

BEFORE THE HON'BLE SUPREME COURT OF HAPPINDIA

ORIGINAL JURISDICTION

CIVIL WRIT PETITION No.0000A of 2019

IN THE MATTER OF

The Merry Nadu Chemists and Druggists Association

.....Petitioner

Rep by its General Secretary, Mr. Rajamallan

versus

The Union of Happindia

.....Respondent

Through the Department of Health and Family Welfare

-AND-

ORIGINAL JURISDICTION

CIVIL WRIT PETITION No.0000B of 2019

IN THE MATTER OF

Miracle Vapour Private Ltd.,

.....Petitioner

Rep by its General Secretary, Mr. Abdul Ajes

versus

The Union of Happindia

.....Respondent

Through the Department of Health and Family Welfare

FACTS OF THE CASE:

GENERAL

Happindia is one of the oldest civilizations in the world with a kaleidoscopic variety and rich cultural heritage. It has achieved all-round socio-economic progress during the last 73 years of its Independence. It has now become one of the top industrialized countries in the world.

Happindia has advanced in terms of digital competitiveness in the world as the country has improved in terms of knowledge and future-readiness to adopt and explore digital technologies. The increasing number of Internet users in Happindia is a result of a number of factors, including the growth in the use of personal computers, advances in high-speed connectivity, and the availability of a broader range of online products and services.

PART-1

Happindia is among the leading global producers of cost-effective generic medicines and vaccines, supplying 20 percent of the total global demand by volume. The country has an established domestic pharmaceutical industry, with a strong network of 3000 drug companies and about 10,500 manufacturing units. Out of these, 1,400 units are World Health Organization (WHO) good manufacturing practice (GMP) approved; 1,105 have Europe's certificate of suitability (CEPs); more than 950 match therapeutic goods administration (TGA) guidelines; and 584 units are approved by the US Food and Drug Administration (USFDA).

The Happindian pharmaceutical industry is aspiring to touch USD 120-130 billion by 2030 from the current USD 38 billion. To achieve the goals of Vision 2030, the stakeholders are accelerating towards the goal of universal healthcare across Happindia and the world by providing access to high-quality affordable drugs.

With the widespread societal use of the Internet, it is of no surprise that a broad and growing array of health care information, services and products, including pharmaceuticals, are being offered online. It is estimated that more than 250 online pharmacies have sprung up in Happindia in recent years, cornering Rs. 1,000 crore (\$140 million) of the Happindian drug market.

Happindia's pharmacy laws are derived from the Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rule, 1945, and the Pharmacy Act, 1948. These laws predate the advent of online commerce in India, leaving the business out of the purview. Drugs and Cosmetics Act, 1940 and Rules 1945 were passed with the aim to ensure that only qualified personnel are engaged in manufacturing, importing, distribution and sale of drugs and cosmetics, confirming safe and effective drugs and cosmetics are being sold. It also prevents entry of substandard drugs and cosmetics in the Indian market.

But the rapid growth of e-commerce continues to pose challenges to the State and Central Governments in the trade of online pharmacy. Massive protests took place all over the country, when Maxon, Spinkart and Smack seal, leading e-commerce companies, entered in general retail, which is being continued in retail medicine.

Meanwhile, a complaint was lodged in Smilepur police station by one Mr. Ashok Hari Singh, that on 15.02.2019, the de facto complainant had taken his minor son to the clinic of Dr. Eesh Samba who administered Polio, DPT and HIB vaccines to the child from his own stock. After returning home the child became very sick and started vomiting and became seriously ill and was taken to doctor known to the informant and after a proper treatment the child was cured. The informant noticed that in the vial both manufacturing date and expiry date were interpolated, where manufacturing date 31st January, 2009 was changed by pen into 2019 and expiry date January, 2012 was converted into 2022. The informant learnt from Dr. Eesh that the said vaccines were purchased at a discounted rate from the e-commerce platform maxon.in. On the basis of the said complaint, Smilepur P.S has registered a First Information Report on 15.02.2019 against Dr. Eesh Samba and Members of the Maxon board, under Sections 274 and 275 of Happendian Penal Code read with Section 27 of the Drugs and Cosmetics Act, 1940. The case against Maxon dominated the country's media on 15.02.2019.

On Investigation, Mrs. Shanthini, Country Head of Maxon Happendia said that Maxon cannot be held liable for third-party seller products as the vaccines are supplied by Allaga Pharma Ltd. She quoted clause 3 of Terms of Conditions of Use which states as follows:

“Maxon is only a facilitator and is not and cannot be a party to or control in any manner any transactions on the website. Accordingly, the contract of sale of products on the website shall be a strictly bipartite contract between you and the sellers on Maxon.in.”

She further stated that Dr. Eesh Samba has purchased the medicine even after the following strong highlighted pop-up notification disclaimer on the webpage:

“The product you are accessing is a Third-party product and any transaction is at your own risk. Kindly ensure using your best and prudent judgment before entering into any transactions through this webpage”

On the basis of the said FIR, after completing the investigation the police submitted the chargesheet on 17.04.2019, against Dr. Eesh Samba and added the name of the proprietor of Allaga Pharma Ltd. but excluded the names of Members of Maxon Board. On the basis of such chargesheet learned SDJM has taken cognizance of offence.

