



## Online RTI Request Form Details

## RTI Request Details :-

RTI Request Registration number	CDSKO/R/E/22/00241
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION

## Personal Details of RTI Applicant:-

Name	[REDACTED]
Gender	Male
Address	[REDACTED]
Country	India
State	Gujarat
Status	Details not provided
Educational Status	Details not provided
Phone Number	[REDACTED]
Mobile Number	Details not provided
Email-ID	[REDACTED]

## Request Details :-

Citizenship	Indian
Is the Requester Below Poverty Line ?	No

(Description of Information sought (upto 500 characters))

<b>Description of Information Sought</b>	
Please provide details of any safety trials conducted on pregnant women and breast feeding women for the following Covid 19 Vaccines: 1. Covishield 2. Covaxin 3. ZyCoV-D	
Concerned CPIO	Sushanta Sarkar
Supporting document <i>(only pdf upto 1 MB)</i>	Supporting document not provided

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Public Authorities Available

# RTI Online

Version 2.0

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## Online RTI Status Form

Note: Fields marked with \* are Mandatory.

Enter Registration Number	CDSKO/R/E/22/00241
Name	██████████
Received Date	30/07/2022
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Status	REQUEST DISPOSED OF
Date of action	25/08/2022
<b>Reply :- As per reply received from the concerned division:</b> The details of safety results from the clinical trials of Covishield, Covaxin and ZyCOV-D vaccines are available in Summary of Product Characteristics (SmPC) which are publicly available on CDSCO website i.e. <a href="http://www.cdSCO.gov.in">www.cdSCO.gov.in</a> and also on the manufacturers official website, Further details of clinical trials are also mentioned on the ICMR CTRI website i.e. <a href="http://www.ctri.nic.in">www.ctri.nic.in</a> .	
CPIO Details :-	Sushanta Sarkar Phone: 011-23216367 <a href="mailto:rti[cell@cdsco]nic[in]">rti[cell@cdsco]nic[in]</a>
First Appellate Authority Details :-	A[dot] K[dot] Pradhan Phone: 011-23216367 <a href="mailto:rti[cell@cdsco]nic[in]">rti[cell@cdsco]nic[in]</a>
<span style="border: 1px solid black; border-radius: 10px; padding: 2px;">Nodal Officer Details :-</span>	
Telephone Number	011-23236973
Email Id	<a href="mailto:jayantwz[at]gmail[dot]com">jayantwz[at]gmail[dot]com</a>

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## Online RTI Appeal Form Details

### RTI Appeal Details :-

RTI Appeal Registration number	CDSO/A/E/22/00091
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION

### Personal Details of Appellant:-

Request Registration Number	CDSO/R/E/22/00241
Request Registration Date	30/07/2022
Name	██████████
Gender	Male
Address	██████████
Country	India
State	Gujarat
Status	Details not provided
Educational Status	Literate
Phone Number	██████████
Mobile Number	Details not provided
Email-ID	██████████

### Appeal Details :-

Citizenship	Indian
Is the Requester Below Poverty Line ?	No
Ground For Appeal	Provided Incomplete,Misleading or False Information
CPIO of Public Authority approached	Sushanta Sarkar
CPIO's Order/Decision Number	Details not provided
CPIO's Order/Decision Date	

(Description of Information sought (upto 500 characters))

<p><b>Prayer or Relief Sought</b></p> <p>Respected Shri A. K. Pradhan sir,</p> <p>I had made a straightforward request for information on safety trials conducted on pregnant women and breast feeding women for 3 Covid 19 Vaccines in India.</p> <p>The response provided was long winding and dismissive.</p> <p>The CPIO has asked me to refer to information provided in SMPC uploaded on CDSO website, however no link to the same has been provided. Upon looking at CDSO website, it is not possible to locate the suggested files. I have located SMPC for one vaccine on the manufacturers website, <a href="https://www.bharatbiotech.com/images/covaxin/covaxin-smpc.pdf">https://www.bharatbiotech.com/images/covaxin/covaxin-smpc.pdf</a></p> <p>However, this done not mention whether safety trials have been conducted or even authorised by the regulatory body.</p> <p>Also the CPIO requested to refer to a website, <a href="http://ctri.nic.in">ctri.nic.in</a>, however, they do not mention how or where I can locate the requisite information. I was unable to get the information I had requested, whether safety trials have been conducted for pregnant women and lactating mothers for 3 Covid vaccines available in India.</p>
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A simple yes or no response would have sufficed for the RTI query. Instead the CPIO seems to be trying to mislead, distract and withhold information available with the office.

I humbly request you to provide the requested information in a simple manner without trying to mislead or dismiss the request. I am repeating my query below for your ready reference:

Please provide details of any safety trials conducted on pregnant women and breast feeding women for the following Covid 19 Vaccines:

1. Covishield
2. Covaxin
3. ZyCoV-D

Looking forward to your prompt and appreciable response.

Thank you.

Supporting document *(only pdf upto 1 MB)*

Supporting document not provided

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**Z-28020/554/2022-DC**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organization,**  
**(RTI CELL)**

**FDA Bhawan,**  
**Kotla Road, New Delhi**

Date: 13<sup>th</sup> Sep. 2022

To,



**Subject: Information under RTI Act, 2005 – Regarding**

**Refer: Registration Number: CDSCO/A/E/22/00091 (Dated 25<sup>th</sup> August 2022)**  
**and CDSCO/R/E/22/00241 (Dated 30<sup>th</sup> July 2022)**

Dear Sir/Madam,

With reference to your RTI appeal application number: CDSCO/A/E/22/00091 Dated 25<sup>th</sup> August 2022 with regards to your application no.: CDSCO/R/E/22/00241 Dated 30<sup>th</sup> July 2022 on the subject cited above.

The matter has been examined and it was found that the reply of above cited RTI application was already provided by the CPIO vide letter even number dated 25<sup>th</sup> August 2022.

**However, on your appeal reply is mentioned as below:**

As per reply received from concerned division, this office has not received application from M/s Serum and M/s Cadila for the grant of permission to conduct such clinical trial. Further, M/s Bharat Biotech had submitted application for grant of permission to conduct clinical trial of Covaxin in pregnant women. Subsequently, however, the said firm has withdrawn the application.

**Accordingly, the RTI appeal is disposed off**

In case the applicant is not satisfy with the same. He/she may prefer appeal to the Central Information Commission within the prescribed time line.

*Yours faithfully*

**(A. K. Pradhan)**  
**First Appellate Authority &**  
**Joint Drugs Controller (India)**

***Address of Second Appellate Authority:***

***The chairman,***  
***Central Information Commission,***  
***CIC Bhawan, Baba Gang Nath Marg, Munirka,***  
***New Delhi – 110067***