

Veg capsules: Nadda sets up panel after Maneka push

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AN EXPERT committee set up by the Health Ministry on “replacing gelatin capsules with plant-based capsules” has, in a notice dated June 2, invited comments from all stakeholders. The committee was set up in March, a year after Union Minister for Women and Child Development Maneka Gandhi gave a “representation” to the Health Ministry on completely “replacing gelatin



**Health
Minister J P
Nadda set up
panel in
March**

capsules” with plant-based ones.

Currently, over 98 per cent of the Indian pharmaceutical industry uses animal-based gelatin capsules. Plant-based capsules are marketed by just two manufacturers — Indian-based

CONTINUED ON PAGE 2

Veg capsules

Associated Capsules, and the American Capsugel. Gelatin is primarily obtained by boiling the connective tissues, bones and skin of animals.

In her representation to Health Minister J P Nadda in March last year, Maneka said, “In a country where there are millions of vegetarians, this hurts religious sentiments and many people avoid medicines that are in capsule form. Representations received from the Jain community have also requested that since there is an option available in the country, consumers must not be forced to use capsules made from animal tissue.”

She added that “they (plant-based capsules) are easier to digest than gelatin capsules”, and that “it is absurd that we continue to use the same unstable product (gelatin capsules) for medicinal purposes”.

According to official documents, Nadda discussed the matter with Drug Controller General of India (DCGI) G N Singh and then health secretary Bhanu Pratap Sharma, and “desired that necessary steps in this regard be taken on priority”.

The issue, however, faced a major hurdle in May last year, when the country’s top drug committee, the Drug Technical Advisory Board (DTAB), shot down the Health Ministry’s initial proposal: marking plant-based capsules with a green dot.

“The members (of the board) opined that unlike food, drugs are not taken for choice but are prescribed by the doctors to save lives and marking them as vegetarian or non-vegetarian origin is not desirable,” stated the minutes of the DTAB meeting held

on May 13. “Some members also pointed out that Hydroxypropylmethylcellulose (HPMC) — a type of cellulose capsules — is basically of synthetic origin and as such cannot be considered as purely of vegetarian origin as in the case of food preparations,” the minutes noted.

However, this did not deter the Health Ministry. Eleven days later, on May 24, it convened a meeting under the chairmanship of the health secretary on “switching the use of gelatin capsules by non-gelatin capsules”.

On November 15, 2016, the DCGI wrote an email to K L Sharma, joint secretary in the Health Ministry, listing three advantages of HPMC or plant-based capsules: “Vegetable capsule for vegetarian society. Suitable for moisture-sensitive product. Unlike gelatin-based capsule, no cross-linking reaction.”

However, he also admitted that no standard for a vegetable capsule had yet been prescribed in Pharmacopoeia — an official book published in every country with a list of drugs, their formulae and other related information — and that such capsules are “about 2.5-3 times costlier in India than gelatin capsules”.

The DCGI listed another disadvantage of plant-based capsules: “As per regulatory requirements, the stability, bioequivalence of the drugs have to be established for the Indian as well as export market”. However, he added that India would be the first country to incorporate vegetable capsules in the Indian Pharmacopoeia (IP).

In December last year, a Health Ministry official wrote in the file: “Changes in rules. WCD (Women and Child Development) Minister has been flagging this issue. DCGI to be reminded. A file to be opened. Please put up on the file urgent.”

The Ministry then decided to form an expert committee on March 20, 2017, to “address all technical issues” pertaining to this matter. The Health Minister did not respond to queries sent by The Indian Express.

When asked about the proposal to replace gelatin capsules with plant-based ones, pharma industry experts said an immediate fallout of such a shift would be a rise in prices.

“It’s simple... The prices of medicines will go up. First, there has to be manufacturing capacity in the country for such plant-based capsules,” said Surajit Pal, pharma analyst with financial services firm Prabhudas Lilladher.

Sudeep Krishna, senior director of consultancy major Deloitte India, said in an email to The Indian Express, “The proposed replacement of gelatin-based capsules with vegetarian capsules would be a change of a mammoth scale with scientific, social and economic/financial/access implications... A selective approach for the shift in the short-term might be beneficial to consider.”

While Krishna conceded that vegetarian capsules have several “scientific benefits” compared to gelatin-based capsules, he added that additional “costs (due to the proposed shift) will need to be absorbed by market participants — government/pharma companies/capsule manufacturers as well as patients and consumers.”

D G Shah, secretary general of the Indian Pharmaceutical Alliance (IPA), a prominent lobbying group of pharma companies, when asked if his association or member-companies had faced any questions from vegetarians on gelatin capsules, said they had “not reported such a problem”.