***ToxicsWatch Alliance (TWA) Occupational Health India (OHI)***

To

Drugs Controller General of India

Central Drugs Standard Control Organization (CDSCO),

Directorate General of Health Services

Union Ministry of Health and Family Welfare,

Government of India

FDA Bhavan, ITO, Kotla Road,

New Delhi -110002

Date: May 27, 2020

Subject- Complaint regarding ongoing exposure of Indians to hazardous asbestos mineral fibers contaminated Talcum Powder of Johnson & Johnson

Sir,

This is to draw your immediate attention of CDSCO towards the announcement dated May 19, 2020 by Johnson & Johnson, a multinational company headquartered in New Brunswick, New Jersey, USA stating that it will discontinue sale of its Talcum Powder products in North America. This announcement is aimed at safeguarding the health of residents and citizens of North America but not the residents and citizens of India. Such doublespeak and double standard in matters of public health in general and children’s health in particular merits urgent intervention of the CDSCO. (Reference: Statement of Johnson & Johnson, May 19, 2020, <https://www.jnj.com/our-company/johnson-johnson-consumer-health-announces-discontinuation-of-talc-based-johnsons-baby-powder-in-u-s-and-canada>)

We wish to point out that “the Company will wind down the commercialization of talc-based Johnson’s Baby Powder in the U.S. and Canada in the coming months. Existing inventory will continue to be sold through retailers until it runs out.” The news report titled *Johnson & Johnson to End Talc-Based Baby Powder Sales in North America* published in *The New York Times* merits attention as well. (Reference: Tiffany Hsu and Roni Caryn Rabin, May 19, 2020, <https://www.nytimes.com/2020/05/19/business/johnson-baby-powder-sales-stopped.html>).

We submit that a study titled "Asbestos in commercial Indian talc" published in the *American Journal of Industrial Medicine* states that “this product study of various talcum powders marketed to combat prickly heat, purchased from Indian retailers both over‐the‐counter and online, demonstrates the ease of general population access to such products and the potential for significant exposure to asbestos. The analytical results of this study confirm that asbestos exposure of the Indian and potentially greater Southeast Asian populations is not limited to traditional occupational settings.” The findings of this study “imply that the asbestos‐related medical and public health implications to consider will need to extend to persons of both genders and all ages among this population group. This study's confirmation of an underappreciated source of asbestos exposure, through personal care products, also highlights the risk that anyone within breathing range of these aerosolizeable, contaminated, talcum products incurs.” The authors of the study observe, “"Until asbestos is also viewed as a hazard in India and banned, there will still be considerable risk to health." There is a need to identify the source of their talc supply as well. (Reference: : Fitzgerald S, Harty E, Joshi TK, Frank AL. Asbestos in commercial indian talc. American Journal of Industrial Medicine. 2019; 1‐8. <https://doi.org/10.1002/ajim.22969> )

We submit that Word Health Organisation (WHO)’s International Agency for Cancer Research (IARC) has recognized presence of asbestos in talcum powder. *IARC Monograph on the Evaluation of Carcinogenic Risks to Humans on Carbon Black, Titanium Dioxide, and Talc* (2010) refers to the presence of asbestos in talcum powder. It also refers to "Use of talc for feminine hygiene". The use of body powder for feminine hygiene can be estimated from the prevalence reported for controls in case–control studies that investigated the association between the use of cosmetic talc for feminine hygiene and the risk for ovarian cancer. It refers to exposure to respirable dust during the use of talcum powders on the face, body and babies. Talc is used as a surface lubricant on the majority of condoms manufactured; contact with condoms may also represent a direct means of exposure of the female genital tract to talc. Exposure to talc can also occur during surgical procedures when using powdered gloves. Talc particles were observed in the navels of small children, in the testes, on the vocal cords, in the urinary bladder tract and after removal of varicous veins. Besides this the Food Chemical Codex (2003) provides specifications for food-grade talc, including the statement that “talc derived from deposits that are known to contain associated asbestos is not food grade.” Under the voluntary guidelines initiated in 1976, the Cosmetic, Toiletry, and Fragrances Association stated that all cosmetic talc should contain at least 90% platy talc (hydrated magnesium silicate) that is free from detectable amounts of fibrous, asbestos minerals. Meanwhile, some 67 countries have banned all kinds of asbestos. World Health Organisation (WHO)’s recommendations have established the infectious nature of Covid-19, the same WHO has underlined that “All types of asbestos cause lung cancer, mesothelioma, cancer of the larynx and ovary, and asbestosis (fibrosis of the lungs).” (Reference: <https://www.who.int/ipcs/assessment/public_health/asbestos/en/> and <https://www.who.int/news-room/fact-sheets/detail/asbestos-elimination-of-asbestos-related-diseases>)

