

Analysis of ENDS RTI

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The government is planning to ban Electronic Nicotine Delivery Systems (ENDS) in India contending that using ENDS will push the youth to smoking cigarettes. Various advisories, policies, etc., have been issued by both the Central as well as various State Governments thereby banning the manufacture, import, sale and purchase of ENDS.

It is quite surprising that while the governments at Central as well as at State levels are making efforts for banning ENDS, in reality, there is no law in India, neither at the Central level nor in any State, regulating or even defining ENDS.

So, to understand why and how the governments are issuing various advisories, regulations, policies, etc., thereby banning ENDS, Heart Care Foundation of India (HCFI) wrote numerous Right to Information (RTI) applications to the Central Government as well as all State Governments.

More than 40 RTI applications have been filed by HCFI to various departments of Central Government and State Governments. However, only half of the RTI applications have been replied by them.

It is quite astonishing that both Central and State Governments are issuing various advisories, regulations thereby banning ENDS when in fact the Directorate General of Health Services (DGHS) in two of its replies has specifically stated that e-cigarettes cannot be regulated under the provisions of Drugs and Cosmetics Act, as they are not covered under the definition of drugs.

Some of the answers received are:

- Reply dated 30.11.2018 received from **DGHS** to the RTI application **dated 31.10.2018** stating that *“Point No. 1 to 20: It is to inform you that, the proposal of regulation of e-cigarettes has already been deliberated in 48th Drugs Consultative Committee (DCC) meeting held on 24.07.2015 and DCC opined that e-cigarettes*

cannot be regulated under the provisions of Drugs and Cosmetics Act as e-cigarettes are not covered under the definition of the term drug.”

- The reply from **Food Safety and Standards Authority of India (FSSAI)** dated 26.11.2018 stated that as per Section 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on sales) Regulations, 2011, *“Product not to contain any substance which may be injurious to health: Tobacco and nicotine shall not be used as ingredients in any food product.”*
- Reply dated 30.11.2018 received from **DGHS** to the RTI application **dated 08.11.2018** stated that *“Point No. 1 to 11: It is to inform you that, the proposal of regulation of e-cigarettes has already been deliberated in 48th Drugs Consultative Committee (DCC) meeting held on 24.07.2015 and DCC opined that e-cigarettes cannot be regulated under the provisions of Drugs and Cosmetics Act as e-cigarettes are not covered under the definition of the term drug”.*
- Reply dated 12.04.2019 received from **Delhi Government** thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government and the matter is *sub judice* in the Hon'ble High Court of Delhi.
- Reply dated 22.04.2019 received from **West Bengal Government** thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government and stating that action regarding the process to ban ENDS in our state was initiated much earlier on 21.06.2018 vide File No. H/TDE/3D-11/2018 and the file has been approved and sent to higher authority for issuing notification by Directorate of Drugs Control, Govt. of West Bengal on 30.08.2018. The Final issuance of notification to ban e-cigarettes is awaited to be issued by Govt. of WB.
- Reply dated 23.04.2019 received from **Uttarakhand Government** thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government and an office order has been issued to all Senior Drugs Inspectors/Drugs Inspector of the state for proper enforcement and implementation of the said order of Govt. of India. Copies of both the orders are also provided.

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- Reply dated 26.04.2019 received from **Himachal Pradesh Government** thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government.
- Reply dated 08.05.2019 received from **Uttar Pradesh Government** thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government.
- Reply dated 14.05.2019 received from **Madhya Pradesh Government** thereby saying that the information sought is personal information so the same cannot be shared.
- Reply dated 16.05.2019 received from **Karnataka Government** provided the copy of the Circular dated 22.04.2019 issued by Government of Karnataka, Drugs Control Department along with the copy of the letter dated 22.02.2019 and advisory dated 28.08.2018 of Central Government.
- Reply dated 03.07.2019 received from **Assam Government** stating that "no letter has been received by the State Nodal Officer, NTCP, Assam issued by Drugs Controller General of India, Directorate of Health Services, CDSCO, Ministry of Health dated 22.02.2019."

