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## Tying up the knotty ENDS

Electronic nicotine delivery systems (ENDS) are stuck in a regulatory mire, with no clarity on whether they are to be treated as “drugs”

**W**HILE THE SALE of Electronic Nicotine Delivery System (ENDS)—e-cigarettes, vapes, etc—continues to be on the rise, the debate with respect to its regulatory framework remains inconclusive. At the core of the debate is the question whether ENDS falls within the definition of ‘drug’ under the Drugs and Cosmetics Act, 1940 (the Drugs Act).

The Delhi High Court, by an order of a single judge passed on March 18, 2019 (Delhi Stay Order), after considering provisions of the Drugs Act observed, prima facie, that ENDS is not a drug under the Drugs Act as it is not sold as a therapeutic device, or as having any medicinal usage for internal or external use of human beings or animals, intended to be used for the diagnosis or treatment of any disease. The Delhi Stay Order also stayed the effect and operation of the Circular dated November 27, 2018 (“Circular”) issued by the Central Board of Indirect Taxes and Customs (Anti-Smuggling Unit) and of

the Advisory dated February 22, 2019, (Advisory) issued by the Union Government. The appeal against the Delhi Stay Order was not entertained by the division bench of the Delhi High Court.

The Circular and the Advisory were issued to all custom authorities and state governments, to ensure that ENDS is not sold (including online sale), manufactured, traded, imported and advertised in their jurisdiction except for the purpose and in the manner and to the extent as approved under the Drugs Act. The Circular and the Advisory were issued on the premise that ENDS is a drug under the Drugs Act.

The Drugs Consultative Committee, a statutory body established under the Drugs Act, in its meeting on June 1, 2019 also concluded that ENDS falls under the definition of “drug” under the Drugs Act. The committee, during its discussion, referred to the fact that nicotine gums (and lozenges) that are used for smoking cessation, are also covered under the Drugs Act and therefore, ENDS should not be treated differently.

Interestingly, this conclusion of the

committee is diametrically opposite to its earlier observation in its 48th Meeting, held on July 24, 2015, when it observed that e-cigarettes are not covered under the definition of the term ‘drug’, and, therefore, the Committee concluded that ENDS cannot be regulated under the provisions of the Drugs Act.

Given the lack of clarity over the regulatory regime governing ENDS, the Delhi High Court, in another pending petition, directed the Union government to file an affidavit, listing the measures that would be brought into effect for regulation of ENDS.

More recently, the Bombay High Court, by an interim order, stayed any further investigation/action by Food and Drugs Administration, Mumbai, in the context of ENDS, in a petition filed by Godfrey Philips India. The Bombay High Court placed reliance on the Delhi Stay Order. The Mumbai petition, like the Delhi one, is pending final adjudication.

The lack of clarity on whether ENDS is a drug or not also leads to the debate whether the Union government can regulate ENDS or it will remain the exclusive domain of the state government(s). This stems from the fact that though public health falls in the State List, drugs and poisons fall under the Concurrent List. Therefore, if ENDS falls within the definition of drug under the Drugs Act, the Centre also will have the constitutional mandate to regulate it. However, an interpretation to the contrary will vest the jurisdiction exclusively with state government to pass regulations with respect to ENDS. The Delhi High Court, in its meeting on June 1, 2019 also concluded that ENDS falls under the definition of “drug” under the Drugs Act. In this view, the impugned circular, in this view, the impugned circular are stayed, till the next date of hearing.”

Amidst the legal debate on the exact nature of ENDS and its regulation, the ministry of electronics and information technology (MEITY) issued the Draft

Information Technology (Intermediary Guidelines) Rules, 2018 (‘Draft ITIG Rules, 2018’), Rule 3(2)(j) of the Draft ITIG Rules, 2018, prohibit the users from displaying, uploading, publishing, transmitting, updating or sharing any information that threatens public health or safety; promotion of cigarettes or any other tobacco products or consumption of intoxicant including alcohol and ENDS. Pertinently, the Draft ITIG Rules, 2018 are yet to be notified.

Further, as of now, 13 states including Punjab, (vide circular dated October 3, 2018), Maharashtra (vide circular dated March 16, 2019), Karnataka (vide circular dated June 15, 2016), Kerala (vide circular dated August 1, 2016), Bihar (vide circular dated November 28, 2017), Uttar Pradesh (vide circular dated November 14, 2017), Jammu & Kashmir (vide circular dated July 24, 2017), Himachal Pradesh, Tamil Nadu (vide circular dated September 3, 2018), Puducherry, Jharkhand and Mizoram (vide circular dated June 8, 2016), have imposed a ban on the sale (including online sale), manufacturing, trading, importing and advertising of ENDS.

