



5<sup>th</sup> October, 2020

**Shri Mansukhbhai Mandaviya,**  
Hon'ble Minister of State for Chemical & Fertilizers,  
Government of India,  
Transport Bhawan, Sansad Marg  
New Delhi.

Dear Sir,

**Sub: Declassification of Spectacles, Spectacles frames and Spectacles lenses as Medical devices**

Greetings from Gujarat Chamber of Commerce & Industry.

We are in receipt of a representation letter from our member mentioning that as per the notification issued by Directorate General Health Services Central Drugs Standard Control Organization dated 3<sup>rd</sup> September, 2020, it is likely that Spectacles, Spectacles frames and Spectacles lenses shall be classified as medical devices and shall be regulated as Drug under the DCA and Medical Device Regulations [MDR].

Sir, classifying Lenses and Spectacles frames as medical devices will add to the burden of compliance by the optical industry, which consists of almost 90% small retailers. It will also have negative impact on the industry since the additional compliances will result in an increase in cost and production time.

This will in turn make it difficult for persons residing in rural areas and those in the weaker sections of society from getting access to pair of Spectacles at reasonable cost.

In view of the facts, we would urge that the Spectacles, Spectacle frame, Spectacle lenses are removed from Medical Device listing as it is a Low Risk Product-Class A.

**Natubhai Patel**  
President

**Hemant N. Shah**  
Sr. Vice President

**K. I. Patel**  
Vice President

**Pathik S. Patwari**  
Hon. Secretary

**V. P. Vaishnav**  
Hon. Secretary (R)

**Sachin K. Patel**  
Hon. Treasurer



Having spectacles removed from Medical Device will therefore save millions of jobs in the optical sector and will give an impetus to Atma Nirbhar mission of our Hon'ble Prime Minister and help us move ahead towards achieving the target of \$5 trillion economy by 2025.

We look forward to your early positive intervention in the matter.

With regards,

**Natubhai Patel**  
President

c.c.

**Dr. V. G. Somani,**  
Drugs Controller General of India  
Central Drugs Standard Control Organization  
FDA Bhavan, ITO,  
Kotla Road,  
New Delhi -110002

**The President**  
Ahmedabad Optical Association  
Anand Complex,  
Opp. "Shilp", C.G. Road  
Ahmedabad-380 009

**Natubhai Patel**  
President

**Hemant N. Shah**  
Sr. Vice President

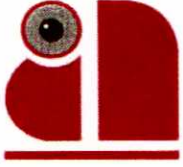
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# Ahmedabad Optical Association

N.T.C.G-13184 dt. 13-08-2004

Anand Complex, Opp. "Shilp", Nr. Navrangpura Muni. Market, C.G. Road, Ahmedabad-380009

Tel. : +91-79-26440756, 26565678, E-mail : ahmedabadopticalassociation@gmail.com

Date: 29<sup>th</sup> Sep. 2020

To,

**Dr.V .G. Somani**  
**Drugs Controller General**  
**Central Drugs Standard Control Organisation**  
**FDA Bhawan, Kotla Road,**  
**New Delhi 110002**

Sir,

We ,at Ahmedabad Optical Association, are 530 member strong association of retail, wholesale, manufacturing opticians located in the city of Ahmedabad. We are a registered association with our head office at Ahmedabad

The Association aims at supporting the optical Trade & industry competitiveness, promote and sustain investments in the optical sector, monitor and generate employment growth and career opportunities, enhance consumer choice, and provide a forum for healthy discussion, interaction and policy dialogue between the industry, government, consumers and other stakeholders.

## **Declassification of Spectacles, Spectacle Frames and Spectacle Lenses at S. No 127,123,124.**

As per the **Notification effective April 1 2020**, the Medical Devices that fall under the following definition will be regulated as Drug under the DCA and MDR

*"All devices including an instrument, apparatus, appliance , implant, material or other article, whether used alone or in combination including a software or an accessory, intended by its manufacturer to be used specifically for a human beings or animals which does not achieve the primary intended action in on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of*

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- *Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder*
- *Diagnosis, monitoring treatment alleviation or assistance for any injury or disability*
- *Investigation, replacement or modification of support of the anatomy or of a physiological process*
- *Supporting or sustaining life*
- *disinfection of medical devices and Control of conception."*

**The Directorate General Health Services Central Drugs Standard Control Organisation has issued a notice dated Sept 3 2020 for a classification of non - notified medical devices.** This is further to the circular published on Feb 11 2020 , the medical devices which are under definition will be regulated in phase wise manner in accordance to Centre Licensing Authority needs to classify such medical devices as per risk based approach and the department has been kind enough in asking for comments/ feedback of the proposed add on of products under medical devices from all stakeholders and associations .