Fitzgerald S et al observe, “With products of this nature being readily available and appealing to both genders, it is necessary to consider what the potential health risks and burdens of disease are for millions of exposed women of childbearing age and the children for whom they provide care. IARC has confirmed the causal association of asbestos with ovarian cancer and other cancers”.

We submit that the CDSCO must undertake the enviro-occupational health audit of the workers who handle asbestos laden talcum powder in the manufacturing facilities of talcum powder products in general besides the health audit of the communities who are in the vicinity of such factories and recommend adequate compensation for those who are exposed to the carcinogenic mineral fibers and are suffering from asbestos related diseases. This will be also relevant for assessing the harm which the unsuspecting consumers continue to face. These consumers include all judges, legislators, officials, their children and grandchildren and the residents of India.

Earlier, an investigative report titled “Johnson & Johnson knew for decades that asbestos lurked in its Baby Powder” was published on December, 14, 2018 which too is relevant for protecting the human rights of Indians. The investigation was conducted by Reuters, a 167 year old international news agency headquartered in London. This investigative report is consistent with the findings of a study by India’s Industrial Toxicology Research Centre (IITR), Lucknow, a constituent laboratory of Council of Scientific & Industrial Research (CSIR), Ministry of Science and Technology, Government of India on “Exposure risk to contaminants in pharmaceutical and cosmetic powders” has found that “There are different types of cosmetic powders such as body powder, baby powder, face powder, eye shadow and powdered blush as well as pharmaceutical powders available in the market. Both the sexes of all age groups are using these powders. These are talc - based. Talc is a mineral product and often contaminated with asbestos fibres.”

The aim of the IITR study “was to investigate the safety of such powders being sold in the market, initially by analyzing the asbestos content. Five branded samples of talcum powder were analysed and all were found contaminated with asbestos fibres. Asbestos fibre contamination in these powders ranged from 10.3 – 15.4%. Fibre length study on two samples revealed that asbestos fibres were 22.8 – 34.7%, 48.2 – 55.1% and 17.1 – 22.1% in the range of <10µm, 10 – 20µm, and > 20µm, respectively. The study indicates risk of human exposure to asbestos through the use of naturally contaminated talcum powder. It is noteworthy that asbestos takes many years to cause asbestosis and carcinogenic malignancies which are irreversible. It also necessitates a regular monitoring and surveillance on all the cosmetic and pharmaceutical powders being marketed for asbestos contamination.” This has been published in the Annual Report Annual Report 2005-2006 of IITR. IITR is accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) for chemical and biological testing and is recognized for GLP (Good Laboratory Practice) toxicity testing. (Reference: <http://www.itrcindia.org/ITRC_Annual_Report_2005-06.pdf> )

