

## **PRESS RELEASE**

The Surgical Manufacturers and Traders Association has approached the Hon'ble High Court of Delhi on 14.12.2020 preferring Writ Petition (Civil) No. 10478 of 2020, titled, "Surgical Manufacturers And Traders Association Vs. Union Of India" impugning the Notification bearing S.O. No. 648 (E) dated 11.02.2020 passed by the Ministry of Health and Family Welfare, Union of India, whereby all devices intended to be used specially for human beings or animals have been declared as drugs, as defined under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940.

The Association has previously also filed Writ Petition (Civil) No. 10514 of 2019, titled "The Surgical Manufacturers & Traders Association Through Its Authorised Representative vs Union of India" challenging an earlier Notification bearing No. 4754 dated 03.12.2018, notifying some medical devices namely the Digital Thermometer, Nebulizer, Blood Pressure Monitoring Device and Glucometer as drugs. The same is also pending before the Hon'ble High Court of Delhi.

Both the Petitions were listed today i.e. 16.12.2020 before The Chief Justice of the High Court of Delhi and Hon'ble Mr. Justice Prateek Jalan, when the Bench was pleased to issue notice on Writ Petition (Civil) No. 10478 of 2020, filed on 14.12.2020 and the Union of India has accepted the notice and entered appearance. The Bench has posted both the writs to be heard together on 29.01.2021.

When the matter was taken up for hearing, the counsel for the Association in Writ Petition (Civil) No. 10478 of 2020 brought to the Court's notice that "The Draft Medical Devices (Safety, Effectiveness and Innovation) Bill, 2020" is pending and has already been circulated for internal discussion and the Impugned Notification bearing S.O. No. 648 (E) dated 11.02.2020 passed by the Ministry of Health and Family Welfare, Union of India only serves as a stop gap arrangement and is liable to be quashed.

The petition filed on 14.12.2020, bearing Writ Petition (Civil) No. 10478 of 2020 seeks the following prayers,

*"a) Issue a Writ Of Certiorari Or Any Other Appropriate Writ, Order or Direction Under Article 226 of the Constitution declaring the impugned notification bearing S.O. No. 648(E) dated 11.02.2020 as ultra-vires Section 3(b)(iv) of the Act;*

*b) pass such further order(s) as may be deemed fit and proper in facts and circumstances of the present case, in the interest of justice."*

and challenges the Notification bearing S.O. No. 648 (E) dated 11.02.2020 mainly on the following grounds:

- i. Amendment under the garb of an notification
- ii. Wednesbury unreasonableness and patent arbitrariness
- iii. Inadequate staffing and refusal to fully adhere to the 82nd Meeting of the Drugs Technical Advisory Board
- iv. Non-consideration of the petitioner association and other similar stakeholders representations
- v. Undue hardship to stakeholders on the supply and demand side

The Association is being represented by counsels Mr. Adit S. Pujari and Ms. Kajal Dalal in Writ Petition (Civil) No. 10478 of 2020 and Mr. Harsh Kumar and Mr. Aditya Awasthi in Writ Petition (Civil) No. 10514 of 2019.