## Our Submission

Spectacles is neither an instrument, apparatus appliance and neither an implant in a human being neither is pharmacological or immunological or metabolic means. Hence by definition Spectacles fall out of the gambit of Medical Devices. In addition, World Health Organisation (WHO) has listed Spectacles under Priority Assistive Product List. Spectacles therefore comes in the category of accessory as defined in Medical Device Regulations Global Overview and Guiding Principles of World Health Organisation document and therefore outside the scope of falling under Medical Device.

Spectacles which is classified by WHO as assistive products enable people to live healthy, productive independent and dignified lives to participate in education, the labour market and civic life. Assistive products also help in reducing the need for formal health and services. Without Spectacles people may suffer exclusion, are at risk of isolation and poverty and may become a burden to their family and on society. Hence bringing Spectacles into Medical Devices would put lakhs of jobs at risk and affecting millions of households whose income are dependent to the optical sector.

Classifying lenses and spectacle frames as medical devices is expected to have the effect of regulating the entire supply chain in the optical industry. Retailers, distributors and importers, apart from manufacturers shall be required to obtain





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registration under the Medical Devices Rules. It is to be noted that the Drugs & Cosmetics, 1940 was not drafted keeping into consideration the objective of regulating lenses, spectacle frames and other day-to-day use optical accessories.

The ramifications of lenses, spectacle frames, etc. getting classified as medical devices are wide, and shall be detrimental to the sustenance of the optical industry in India. The added layers of compliance and regulation shall lead to both increase in cost of optical products as well as timelines, thus impeding access to affordable and timely corrective vision care to the public. It may be considered that majority of optical retailers in the country, especially in areas other than metropolitan cities, are micro/small businesses that serve and provide accessible and timely vision care to people residing in a large radius around their geographic proximity. In most cases, especially in the context of India's rural population that accounts for approximately 65.53% of the total population, a single optical retailer may be catering to people living across several kilometres in radius around the shop. The mechanism of regulation proposed under the Drugs & Cosmetics Act as well as the Medical Devices Rules is elaborate, complex, expensive and may consequently lead to several optical shops (traditionally micro/small businesses) to shut, thereby denying healthcare to millions of people.

The Optical industry and trade comprises of approximately 100,000 retailers who employ over a million people directly or indirectly. Most of them (almost 90 per cent) are small retailers, who have largely opted for the Composite GST scheme. When it is difficult for retailers to understand the simple working of GST laws, how can we presume that they will be able to understand the complex structure of Medical Device regulations. In our submissions, this will lead to the closure of several numbers of shops leading to large scale unemployment and thus would hamper the self-employment mission of the government. Please note that these simple, composite retail opticians are the first point of contact for any vision problem, and if they are involved with complexities of the law, they will shut down and a large segment of the population will be deprived of primary vision care.

For importers, the Rules allow for a 9-month window for applications seeking registration to be processed by the Central Licensing Authority. The average lifecycle of the delivery of a consignment of lens / spectacle frames and related optical products is approximately 30 days. This 30-day period covers the placement of order, shipment of consignment, arrival of consignment in India, custom clearance and delivery of the consignment at the importer/distributor's warehouse for onwards distribution in the retail network. A 9-month (or even a 45 day) period to process registration in this digital age shall lead to severe delays in the trade pipeline, with the cascading effect reaching the end-consumer resulting in delayed access to corrective eye care.

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The blanket classification of all kinds of optical lenses and spectacle frames as medical devices (and consequently as 'drugs', pursuant to the notification dated 11 February 2020) shall have the effect of lenses, spectacle frames etc. getting covered under the Essential Commodities Act. Without *intelligible differentia* between basic lenses/spectacle frames that are simply meant for the essential use of correcting vision, versus lenses/spectacle frames that are used for vanity, comfort, fashion and other purposes (and the sales of which contribute significantly towards collection of import duty as well as GST), the latter are exposed to unjust price control regimes and caps on price revisions, which shall act as a nail in the coffin of the already deteriorating trade and industry.

## Annexures attached to support our Submission

### Spectacles – Serial No 127

Spectacles consists of frame (SNo123) and lens (SNo124) for the people to see better and improve their ability to see normally. Correcting people with spectacles as it is called helps in socio economic development. Globally 2.5 Billion people are estimated to be living with poor vision unnecessarily since they don't have spectacles.

In Sept 2015 the United Nations launched the Global Goals for sustainable Development a series of ambitious targets intended to drive action and investment to end poverty, combat climate change and fight injustice and inequality by 2030. This report makes the case for how proper vision serves as a critical input to achieving a number of global goals and stern the unnecessary loss of global GDP from lost productivity and spectacles is the cheapest way for sustainable offering.