The investigation by Reuters corroborates the findings of IITR. This recent investigation was undertaken in the wake of three verdicts in New Jersey, California and St. Louis awarding compensation to plaintiffs who blamed asbestos-tainted Johnson & Johnson talc products for their mesothelioma, a type of cancer that develops from the thin layer of tissue that covers many of the internal organs. The connection between asbestos exposure and mesothelioma was discovered in the 1970s. The third verdict was a watershed in in St. Louis: The 22 plaintiffs were the first to succeed with a claim that asbestos-tainted Baby Powder and Shower to Shower talc, a longtime brand the company sold in 2012 that caused ovarian cancer, which is much more common than mesothelioma. The jury awarded them $4.69 billion in damages. Most of the talc cases have been brought by women with ovarian cancer who say they regularly used Johnson and Johnson talc products as a perineal antiperspirant and deodorant. The inclusion of ovarian cancer besides mesothelioma has broadened the potential liability of Johnson & Johnson, a 132 year old multinational medical devices, pharmaceutical and consumer packaged goods manufacturing company headquartered in New Brunswick, New Jersey, USA.

Earlier, British Medical Journal (BMJ) published an article titled “Jury awards $4.7bn damages against Johnson & Johnson in talcum cancer case” published in the renowned British Medical Journal (BMJ). As per BMJ’s article, “More than 9000 former US talcum customers have lodged suits against the company. Most claim damages for ovarian cancer, but some allege that using the product led them to develop mesothelioma. The award is by far the biggest yet against Johnson and Johnson in litigation relating to talcum powder and the first case in which plaintiffs alleged that asbestos in talcum powder caused their disease. The verdict was handed down in the Circuit Court of the City of St. Louis. ((Reference: BMJ 2018; 362 doi: <https://doi.org/10.1136/bmj.k3135>)

We reiterate that this investigative report is of deep relevance for the public health of present and future generation of Indians given the fact that Johnson & Johnson company has admittedly been in India for last 70 years. The company has brought many products in consumer healthcare, medical devices and pharmaceuticals. In 1947, Johnson & Johnson expanded into India, marketing Johnson’s Baby Powder. In September 1957, Johnson & Johnson incorporated as a legal entity in India. The production in its first manufacturing facility began in 1959 at the Johnson & Johnson India plant in Mulund, Mumbai, for Johnson’s Baby Powder and other specialized products. In 1968, the company introduces the Stayfree brand to India. A situation emerged wherein Johnson & Johnson reached almost every household in India.

The Reuters investigative report refers to the findings of Dr. Irving J. Selikoff who had conclusively established a link between the inhalation of asbestos particles and lung-related ailments in the 1960s itself that paved the way for ban on asbestos of all kinds in some 60 countries. Dr. Selikoff was the director of the Environmental and Occupational Health Division of Mount Sinai Hospital in New York. It is significant that Ms Lisa Girion of Reuters has shared the official documents on the basis of which she has made these startling claims in her investigative report.

(Reference: <https://www.reuters.com/investigates/special-report/johnsonandjohnson-cancer/>)

We wish to reiterate that in a Terms of Reference dated October 25, 2010 issued by Union Environment & Forests Ministry for a proposed Asbestos cement sheet and accessories manufacturing unit of 1,80,000 Tonnes Per Annum capacity at Narsimharaopalem Village, Veerulupadu Tehsil, Krishna District, Andhra Pradesh by M/s Sahyadri Industries Limited made reference to "talc and chrysotile”.

Prior to the Reuters report, a 2014 paper published in the *International Journal of Occupational and Environmental Health* titled "Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women" by Ronald E Gordon et al concluded "we found that a specific brand of talcum powder contained identifiable asbestos fibers with the potential to be released into the air and inhaled during normal personal talcum powder application. We also found that asbestos fibers consistent with those found in the same cosmetic talc product were present in the lungs and lymph node tissues of a woman who used this brand of talc powder and developed and died from mesothelioma. This study was published in October 2014. (Reference: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164883/>)

