Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India

NOTICE INVITING EXPRESSION OF INTEREST FOR

Selection of Software Services Provider (SSP) for Digital Transformation of Central Drugs Standard Control Organization, IPC & NIB

(Digital Drugs Regulatory System)

Corrigendum to

EoI IT-13011(17)/1/2023-CDSCO

Dated 10th November 2023

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Ministry of Health and Family Welfare

Government of India

November 2023

FDA Bhawan, Kotla Road, New Delhi-110002

Invitation of EoI for Selection of Software Services Provider (SSP) for Digital Transformation of Central Drugs Standard Control Organization, IPC & NIB (Digital Drugs Regulatory System)

Central Drugs Standard Control Organization (CDSCO) is the National Drugs Regulatory Authority of the Government of India and is responsible for laying down the standards for Drugs, approval for Clinical Trials and New Drugs, control over the quality of imported Drugs, coordination of activities of State Drugs Control Organizations, enforcement of the Drugs and Cosmetics Act, granting and renewal of licenses for specified critical categories of Drugs such as blood and blood products, Vaccine and Sera, r-DNA products.

The regulatory landscape is continuously evolving, striving for alignment with global standards, while ensuring affordability and accessibility for its vast population. India's with its vast population and diverse health challenges, ensuring the availability of safe and effective medicines is not just a commercial imperative but also a significant public health concern.

To build a robust yet enabling digital regulatory ecosystem in India, CDSCO invites Expression of Interest from interested Software Services Provider for the Development and Maintenance of Digital Drugs Regulatory System (DDRS) of Central Drugs Standard Control Organization, IPC & NIB for an expected period of about 8 to 10 years.

The aim is to develop DDRS as a unified digital ecosystem. Once operational, all existing portals will be discontinued, and DDRS will serve as a Single Window, Single Sign On, and Unified Portal for all regulatory activities. This platform is envisioned to serve as a new approach to regulatory system in the form of India’s DPI for regulatory systems, thereby ensuring quality medicines for India and the world.

The system needs to be developed using a platform design approach, open-source technology stack, and open standards.

For overview of the existing system, scope, pre-qualification criteria, other terms and conditions and suggested response formats, please refer to specific sections of this EoI document.

Interested Service Providers who meet the pre-qualification criteria may furnish their Expression of Interest with all the necessary documents on or before 16:00 hours on Wednesday, 7th December 2023 at the email admn@cdsco.nic.in.

Schedule of events & bid details

S No	Particular	Details
1	Start date of issuance of EOI document	2nd November 2023
2	Last date for Submission of Queries (by email only)	22nd November 2023
3	Pre-Bid Conference (In hybrid mode)	Date and Time: 29th November 2023 at 2:00 P.M. Meeting link: https://cdscofda.webex.com/cdscofda/j.php?MTID=m8f94101f113eb8acfee63387705895d3 Address: Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi-110002
4	Last date and time for EOI Submission	7th December 2023