Pertinently, Haryana has also notified ‘Nicotine in its pure chemical form’ as ‘poison’, vide notification No. S.O.152/C.A.12/1919/S.2 and 8/2015 dated October 15, 2015 under the Poisons Act, 1919.

Interestingly, most of the state ban circulars, do not prohibit the use of ENDS by an individual and only prohibit the sale (including online sale), manufacturing, trading, importing and advertising. Therefore, it remains unclear whether ENDS, bought in a state where it is not prohibited, can be used in a state that prohibits it. Some of these state bans have been challenged before the respective High Courts.

The legal question involves various multi-layered issues ranging from exact nature of ENDS, extent of right of choice of the consumer to limitations to freedom of trade and commerce, amongst others, and it remains to be seen how the courts deal with them.

**The legal question involves various multi-layered issues ranging from the exact nature of ENDS to freedom of commerce**

### CONSUMER PROTECTION LAW

## Caveat emptor to caveat venditor?

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The new consumer protection law truly enforces the rights of the consumer

**T**HE CONSUMER PROTECTION Act, 2019 (Act), published in the official gazette on August 9, 2019, seeks to replace the Consumer Protection Act, 1986. Such legislative reform became essential due to changes in the marketplace, variety of options available to consumers, global supply chain and indispensability of e-commerce.

The Act defines a ‘Consumer’ as a person who buys any goods or hires/avails any service for consideration. This excludes a person who obtains a good for resale or for commercial purpose. The definition includes e-commerce transactions, thereby bringing a much-required revamp in law.

The Act introduces the Central Consumer Protection Authority (CCPA)—it will regulate matters relating to violation of consumer rights, unfair trade practices and false/misleading advertisements. It shall have an Investigative Wing headed by a Director-General that may conduct inquiry/investigation as directed by CCPA. The CCPA has been empowered to, *inter alia*, take *suo motu* actions, pass orders, impose penalty, issue guidelines in public interest.

The Consumer Dispute Redressal Commissions (CDRCs) shall exist at the district, state and national level. The Act has now increased the pecuniary limits of the commissions due to which the district commission can now entertain complaints where the value paid doesn't exceed ₹1 crore. For state commissions, the jurisdiction range is ₹1-10 crore and beyond ₹10 crore for the national commissions. The active functioning of the district commissions will increase accessibility and bring about maximum reduction in the backlog.

Another crucial change is that the Act allows filing of complaint from anywhere (including e-filing) and hearing/examination of parties through video-conferencing in district commissions. It introduces attachment of consumer-mediation cell to each CDRCs. Each cell shall maintain a list of qualified, empanelled mediators. This will aim at further reducing backlog of cases in consumer courts. A product manufacturer, producer/service-provider and a product seller are liable to compensate for any defect in the product or deficiency in services.

The definition of ‘product seller’ now includes any person who, *inter alia*, imports, sells, installs, repairs a products and places products for commercial purposes. As such, it appears that e-commerce platforms will fall under the wide gamut of ‘product seller’. Further, the product manufacturer is liable even if he proves he was not negligent or fraudulent in making the express warranty of a product.

Any advertisement which falsely describes the product or deliberately conceals important information or conveys an express/implied representation constitutes an unfair trade practice.

The penalty for misleading advertisement is set at imprisonment (extendable to 2 years) and fine (extendable to ₹10 lakh). The Act also extends liability for misleading ads to the endorser. Celebrity endorsement is generally viewed as a viable option for brands to promote their products and build credibility. However, given celebrities enjoy larger-than-life cult status, such endorsers cannot merely play the role of information disseminators, and will now be required to exercise due diligence and verify claims made in the advertisement.

The Act deems a contract that hampers the right of a consumer due to its unfair conditions such as, disproportionate penalty, assignment of contract to detriment of consumer, excessive security deposit, unfair unilateral termination of contract, as an unfair contract. This will ensure that a dominant party is unable to coerce its way into unfairly profiting.

The Act truly reinforces the rights of the consumer. While new forms of business practices have given a plethora of options to consumer, they have also exposed consumer to vulnerabilities of unfair practices. With the Act, the era of ‘caveat emptor’ is giving way to that of ‘caveat venditor’. Although the Act expects a reasonable degree of caution to be observed by consumer, yet a high standard of care and diligence in trade is required from the product manufacturer/seller/service-provider.