Coming to India over 100 million people need access to a pair of spectacles but do not have one. The major impediments are access and awareness. In many rural parts of India people are not aware that they cannot see well because they don't have access to a pair of spectacles. The absence of optical shops makes it a challenge for half of India's population living in rural areas to be fully productive in life. In a study of working men and women in India wearing reading spectacles was found to increase productivity by 34% and workers income by 20%.

GDP loss per head in India is approx. INR 2.85 Lakhs per and estimated productivity loss is INR 285000 Crores.

India overall has big shortage of Optometrists. For its current population India will need 125000 trained optical professionals including 2- and 4-year trained professionals. It currently is estimated to have only 1/3 the number it needs based on a population to number of Optometrists ratio. Because of this tier 3-4 cities and villages have millions that need access to a pair of spectacles and don't have one today.

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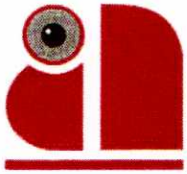
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The National Commission for Allied and Healthcare Professions Act 2020 has been tabled on Sept 15 2020 to address the primary health care professionals comprising of Optometrists, Ophthalmic Assistants and Vision Technicians to fill the gap of supply of skilled resources reaching the entire population of the country with minimum standards to be recommended by the committee.

## Barriers

**Demand side-** Although spectacles are not new as they were invented 700 years back while potential customers are unaware that they have correctable vision problems and many as well do not know that this simple solution of spectacles that does not touch the human eye help them see clearly, increase their productivity and improve their quality of life.

**Supply Side-** Shortage of eye health workers represents a key barrier in rural market wherein in cities and major towns Ophthalmologists, Optometrists either independent or attached to an optician prescribe and Opticians dispense spectacles.

Also, technology innovation and disruptive technologies are getting into market and E commerce is making eye care accessible to larger population.

It is important to draw the attention once again that the above categories are the only products in the A Category of Medical Device proposed but they are assistive accessories only as spectacles with frame holding the lens on the face of the wearer without touching the eyes.

## Indian Optical Industry

Coming to the Indian optical scenario, the need of the hour is to support the Indian entrepreneurs to replace the imports happening from China in most of the categories of optical products.

Atma Nirbhar is very much relevant to the optical industry now than ever before in India and all trade associations are welcoming Indian manufacturing. In addition, the optical retailers are going through the most turbulent times – pandemic unprecedented in a century and any regulation will add to complex procedures to be adapted and cost thereof. Also, the presence of optical stores is very much skewed towards metros, mini metros and up to Tier 2 cities wherein access and buying spectacles remains a problem in rural sector.

Any notification under medical device would result in loss of employment to lakhs employed in the Optical sector- Fitter technicians, counter sales staff, Optometrists primarily being small scale enterprises and would lead to a situation for MNCs to dislodge Indian business houses and family run houses for more than 3 generations which are small and medium in nature. The average sale price of spectacles sold by





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a small retailer range from Rs. 400/-to Rs. 600/-. Whereas the average sale price of spectacles sold by MNCs is around Rs. 5000/-.

Given that the Indian optical industry is highly fragmented and employing a very large work force in the back end of the service sector, we would urge that the Spectacles, Spectacle frame, Spectacle lenses are removed from Medical Device listing as it is a Low Risk product-Class A. This will millions of households dependent on this sector at risk of losing employment.

## Other developed and developing countries

To state some few examples of other countries Singapore does not list Spectacles under Medical Devices category and is exempted as like many other countries while some BRICS countries like Brazil also exempts spectacles being called as Medical Devices and has a Self-Regulation Mechanism for Eyewear Industry under the umbrella of the recognized trade body.

We wish to draw the attention also that in United States of America (U.S.A) Spectacle frame, spectacle lenses are medical devices exempted from Pre-market Notification 510(k) submission to the Food and Drug Administration. (FDA)

## Conclusion

Having spectacles removed from Medical Device will therefore save jobs in millions working in optical sector and will give an impetus to Atma Nirbhar mission that our Hon'ble Prime Minister has asked all Indian businessman to look at seriously and make it happen, and our optical industry can demonstrate by making India a manufacturing destination for India and for exports, and encourage more small and micro entrepreneurs to be self-employed in addition to being employable.

We trust that you will consider these submissions on behalf of the industry favourably. In order to further explain/discuss the abovementioned issues, we request you to grant us time for an urgent meeting with you at your earliest convenience where some office-bearers and members of the Association, would like to be present.

Thanking you,

Yours sincerely,

For, Ahmedabad Optical Association

**Shashikant Pandya**

**Yogeshbhai Patel**

Hon. President

Hon. Secretary