REVA Pharma
Caring for Healthier Lives

NEWS LETTER
For Private Circulation only

Discount-Hunting For Medicines May Be Injurious To Health, Says Drug Manufacturers' Body Chief

The lure of a discount may not be as healthy as it appears, say pharma indu try representatives, cautioning consumers against hefty discounts on medicines.

Consumers need to be watchful when buying medicines with hefty discounts, because "knowingly or unknowingly, they may be creating a space that wrong elements fill," said Viranchi Shah, President of the Indian Drug Manufacturers' Association (IDMA). Authorised retailers do not have the ability to give hefty discounts, because it cuts into their retail margins on scheduled (price-controlled) and non-scheduled medicines (at 16 and 20 percent, respectively), Shah told businessline, responding to concerns on spurious drugs that possibly circulate in the distribution channel.

Drugs of subpar quality

Recently, the Central Drugs Standard Control Organisation (CDSCO) had come out with its list of "Not of Standard" Quality (NSQ) drugs (for August), listing 50-plus samples. But four of the companies/brands mentioned on the list, including Sun Pharma, Glenmark, Alkem and Shelcal (Torrent Pharma) had clarified and told the stock-exchanges that the tested samples were spurious or counterfeit, raising concerns on how they can be identified.

Not all discounts are bad, as some retailers may indeed be managing discounts through authentic sourcing from companies, Shah clarified. But when larger discounts bring in more consumers, it could create a space for the wrong kind of practices, he said, adding that retailers too need to buy from authorised stockists. Shah did not make a distinction between medicines sold by offline chemists and online aggregators/pharmacies.

Between looking for abnormal discounts and cross-checking the QR code on the label - consumers and retailers can check the authenticity of the medicine with the company, an industry -insider added.

Commenting on the NSQ list put out regularly by the Centre, Shah said, it revealed two kind of samples – those that did not meet specifications; and those that are spurious (not belonging to the company it claimed to be).

The aim is to get to "zero-errors" in terms of meeting specifications, he said. But to weed out dangerous spurious drugs from the system, however small it's incidence, the Centre has brought out draft Good Distribution Practices (GDP) for pharmaceutical products that cover transportation, storage, handling, recall etc, so that companies can track their products and undertake effective recalls, he said. This end-to-end traceability, through storage, transportation and retail, will make it difficult for wrong elements to enter the supply chain, he added.

In February 2017, the Union Health Ministry had cited the national drug survey and said, "The percentage of NSQ Drugs in India has been found to be at 3.16 per cent and that of spurious drugs at 0.0245 per cent." (Source: Business Line)

Pharmacy Closures In England Threaten Plan To Use Them Instead of GPs For Some Care

High street pharmacies are closing at such an alarming rate that it threatens the drive to use them instead of GPs to care for millions of people, the NHS's patient champion warns today. A total of 436 community pharmacies in England shut permanently last year and there were also 13,863 temporary closures, which stopped patients from obtaining health advice and medication.

What appears to be a growing trend of permanent closures is hitting rural areas, those with larger numbers of older people and deprived communities hardest, according to Healthwatch England. Its findings, which were based on figures supplied by NHS bodies, prompted fears that closures are leaving some parts of England as "pharmacy deserts" where patients struggle to access care.

The watchdog received responses to freedom of information requests it submitted from all but one of the 42 NHS integrated care boards (ICBs), regional bodies that commission and pay for NHS services. They showed that 436 pharmacies closed down between 1 January and 31 December 2023 – an average of more than one a day. In addition, pharmacies also closed temporarily 13,863 times, for a total of 46,823 hours and for an average of almost 18 hours at a time in some places, the data from ICBs showed.

"Staff shortages, the key driver of permanent and temporary closures, call into doubt the potential of Pharmacy First, meaning people can't get the advice, care and medications they need and when they need them", said Louise Ansari, Healthwatch's chief executive.

Pharmacy First is the government's drive to reduce the strain on overworked GPs through pharmacists treating what it hopes will be millions of patients a year for seven minor ailments such as a sore throat, earache, infected insect bite or sinusitis. "It's clear that rising levels of closures are risking leaving some areas of the country as pharmacy deserts, with people having to travel much further to get access to vital services", said Paul Rees, the chief executive of the National Pharmacy Association.

"Community pharmacies act as the front door to the NHS. If people lose access to them it will force more patients into the eight o'clock scramble at their GP surgery, putting pressure on the rest of our NHS system." Responses from ICBs show that staff shortages, including the difficulty in finding locum pharmacists, lie behind many of the temporary closures, Healthwatch added.

Temporary closures "are adding to the deepening crisis in the sector". It also acknowledged longstanding complaints from pharmacy organisations that lack of government funding is hampering their activities by asking ministers to "evaluate" the money the sector receives.