Date	RTI Applications/Replies
26th September, 2018	RTI application to Central Government asking for list of NRT items.
26th September, 2018	RTI application to Central Government w.r.t. Notification dated 28.08.2018 issued by Ministry of Health and Family Welfare.
19th October, 2018	RTI application to Karnataka Government seeking copy of minutes of all meetings conducted by the Department of Health on ENDS.
19th October, 2018	RTI application to Central Government w.r.t. Notification dated 28.08.2018
19th October, 2018	RTI application to Drug Controller asking the amount of nicotine used in ENDS and other information.
19th October, 2018	RTI application w.r.t. Notification dated 28.08.2018: <ul style="list-style-type: none"> i. Mizoram ii. Kerala iii. Uttar Pradesh iv. Bihar v. Punjab vi. Jammu & Kashmir
19th October, 2018	RTI application to Kerala Government w.r.t. Notification dated 28.08.2018.
19th October, 2018	RTI application to FSSAI seeking information whether ENDS is considered as food item under FSSAI Act or not.
26th November, 2018	FSSAI reply dated 26.11.2018 stating that as per Section 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on sales) Regulations, 2011, "Product not to contain any substance which may be injurious to health: Tobacco and nicotine shall not be used as ingredients in any food product."
31st October, 2018	RTI application to DGHS
30th November, 2019	Reply dated 30.11.2018 received from DGHS to the RTI application dated 31.10.2018 stating that "Point No. 1 to 20: It is to inform you that, the proposal of regulation of e-cigarettes has already been deliberated in 48th Drugs Consultative Committee (DCC) meeting held on 24.07.2015 and DCC opined that e-cigarettes cannot be regulated under the provisions of Drugs and Cosmetics Act as e-cigarettes are not covered under the definition of the term drug."
8th November, 2018	RTI application to DGHS.
30th November, 2019	Reply dated 30.11.2018 received from DGHS to the RTI application dated 08.11.2018 stating that "Point No. 1 to 11: It is to inform you that, the proposal of regulation of e-cigarettes has already been deliberated in 48th Drugs Consultative Committee (DCC) meeting held on 24.07.2015 and DCC opined that e-cigarettes cannot be regulated under the provisions of Drugs and Cosmetics Act as e-cigarettes are not covered under the definition of the term drug."
08th November, 2018	RTI application to Delhi Government seeking information w.r.t. grants/donations from private NGO.
9th January, 2019	Reply by Delhi Government

Date	RTI Applications/Replies
28th November, 2018	RTI application to Gujarat Government w.r.t. Bloomberg Initiative to reduce tobacco use
29th December, 2018	Reply dated 29.12.2018 stating no such information available
28th November, 2018	RTI application to Tamil Nadu Government w.r.t. Bloomberg Initiative to reduce tobacco use
29th December, 2018	Reply dated 29.12.2018 stating funds were received by Tamil Nadu Government
28th November, 2018	RTI application to Mizoram Government w.r.t. Bloomberg Initiative to reduce tobacco use
6th March, 2019	RTI applications dated 06.03.2019 w.r.t. letter dated 22.02.2019 issued by Drugs Controller General India sent to: <ul style="list-style-type: none"> i. Bihar ii. Delhi iii. DGHS, Ministry of Health, Union Government iv. West Bengal v. Rajasthan
12th April, 2019	Reply dated 12.04.2019 received from Delhi Government thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government and the matter is <i>sub judice</i> in the Hon'ble High Court of Delhi.
22nd April, 2019	Reply dated 22.04.2019 received from West Bengal Government thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government and stating that action regarding the process to ban ENDS in our state was initiated much earlier on 21.06.2018 vide File No. H/TDE/3D-11/2018 and the file has been approved and sent to higher authority for issuing notification by Directorate of Drugs Control, Govt. of West Bengal on 30.08.2018. The Final issuance of notification to ban e-cigarettes is awaited to be issued by Govt. of WB.
18th March, 2019	RTI applications dated 18.03.2019 w.r.t. letter dated 22.02.2019 issued by Drugs Controller General India sent to: <ul style="list-style-type: none"> i. Punjab ii. Chandigarh iii. Odisha iv. Uttar Pradesh v. Andhra Pradesh vi. Maharashtra vii. Goa viii. Karnataka ix. Kerala x. Andhra Pradesh xi. Madhya Pradesh xii. Assam xiii. Mizoram xiv. Uttarakhand xv. Nagaland xvi. Meghalaya xvii. Agartala xviii. Himachal Pradesh
23rd April, 2019	Reply dated 23.04.2019 received from Uttarakhand Government thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government and an office order has been issued to all Senior Drugs Inspectors/Drugs Inspector of the state for proper enforcement and implementation of the said order of GOI. Copies of both the orders are also provided.
26th April, 2019	Reply dated 26.04.2019 received from Himachal Pradesh Government thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government.