**The Act doesn't spare the consumer of the need for caution, but it does require the part of the manufacturer/seller**

## Anchoring IPOs to valuation certainty

Anchor investors help underwriters market hard-to-place offerings

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**I**NITIAL PUBLIC OFFERING (IPO) activity, allocation to investors and pricing have been the subject of much debate over the last two decades. A major difficulty in IPO research is the lack of direct evidence on IPO allocations made to institutional investors because book building details are not open to the public. We bridge this gap by using a legal experiment in India. On July 9, 2009, Sebi allowed a two-stage IPO process in which qualified institutional investors were allowed to act as anchor investors (or lead investors) in IPOs. Under the law, anchor investors are allotted shares on a discretionary basis and the price at which the allocation is made is disclosed by the lead investment bank one day before the opening of the offer to the public. If the price fixed for public issue through the book-building process is higher than the price at which the allocation is made to anchor investors, the additional amount is to be paid by anchor investors. However, if the price fixed for public issue is lower than the price at which the allocation is made to anchor investors, the difference is not payable to anchor investors. These investors face a short lock-up period of 30 days from the date of allotment. Thus, the Indian IPO process is a sequential hybrid mechanism in which anchor investors lead the price-setting process.

Here, we answer several important questions: How does the involvement of anchor

investors affect underpricing? How do anchor investors decide in which issues to request allocations? Are anchor investors given disproportionate allocations in substantially underpriced IPOs? Do they have a destabilising impact on stock prices around the lock-up expiration date? Do anchor-backed IPOs have higher risk-adjusted returns in the long run?

Regulators have been concerned about the potential conflict of interest between investment banks and investors for many years. Investment banks have the discretion to allot shares in an IPO. Research on IPOs in the US has shown that investment banks allot shares in hot IPOs (i.e., highly under-

priced IPOs) to institutional investors in return for assured investment in future IPOs. Our setting allows us to examine whether this is the case. By studying the Indian experiment, a larger issue we address is whether regulators should consider moving to a two-stage IPO mechanism and, if they do, how the process would affect issuers and investors.

If anchor investors have to truthfully reveal information about the intrinsic value of the IPO firm, then they must be offered more allocation or underpricing. We find that anchor backed IPOs are less underpriced. Underpricing falls by 6.4% when anchor investors are involved. This could be



due to the certification effect anchor investors have on IPOs. It could also be that anchor investors solve valuation uncertainty for IPOs. IPOs backed by anchor have a narrower price band and these investors bid low, i.e., towards the lower end of the price band. Since later investors learn from valuations submitted by anchor investors, their bids tend to be in line with the latter's bid. Consequently, these IPOs are less underpriced.

Who requests anchor investors to submit their bids? Naturally, smaller firms and smaller IPOs that suffer from asymmetric information (i.e., managers of the firm know more about the firm than outside investors) or firms facing difficulty in going

public (measured by the time elapsed between the prospectus filing date and the offer date) would find an association with anchor investors beneficial. Indeed, this is what we find. Anchor investors are more likely to invest in these firms.

Research in the US shows that institutional investors are allotted disproportionately large number of shares in hot IPOs. In the Indian context, this is not an issue. Anchor investors receive allocations in both under- and over-priced IPOs. In other words, the nature of book building in India prevents investment banks from expropriating wealth from retail investors.

As anchor investors invest in hard-to-place offerings, it must be that they are compensated for their efforts. The lock-up provision restricts them from selling shares on the listing day. Profits are determined by the allocation decision of underwriters and they may reward anchor investors by allocating shares in underpriced issues. Because anchor investors face a 30-day lock-up, first-day returns (traditional definition of underpricing) are less relevant to them. We calculate the hypothetical returns to anchor investors if they were to sell upon lock-up expiration. Returns are calculated as the percentage difference between the price at which anchor investors are allotted shares and the price that prevails on the lock-up expiration day. IPOs backed by reputed anchor investors, on average, produce 137%

returns up to the lock-up expiration date.

However, after adjusting for risk, IPOs backed by anchor investors do not earn abnormal returns in the long run. While all anchor-backed IPOs do not earn abnormal returns after adjusting for risk, it is likely that anchor-backed IPOs earn superior returns through monitoring when anchor investors invest along with certain types of investors. If monitoring causes superior performance, we expect the performance advantage to be the highest for firms backed by anchor investors, UTI, other mutual funds, and VCs and the lowest for firms with little or no investment from anchor investors, UTI, and VCs. Because of economies of scale in monitoring, institutional investors such as anchor investors may resort to active monitoring only when the level of institutional shareholding is above a threshold. The results confirm our prediction that IPOs backed by anchor and other institutional investors perform better than IPOs with little institutional investor involvement. These firms generate a positive alpha of 1.25% per month (or 15% per annum).

Our article shows that the two-stage IPO process has several features that issuers, investors, and regulators consider desirable. Anchor investors help underwriters market hard-to-place offerings. The presence of reputed anchors can potentially reduce valuation uncertainty and underpricing.