- Healthwatch's findings showed that:
- Cheshire and Merseyside ICB saw the most permanent closures last year – 51
- The North East and North Cumbria ICB had the highest number of temporary closures – 1,438
- The same area also saw the highest number of hours lost to temporary closures – 4,054
- And pharmacies in the Norfolk and Waveney ICB area shut temporarily for the longest number of hours on average – 17.48
- The Department of Health and Social Care said that it plans to review the funding that goes to a sector that had been "neglected for years" under the Conservatives.
- "This government inherited a broken NHS where pharmacies have been neglected for years", a spokesperson said.

"Pharmacies are key to making healthcare fit for the future as we shift the focus of the NHS out of hospitals and into the community. "We will make better use of their skills by increasing the number of pharmacists able to prescribe medication themselves and launch a review of community pharmacy funding." (Source: The Guardian)

DCGI Suspends Approval Of Entod's Yet-To-Be-Launched Eye Drops

The Drugs Controller General of India (DCGI) has suspended its approval for Entod Pharmaceuticals' yet-to-be-launched eye drops, for reasons including unauthorised promotion and concern that the by-prescription product would be used like an over-the-counter drug. The approval is for the manufacture and marketing of Pilocarpine Hydrochloride Opthalmic Solution USP 1.25 per cent, for the treatment of Presbyopia in adults, the DCGI order said. Outlining claims made by the company, the regulator said the product had not been approved for the claim that it was "designed to reduce the need for reading glasses". On the drops being "a non-invasive option that can enhance near vision without the need of glasses", The DCGI said, it had not approved such a claim. The regulator said it had not approved a claim indicating that the product provided an advanced alternative that augments vision in 15 minutes. Further, it added, the company had not obtained approval from the Central Licensing Authority to make the above outlined claims. Entod's PresVu eye drops had been slated for launch in October, its representatives had told businessline.

Likely to challenge

Responding to the DCGI's order, Nikkhil K Masurkar, Entod's Chief Executive, said in a statement that they had not made an "unethical or false presentation of facts" on their eye drops. "All facts disclosed to the media were strictly on the basis of the recent DCGI approval for treatment of presbyopia in adults and the results of the phase 3 clinical trial conducted by us in India," he said, adding that they had "decided to challenge this suspension in the court of law to get justice." Addressing interest in its eye drops, he said, "In our case, media reports went viral and public imagination led to an unusual escalation for which Entod Pharmaceuticals is not responsible. Our approval by DCGI was based on a valid controlled clinical trial in 234 patients which was successful in showing efficacy and safety of these eye drops in patients of Presbyopia, who used these drops without eye glasses and could read additional lines on Snellen's chart which is a yardstick of near vision improvement.

Such eye drops with same active ingredient and same concentration has been approved by the US FDA and marketed in the US for last 3 years without any serious complications. FDA didn't take any action on the companies marketing the same in the US." The company said the DCGI's order "made no reference to any specific violation of Drugs and Cosmetics Act for this action. The logic applied here is the contents of our press release which has described the application of this new drug for the benefit of the lay press in more verbose terms than the exact wording of the approved indication which is – Treatment of Presbyopia." The company intends to challenge the suspension, the note said adding, "Our fight will not only allow innovative medicines to be available in India but also encourage other pharmaceutical entrepreneurs and companies in the MSME sector to continue the research drive in India without facing similar obstacles." The lure of a discount may not be as healthy as it appears, say pharma industry representatives, cautioning consumers against hefty discounts on medicines.

Consumers need to be watchful when buying medicines with hefty discounts, because "knowingly or unknowingly, they may be creating a space that wrong elements fill," said Viranchi Shah, President of the Indian Drug Manufacturers' Association (IDMA). Authorised retailers do not have the ability to give hefty discounts, because it cuts into their retail margins on scheduled (price-controlled) and non-scheduled medicines (at 16 and 20 percent, respectively), Shah told businessline, responding to concerns on spurious drugs that possibly circulate in the distribution channel.

Drugs of subpar quality

Recently, the Central Drugs Standard Control Organisation (CDSCO) had come out with its list of "Not of Standard" Quality (NSQ) drugs (for August), listing 50-plus samples. But four of the companies/brands mentioned on the list, including Sun Pharma, Glenmark, Alkem and Shelcal (Torrent Pharma) had clarified and told the stock-exchanges that the tested samples were spurious or counterfeit, raising concerns on how they can be identified. Not all discounts are bad, as some retailers may indeed be managing discounts through authentic sourcing from companies, Shah clarified. But when larger discounts bring in more consumers, it could create a space for the wrong kind of practices, he said, adding that retailers too need to buy from authorised stockists. Shah did not make a distinction between medicines sold by offline chemists and online aggregators/ pharmacies. Between looking for abnormal discounts and cross-checking the QR code on the label - consumers and retailers can check the authenticity.