On 22.04.2019, a Writ Petition has been filed in Supreme Court of Happendia for blocking the link of all such websites from Happendia, who are engaged in online sale of medicines in violation of the Drugs and Cosmetics Rules, 1945. The petitioner is an Association of the Merry Nadu Chemists and Druggists (The Merry Nadu Chemists and Druggists Association) represented by its General Secretary Mr. Rajamallan. His contention is that permitting sale of drugs through Internet/online defeats the purpose of the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules framed thereunder to safeguard the public interest, which regulates the manufacture and sale to ensure quality and availability under prescribed storage conditions by qualified pharmacists. It is averred in the petition that there are provisions under the Drugs and Cosmetics Act for recalling drugs due to very serious side-effects from the market and this would be possible only if the medicines are sold by the pharmacists, who are aware of the movement of the medicines till it reaches the patients. There is no guarantee for data privacy if the medicines are sold online. Diseases and treatments are private and confidential information of the patients, which cannot be made available for data mining and for commercial use by online pharmacists. The petition also contains the facts and details of the FIR filed against Maxon.

While the respondent relied upon the benefits and advantages of e-pharmacies, it is also stated by the respondent that the Sub-Committee constituted by the Drugs Consultative Committee (DCC) to examine the issue relating to the sale of drugs over the internet has submitted its report to the DCC, which in turn, in its 50th meeting held on 4th and 5th November, 2016, has accepted the report and the same has been forwarded to Ministry of Health and Family Welfare for consideration. Based on the report, on September 2018, the Union Health Ministry of India released the draft rules on sale of drugs by E-Pharmacies in order to regulate online sale of medicines in Happendia. And the same is pending for further discussion. It is argued that until the implementation of draft rules there should not be any distinction between online and conventional pharmacy. The person or company having license to sell medicine and drugs in

retail store, should be permitted to sell it online. Further, the respondent mentioned that the facts and details of the FIR filed against Maxon are irrelevant to instant case.

Hearing the arguments, the Supreme Court has imposed an interim ban on the sale of drugs online in Happindia on 18th September 2019.

PART-2

According to the World Health Organization (WHO), Happindia is home to 12% of the world's smokers. More than ten million Happindians die every year from tobacco-related diseases. This is more than the number of deaths due to motor accidents, AIDS, alcohol and drug abuse put together.

The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003(COTPA), was first ever anti-tobacco legislation in Happindia. This important Act was introduced in the face of stiff resistance of the tobacco lobby. The preamble of the Act states “it is expedient to prohibit consumption of cigarettes and other tobacco products which are injurious to health with a view to achieving improvement of public health in general as enjoined by Article 47 of the Constitution.” Happindia is now looking to amend COTPA 2003 to plug its loopholes.

Despite strenuous opposition, Happindia succeeded in getting large size (85%) warning on tobacco packs along with the Quit line number. Free multilingual telephonic counselling is successfully assisting tobacco users to quit the habit. Happindian Government ensured better implementation of gutka and flavoured chewing tobacco ban. It also launched one of the most graphic anti-tobacco awareness campaigns on Happindian television and cinema halls.

With the advent of various outstanding “Tobacco Free Happindia” programmes, Happindia has shown 17% relative decrease in tobacco consumption between 2010 and 2016.

In the midst of declining cigarette consumption, cigarette companies introduced e-cigarettes to remain profitable. These newer products are being deceptively promoted as a less harmful alternative to cigarettes. The liquid in the e-cigarette usually contains nicotine, which is toxic, highly addictive and known to be a lethal chemical. To make it more appealing to kids, more than 7,000 varieties of flavours are mixed in the liquid. Apart from nicotine, e-cigarette

cartridges can also be used as delivery devices for addictive and harmful substances such as cannabis and opiates.

E-cigarette industry targets youth as potential customers – many of whom are never-smokers who view the devices as a form of recreation and sometimes a fashion statement. When used by never-smokers, these devices can be a gateway for cigarette smoking and other drug use. As per the Happindia National Youth Tobacco Survey, e-cigarette use acquired epidemic proportions and increased by 77.8% among high school students and by 48.5% among middle school students from 2017 to 2018, only in one year. Even though there are apparent evidences of “harm reduction” as well as any cessation benefits of these products, a contradicting newer evidence of harm is emerging, as demonstrated by the outbreak of severe lung disease due to vaping in Happindia, where more than 400 people were affected and 12 reportedly died. Their use for cessation is not yet approved under the Drugs and Cosmetics Act. Alarmed by these statistics and emerging evidence, various expert committees and institutions petitioned the ministry of health to ban e-cigarettes before they became an epidemic.

However, no legislation were in place to ban these hazardous products across Happindia. Therefore, on September 18, 2019, Happindia government took a bold step by promulgating the Prohibition of Electronic Cigarettes (production, manufacture, import, export, transport, sale, distribution, storage and advertisement) Ordinance, 2019.

Miracle Vapour Private Ltd., moves the writ petition in Supreme Court of Happindia challenging the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019 dated 18th September, 2019.

GENERAL

Concerning the importance of public health and safety in both part-1 and part-2 cases, the Chief Justice of Happindia established a special bench and termed it as BAN BENCH to decide upon the lifting of ban imposed on E-pharmacies and E-cigarettes.

- The Ban Bench posted both the cases for final hearing.

As a matter of rule, Speaker-1 will be the representing counsel for Part-1 dispute and Speaker-2 will be for Part-2 dispute.

The legal system and legislations of Happindia are in parimateria with that of Republic of India

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None of the facts above are intended to depict anyone or any pending litigation. All facts stated herein are for the purpose of academic research and may be taken in that light only.
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