We submit that the investigation by Reuters reveals that “Johnson & Johnson developed a strategy in the 1970s to deal with a growing volume of research showing that talc miners had elevated rates of lung disease and cancer: Promote the positive, challenge the negative. That approach was summed up by a J&J applied research director in a “strictly confidential” March 3, 1975, memo to managers of the baby products division, which used the talc in J&J’s signature Baby Powder. Its approach reads: “Our current posture with respect to the sponsorship of talc safety studies has been to initiate studies only as dictated by confrontation,” the memo said. “This philosophy, so far, has allowed us to neutralize or hold in check data already generated by investigators who question the safety of talc.” It reveals that scientific ghostwriters have been hired for long to hide evidence of “cancer concern associated with exposure to talc.” Based on an Italian study, one such ghost authored article that appeared in the Journal of Occupational and Environmental Medicine, in 1976 found no mesothelioma, the signature cancer of asbestos exposure. The Italian study in question has been updated three times – in 1979, 2003 and 2017 – “confirming the lack of association between exposure to asbestos-free talc, lung cancer and mesothelioma.” The investigative underlines that Johnson & Johnson got a lot of mileage out of the study. It was cited in a review article titled “The Biology of Talc,” published Nov. 1, 1976, in the British Journal of Industrial Medicine.

(Reference: <https://pdfs.semanticscholar.org/77df/7030e57e91ee73c8e313d6b54e0ea0b7c498.pdf>)

In addition to dozens of published studies, the review cited unpublished research, including one experiment that used a doll as a proxy for infants and that supported the company’s position on the safety of talc. It didn’t disclose that Johnson & Johnson had commissioned the unpublished research. The author of the review article concluded that the “concern that has been expressed about the possible health hazard from consumer exposure to cosmetic talc is unwarranted … There is no evidence that its normal use poses a hazard to health.” The author was Hildick-Smith, the Johnson & Johnson physician executive who had overseen the Italian study and played a key role in the company’s talc safety research. The article did not disclose his Johnson & Johnson connection, identifying him only as a Rutgers University Clinical Assistant Professor of Pediatrics.

In a related event, I was a panelist at a Round Table Conference on Issues Related to Asbestos Use in India held at India International Centre, New Delhi on December 21, 2009, wherein Dr Iqbal Ahmad, a scientist from IITR, Lucknow said that there are many different sources of asbestos exposures which need to be looked at. He identified talc (powder) as a major source which has asbestos contamination and exposes a large section of population, especially children and women. Talc is used in several industries as raw material. He said that we do have numbers of talc based cosmetic powders in India. China is the largest producer of talc. Some 47 companies which used to procure Chinese talc powder had to withdraw their product from market in South Korea due to high asbestos contamination.

We submit that CDSCO’s intervention will be germane in the light of the judgment of Hon’ble Supreme Court in Consumer Education and Research Centre (CERC) Vs Union of India (1995 AIR 922, 1995 SCC (3) 42) that recognized right to health as part of right to life and had directed central and state governments to revise their law related asbestos in keeping with fresh resolutions of International Labour Organisation (ILO). ILO’s asbestos related resolution of June 2006 is relevant in this regard (Reference: <https://www.ilo.org/safework/info/standards-and-instruments/WCMS_108556/lang--en/index.htm> . The ILO resolution was followed by a joint publication of WHO and ILO titled "Outline for the Development of National Programmes for Elimination of Asbestos-Related Diseases" published in December 2007. It creates a logical compulsion for urgent remedial action. (Reference: <https://www.ilo.org/global/topics/safety-and-health-at-work/resources-library/publications/WCMS_108555/lang--en/index.htm>)

In view of the above, we submit that instead of waiting for the coo withdraw its asbestos-laden talcum powder products-both baby powder and adult powder, the CDSCO must prevent preventable diseases and deaths by banning these products with immediate effect.

Thanking You

Yours faithfully

Gopal Krishna

ToxicsWatch Alliance (TWA)

Occupational Health India (OHI)

First Floor, A-124/6, Katwaria Sarai

New Delhi-110016

Mb: 9818089660

E-mail:krishnaruhani@gmail.com

Web:www.toxicswatch.org