The medicine with the company, an industry-insider added. Commenting on the NSQ list put out regularly by the Centre, Shah said, it revealed two kind of samples – those that did not meet specifications; and those that are spurious (not belonging to the company it claimed to be). The aim is to get to "zero-errors" in terms of meeting specifications, he said. But to weed out dangerous spurious drugs from the system, however small it's incidence, the Centre has brought out draft Good Distribution Practices (GDP) for pharmaceutical products that cover transportation, storage, handling, recall etc, so that companies can track their products and undertake effective recalls, he said. This end-to-end traceability, through storage, transportation and retail, will make it difficult for wrong elements to enter the supply chain, he added. In February 2017, the Union Health Ministry had cited the national drug survey and said, "The percentage of NSQ Drugs in India has been found to be at 3.16 per cent and that of spurious drugs at 0.0245 per cent." (Source: Business Line)

NSQ Alerts: Stringent Action Needed To Instil Consumer Confidence

Sudarshan Jain with the Indian Pharmaceutical Alliance (IPA), called on consumers to buy from authorized retailers, on a prescription and with a bill (so it is traceable if something is amiss), and to check QR codes The Centre's recent alert on "not of standard" quality (NSQ) drugs has reinforced the call for stringent action against spurious drug makers, and greater transparency on follow-up action, say experts.

In its latest NSQ alert (for August), the Central Drugs Standard Control Organisation (CDSCO) listed over 50 medicine samples, including those used to treat diabetes, blood pressure, certain antibiotics and calcium supplements, to name a few.

This has left consumers unsettled on their daily dose of medicine, and the absence of information on action taken by companies and the Centre, following these alerts, has added to their safety concerns. Large drugmakers featured on the list including Sun Pharma, Alkem and Glenmark, have distanced themselves from the NSQ samples, calling them counterfeits or "spurius".

Samples of familiar medicines/ brands listed as NSQ include Cefixime Oral syrup, Metformin Hydrochloride Sustained-release (Glycimet-SR-500), Amoxicillin and Potassium Clavulanate Tablets IP (Clavam 625), Calcium and Vitamin D3 Tablets Shelcal 500, Telmisartan Tablets 40 mg etc.

Sun Pharma, Alkem and Glenmark have said the tested samples are "spurious" or counterfeit. Companies are adopting QR codes, 3D security strips, unique product identifiers etc , so consumers can check authenticity of the medicine. The Centre too sought to allay consumer fears, saying NSQs "are not generally life threatening", and risks were negligible. A Government official clarified, that samples were picked up from State warehouses and distributor warehouses, before it entered the market.And entire batches of NSQ products were discarded.

Outlining anti-counterfeiting measures, companies said they'd adopted 3D security strips, QR codes, unique product identifiers and difficult-to-replicate packaging, to stay ahead of counterfeiters that sold medicines with similar sounding names. Sudarshan Jain with the Indian Pharmaceutical Alliance (IPA), called on consumers to buy from authorized retailers, on a prescription and with a bill (so it is traceable if something is amiss), and to check QR codes. (IPA is a platform for large domestic drugmakers.)

Spurious alarm

The "spurious" label, though, brings in an element of "criminality" - where the medicine may not have the drug's active ingredient or may have minimal quantities of it – making it ineffective in treating fever in children, or diabetes or blood pressure, in adults, experts point out.

"The Centre should take stringent action on those making spurious drugs, it is a crime," says Jain, concerned on the impact these incidents are having on the industry. Former Director General with the Pharmaceuticals Export Promotion Council of India, R Udaya Bhaskar, puts the responsibility on manufacturers to track and recall substandard drugs. And, since health is a State subject, there should be better coordination between Central and State drug regulators, so a suspicious product flagged in one state is communicated and acted upon by others, he says.

Regulatory expert Dr Chandra Gulati pointed to the mismatch between 10,000 manufacturing units and regulatory officers to inspect them; and the competition between States involving more manufacturing plants - as the core problem, leading to products slipping between the regulatory cracks. Industry-insiders point to regulators like the US Food and Drug Administration that put information in public domain, including the transgression by companies and follow-up action, till it is resolved. Pointing to the international cough syrup issue, where deaths of children were linked to products from India, an industry-watcher said, action taken by the companies and the regulator need to be publicly available to instil confidence in consumers.

More central action

Government officials said, the CDSCO is in discussion with State regulators to up the drive against NSQs and bring it below 4 percent, (from 15 percent, several years ago). In February 2017, the Union Health Ministry cited the national drug survey and said, "the percentage of NSQ Drugs in India has been found to be 3.16 per cent and that of Spurious drugs 0.0245per cent." The Centre has also been undertaking risk-based inspections at manufacturing sites and mandated QR codes on large brands, to keep track of the supply chain.

This August, Union Health Minister JP Nadda said in Parliament, that Central and State drug authorities conducted risk-based inspections across 400 premises/ firms - identified on their risk criteria, including number of drugs declared NSQ, complaints, criticality of the products etc. Subsequently, 300-plus actions including issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses etc, have been taken by State authorities in line with the Drugs Rules 1945. (Source: Business Line)