Date	RTI Applications/Replies
8th May, 2019	Reply dated 08.05.2019 received from Uttar Pradesh Government thereby confirming that a letter dated 22.02.2019 has been issued by the Central Government.
14th May, 2019	Reply dated 14.05.2019 received from Madhya Pradesh Government thereby saying that the information sought is personal information so the same cannot be shared.
16th May, 2019	Reply dated 16.05.2019 received from Karnataka Government providing the copy of the Circular dated 22.04.2019 issued by Government of Karnataka, Drugs Control Department along with the copy of the letter dated 22.02.2019 and advisory dated 28.08.2018 of Central Government.
3rd July, 2019	Reply dated 03.07.2019 received from Assam Government stating that "no letter has been received by the State Nodal Officer, NTCP, Assam issued by DCGI, Directorate of Health Services, CDSCO, Ministry of Health dated 22.02.2019."



Health Care Spending by the Government

As per National Health Accounts (NHA) Estimates, Government Health Expenditure as a percentage of GDP has increased from 1.13% in 2014-15 to 1.18% in 2015-16. The National Health Policy, 2017 envisages raising public health expenditure to 2.5% of GDP by 2025 in a time bound manner. It also envisages increasing State sector health spending to more than 8% of their budget by 2020... (PIB, Ministry of Health and Family Welfare, July 23, 2019)

Do Herbs Contain Modern Drugs?

Herbs are pharmacologically active and therefore can positively and negatively impact patient health. Positive effects may include improvement of disease-specific outcomes. Negative effects may include adverse effects and drug-herb interactions. For these reasons, the Joint Commission in the United States now requires that herb and supplement use be recorded as part of the medication list in the hospital medical record.

WHO Recommends Dolutegravir as Preferred HIV Treatment Option in all Populations

Based on new evidence assessing benefits and risks, the WHO recommends the use of the HIV drug dolutegravir (DTG) as the preferred first-line and second-line treatment for all populations, including pregnant women and those of childbearing potential.

Initial studies had highlighted a possible link between DTG and neural tube defects (birth defects of the brain and spinal cord that cause conditions such as spina bifida) in infants born to women using the drug at the time of conception. This potential safety concern was reported in May 2018 from a study in Botswana that found 4 cases of neural tube defects out of 426 women who became pregnant while taking DTG. Based on these preliminary findings, many countries advised pregnant women and women of childbearing potential to take efavirenz (EFV) instead.

New data from two large clinical trials comparing the efficacy and safety of DTG and EFV in Africa have now expanded the evidence base. The risks of neural tube defects are significantly lower than what the initial studies may have suggested.

DTG is a drug that is more effective, easier to take and has fewer side effects than alternative drugs that are currently used. DTG also has a high genetic barrier to developing drug resistance, which is important given the rising trend of resistance to EFV and nevirapine-based regimens. In 2019, 12 out of 18 countries surveyed by WHO reported pre-treatment drug resistance levels exceeding the recommended threshold of 10%.