1.4) Short description

NHS England and NHS Improvement (NHSEI) has published this Prior Information Notice (PIN) in relation to regulatory work to secure a licence variation for Anastrozole. The PIN seeks to gather information and feedback from pharmaceutical manufacturers of anastrozole, to inform NHSEI's strategy to contract for this regulatory work.

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.2) Additional CPV code(s)

- 33600000 - Pharmaceutical products
- 33600000 - Pharmaceutical products

II.2.3) Place of performance

NUTS codes

- UKE - Yorkshire and the Humber

II.2.4) Description of the procurement

The Medicines Repurposing Programme has been established by NHS England and NHS Improvement (NHSE/I, the "Authority") to identify and pursue opportunities to strengthen the evidence base, licensing, supply, cost-effectiveness and equitable adoption of medicines used outside of their original marketing authorisation. The Programme is jointly

sponsored by NHSE/I, the Department of Health and Social Care (DHSC), Medicines and Healthcare products Regulatory Agency (MHRA), National Institute for Health and Care Excellence (NICE), and National Institute for Health Research (NIHR). Further details can be found at: <https://www.england.nhs.uk/medicines-2/medicines-repurposing-programme/> The Medicines Repurposing Programme is inviting those interested organisations to express an interest to seek a major (type II) MHRA Marketing Authorisation variation for anastrozole. The variation is to add a new indication to the current licence using published evidence. The selected company (the “Bidder”) would need to prepare a dossier for the MHRA, apply for the licence variation, and if granted update their licence, Summary of Product Characteristics and patient information leaflet with the new indication and related data, according to the regulatory review. Interested organisations can access the PIN and register their interest here <https://health-family.force.com/s/Welcome> We will also be making time available for individual organisation discussions with NHSEI between 13th and 24th September 2021 should this be considered helpful. Once registered, please contact liz.fleetwood1@nhs.net with your availability. Deadline is 24th September @ 12:00noon

II.3) Estimated date of publication of contract notice

1 October 2021

Section IV. Procedure

IV.1) Description

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes