

FUNCTIONING AND DEVELOPMENT OF THE
COURT ENFORCEMENT AND REGULATORY
SYSTEM IN PAKISTAN

By

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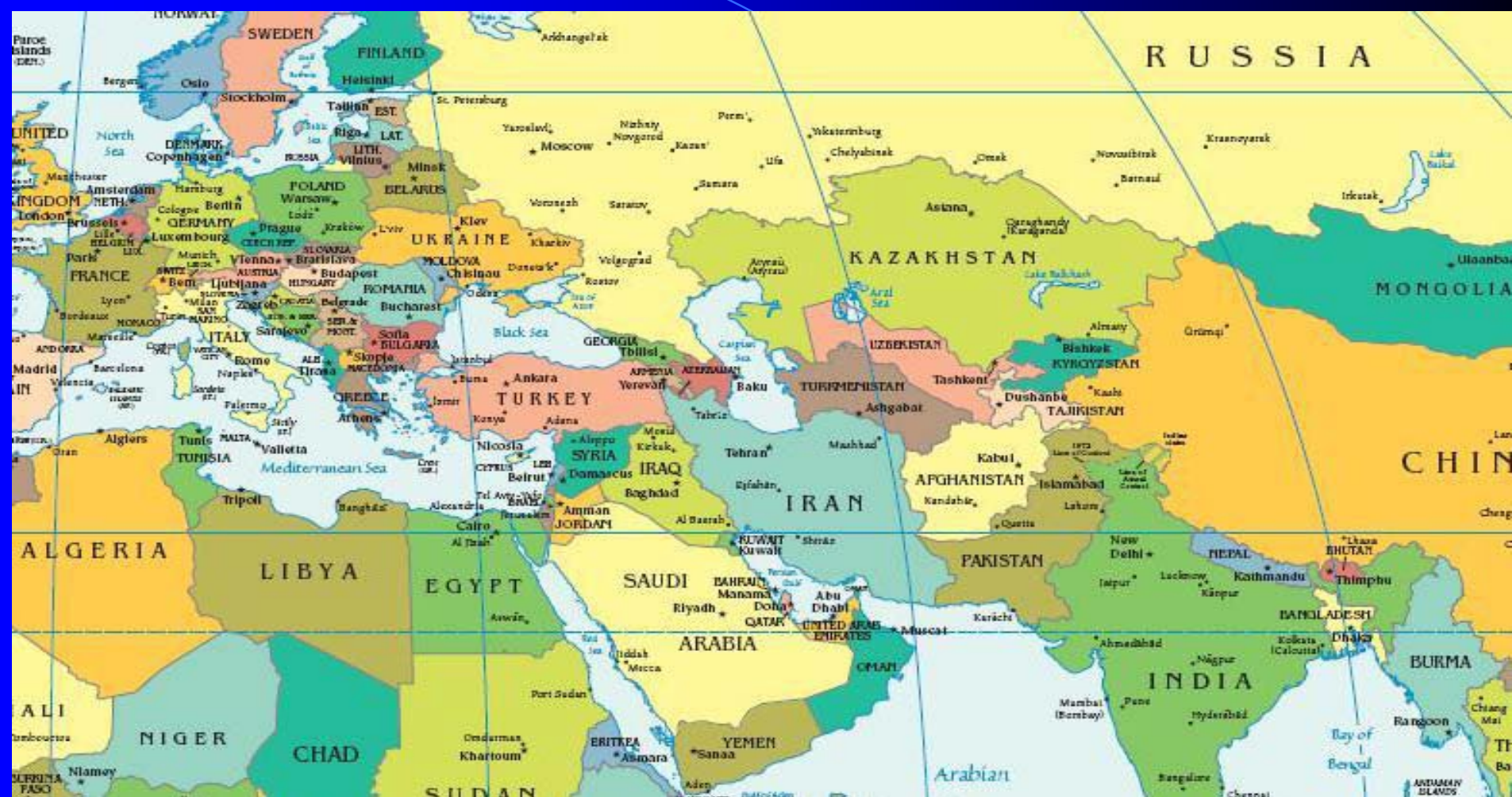
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Population
241,499,431

Per Capita Income
US\$1,597

GDP
US\$ 376.49 billion



Key statistics of the Pakistan pharmaceutical sector:

Indicators:	Statistics
Total Market Size:	US\$3.2 billion
Growth Rate:	Growing steadily-average of 7.5% for the last 3 years. The market size will double in the next 10 years in Pakistan.
International Ranking Value Wise	45
Pharmaceutical Export	US\$268 million during 2021
National Manufacturers	55.7%
MNCs	44.3%

Source: Board of Investment (BOI) Pakistan
Pharma Bureau

Total number of Licensed Pharmaceutical Manufacturers in Pakistan

Province	Numbers of Licensed Manufacturers	Local Licensed Manufacturers	MNCs Licensed Manufacturers
PUNJAB	374	366	8
SINDH	143	118	25
KPK	87	87	-
BALUCHISTAN/ Hub Industrial Areas	11	8	3
AZAD KASHMIR	5	5	-
Total	620	584	36



Basic / Semi-basic Manufacturing of API's (around)	20
Biotech / Biologicals (around)	15
Importers of Drugs	1000+
Local Companies Export (2021)	US\$ 268.64 million
(2022-23)	US\$ 713 million
Foreign Companies Export	US\$131 Million

Countries exported to

Asia:

Afghanistan, Sri Lanka, Malaysia, Bangladesh, Singapore, Cambodia, Laos, Myanmar, Philippines, Vietnam, Kazakhstan, Tajikistan, Maldives, Myanmar,

Africa:

South Africa, Uganda, Djibouti, Somalia, Libya, Kenya, Mauritius, Nigeria, Sudan, Ghana, Benin, Burkina, Faso, Cameroon, Congo, Cote, d'Ivoire, Mali, Mauritania, Nigeria, RCA, Senegal, Zambia

Middle East:

Yemen, Iraq, Qatar,

Others:

United Kingdom, Peru, Guatemala,

OUR GLOBAL PRESENCE

PRESENCE IN
24
COUNTRIES

400+ OVERSEAS
AUTHORIZATIONS

250+ UNDER
EVALUATION

- ▶ Afghanistan
- ▶ Benin
- ▶ Burkina Faso
- ▶ Cambodia
- ▶ Cameroon
- ▶ Congo
- ▶ Côte d'Ivoire
- ▶ Ghana
- ▶ Guatemala
- ▶ Iraq
- ▶ Kenya
- ▶ Maldives
- ▶ Mali
- ▶ Mauritania
- ▶ Myanmar
- ▶ Nigeria
- ▶ Pakistan
- ▶ Philippines
- ▶ Qatar
- ▶ RCA
- ▶ Senegal
- ▶ Sri Lanka
- ▶ Vietnam
- ▶ Zambia



Rights Conferred by Registration **(Section 39):**

- # Trademark is personal property.
- # Exclusive rights.
- # Right to prevent use of trademark without consent.

Non-use - **5 years**

Now counted from the date the trademark is put on the Register and **NOT** from the date of registration (filing date)

Infringement (Section 40)

- # Identical or deceptively similar mark, identical or similar goods or goods of description or services and there exists a likelihood of confusion to public including likelihood of association.
- # Services closely related to goods and goods closely related to services of registered trademark

Identical or deceptively similar trademark

and goods or services NOT SIMILAR to those of
registered trademark

where

- a) mark is a well-known mark or
- b) has a reputation in Pakistan

AND

- # Use of the mark, without due cause, takes unfair advantage of, and is detrimental to the distinctive character or repute of the mark
- # Use of registered trademark as tradenname or part of tradenname (name used to denote trade or calling and include firm and company name)
- # Use as domain name or part of domain name or obtaining such a domain without consent for selling to another or proprietor of registered trademark.

Types of Action

Civil:

- a) Suit for infringement of registered trademark.
- b) Suit for infringement of proprietary rights in an unregistered trademark based on prior use (prior user rights).
- c) Passing off action.
- d) Protection of well-known marks (not used, nor registered in Pakistan).
- e) Prevention of Unfair Competition.

Unfair competition “any act of competition contrary to honest business practices in industrial or commercial matters” include

- (a) all acts that create confusion by any means
- (g) fraudulently registering or applying for registration of a trade mark.

Who Can File:

- a) Trademark Owner
- b) Licensee, if trademark owner fails to act.

Reliefs:

- Injunction
- Damages (very rare)
- Accounts
- Eraser of offending mark or destruction of goods
- Delivery up
- Costs (very rare)

Criminal Actions (Counterfeiting):

Pakistan Penal Code, 1860

Sections 28, 478, 480, 482, 483, 485, 486

- a) Raid
- b) Criminal prosecution (with or without raid)

It is not essential to counterfeiting that the imitation should be exact.

“the expression “trade mark” includes any trade mark which is registered”

Using a false trade mark *“imprisonment which may extend to one year, or with fine, or with both.”*

Counterfeiting a trade mark *“imprisonment which may extend to two years, or with fine, or with both.”*

Making or possession of any instrument for counterfeiting a trade mark *“imprisonment which may extend to three years, or with fine, or with both.”*

Selling goods marked with a counterfeit trade mark *“imprisonment which may extend to one year, or with fine or with both.”*

Jurisdiction for IP Disputes

- District Judge (Trademarks Act, 1940 & Trademark Ordinance, 2001)
- IP Tribunal – IPO Act, 2012
- Transfer of cases to IPT
- Jurisdiction of IPT
- Multazim Raza Case SC
- Shaheen Cosmetics Case IHC

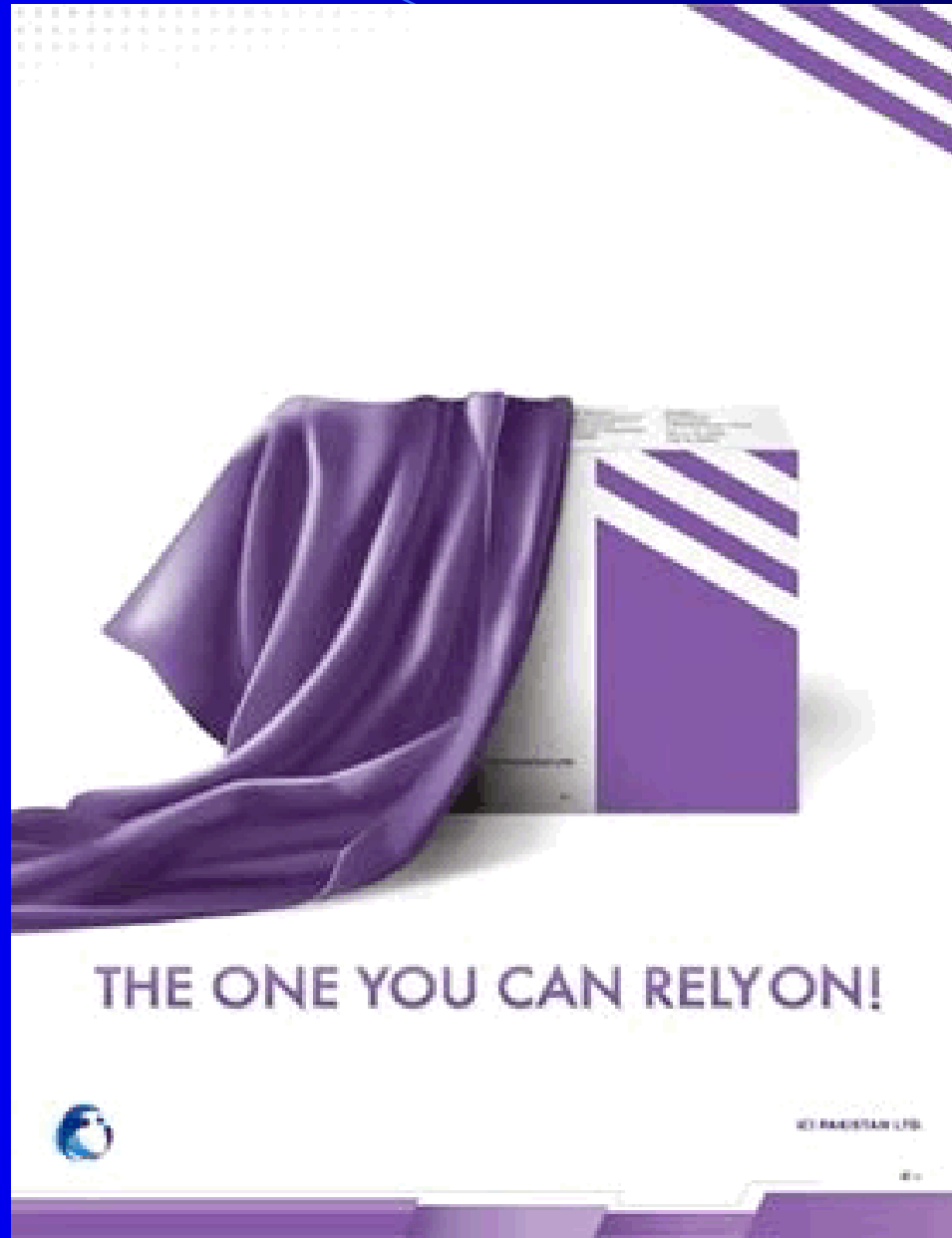
Trademarks Amendment Act, 2023 – August 16, 2023

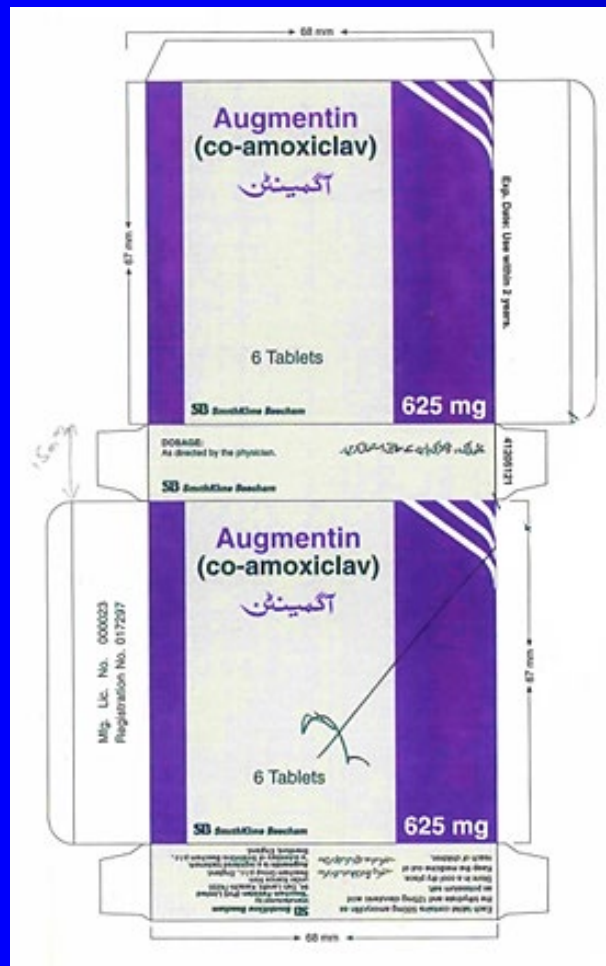
- # Comes into force at once
- # International Registration under Madrid Protocol.
- # Trademarks Rules not amended.
- # Deposited instrument of Accession on the Madrid Protocol on February 24, 2021.
- # Entered into force on May 24, 2021.
- # No Validation clause.

Border Enforcement:

- SRO 170(1)/2017 dated : 16th March, 2017
- Procedure
- Intervention application (Security of Rs. 500K (US\$ 1772)+ Bond.
- Appeals under Customs Act, 1969

Infringement by Local Companies





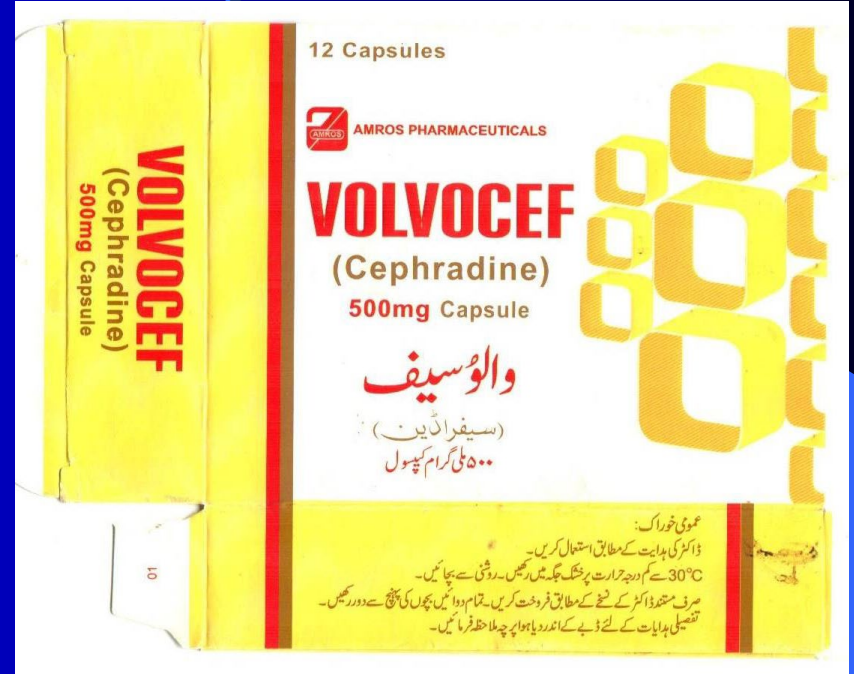




Strategy:

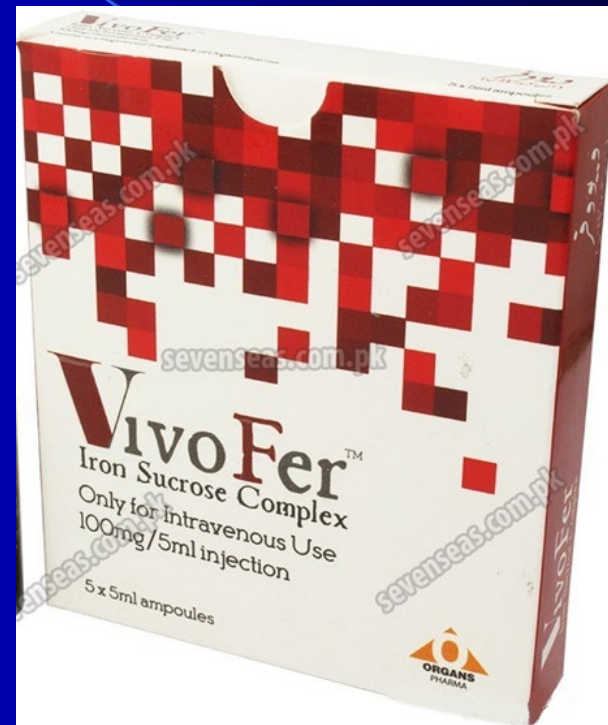
- 1) Consistent use of purple, black & white colours.
- 2) Reputation & goodwill in these colours.
- 3) Residual reputation of earlier packaging.
- 4) Bad faith adoption.
- 5) Examples of co-amoxiclav packagings used by other companies.





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Foreign marks adoption

















Tests for Infringement

Ciproxin Vs. Ciprocide

Ciproxin Vs. Ciproquin

Use of name / Part of name as part of Local Company name

- Bayer AG Vs. Bayhealth Care (Pvt.) Ltd.
- Vifor (International) Inc. Vs. Vifor Pharma (Private) Limited

- Section 40(5) of Trademark Ordinance, 2001.

“Infringement of registered trade mark by use as a trade name or part of trade name.”

Companies Act, 2017

No company can be registered by a name

- (a) identical with or resemble or similar to the name of a company; or
- (b) inappropriate; or
- (c) undesirable; or
- (d) deceptive; or

XENON

Xenon Pharmaceuticals Inc.

3650 Gilmore Way
Burnaby, BC V5G 4W8

Tel: 604.484.3300

Fax: 604.484.3450

info@xenon-pharma.com



Xenon Pharmaceuticals

9.5 KM Lahore - Sheikhupura -
Faisalabad Rd, Kot Abdul Malik,
Lahore, Sheikhupura, Punjab



10835 Road to the Cure, Ste. 100
San Diego, CA, 92121



Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi
74900, Pakistan

Registration of Packaging as a Copyright



71AAF
07.07
07.10

Batch No. Mfg. Date: Exp. Date:

71AAF
07.07
07.10

Batch No. Mfg. Date: Exp. Date:

M.R.P. Rs. 22.10
RN 000394 ML 000017 & 000233

IMPORTANT
Where bandages are employed over this ointment, they should be light and loose, neither tight nor airexcluding.

ضروری صلاحیت: جوتاڑنے پر یوڈیکس مرہم
پھیلا کر کئی دھرتے وقت سے بات کا خیال رکھیں کہ
پٹی کھلی اور دھکیلی ہو۔ ٹھک اور ہار کے والی نہیں ہوں۔

IODEX 28g.
(Iodine + Methyl Salicylate)
CMS Ointment

ایوڈیکس
سی ایم ایس مرہم

Resublimed Iodine 4% w/w
7 Methyl Salicyl, 5% w/w
In a Petrolatum base

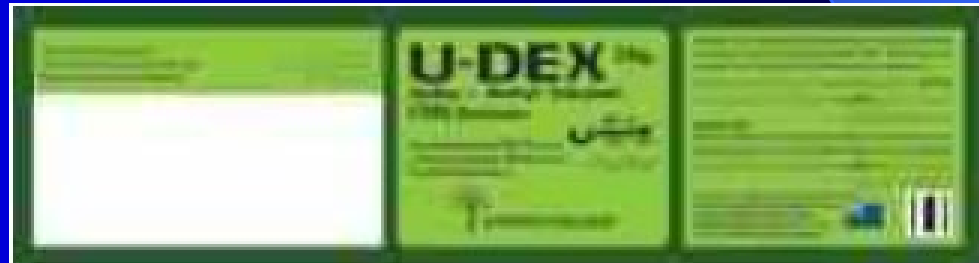
gsk GlaxoSmithKline

May be used externally with advantage in many conditions requiring a soothing and penetrating balm. Where the skin is unbroken, rub in gently until the colour disappears.

یوڈیکس استعمالی اور کئی حالت میں
میتھیل سالیسیلک ایسٹریل کے ساتھ
مرہم جو دھکیں جب توڑا نہ ہو تو اس کا استعمال
جوتاڑنے پر یا زخموں پر جوتاڑنے میں کئی کے ٹھک
تک کر سکتا ہے۔ یہ مرہم جوتاڑنے کے لئے
بہترین ہے۔

FOR EXTERNAL USE ONLY
STORE IN A COOL DRY PLACE
KEEP OUT OF THE REACH OF CHILDREN

IODEX is a registered trademark of the
GlaxoSmithKline Group of companies
GlaxoSmithKline Pakistan Limited
35-Dockyard Road, West Wharf, Karachi LBI 1 0704





Regulatory Environment

- DRAP Act, 2012
- Drugs Act, 1976
- The Drugs (Labeling and Packaging) Rules 1986
- The Drugs (Licensing, Registration and Advertisement) Rules 1976
- Alternative Medicines and Health Products (Enlistment) Rules, 2014
- Medical Devices Rules 2017

Section 2(xxxvi) of the DRAP Act, 2012

“Therapeutic goods” includes drugs or alternative medicine or medical devices or biologicals or other related products as may be notified by the Authority.”

Section 2(ii) of the DRAP Act, 2012

"Alternative Medicine" means a product used exclusively in Homeopathic, Unani, Ayurvedic, Biochemic, Chinese or other traditional system of treatment;”

Section 2(xv) of the DRAP Act, 2012

"health and OTC Products (non-drugs)" include probiotics and disinfectant, nutritional products, food supplements, baby milk and foods, medicated cosmetics, medicated soaps and medicated shampoos;"

Schedule I(3) of the DRAP Act, 2012:

MEDICAL DEVICES include,

- (a) instruments, medical equipment, implants, disposables and software, used mainly for the purpose of diagnosis, monitoring and treatment of disease, or

- (b) any other item which the Federal Government may, by notification in the official Gazette, declare as medical device;

Schedule I(4) of the DRAP Act, 2012:

MEDICATED COSMETICS include,
Cosmetics containing drugs and are defined as articles containing active drug ingredients intended to be rubbed, poured, sprinkled, or- sprayed on, or introduced into, or otherwise applied to human body or part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles; except that such term shall not include soap.

Labeling requirement for an imported Medical Device as per Rule 14 (6) of the MDR, 2017:

“Complete labelling and prescribing information of medical devices, where applicable, shall be same as approved in the country of origin or as approved in European Union, USA, Japan, Canada or Australia. Application for registration may be supported by relevant rules and certification from the manufacturer accordingly.”

Enforcement by DRAP

Counterfeit Drug: means a drug the label or outer packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive the label or outer-packing of a drug of another manufacture;

Spurious Drug: means a drug-

- (ii) which purports to be the product of a manufacturer, place or country of whom or of which it is not truly a product; or

Penalties:

DRAP Act provides violation of the provisions of the DRAP Act and Rules to be punishable with imprisonment not be less than three years and not more than ten years or fine upto ten lakh rupees (US\$ 3500/-).

Action by Drugs Inspector only for violation of provisions of Drug Act

Jurisdiction of Drug Court only.

Any dispute relating to IP Rights will go to IP Tribunal and not to Drug Court.

DRAP refusal to enforce order of IP tribunal for not being a party.

- Vifor Vs. Akson
- DRAP actions erratic / unpredictable.
- DRAP decision relating to Patents.

MINUTES OF 297th MEETING OF REGISTRATION BOARD HELD ON 12th, 13th, 14th & 15th JANUARY, 2021.

Decision: “After detailed deliberations, Registration Board decided that grant of marketing authorization / registration has no linkage with patent status of the originator’s product and advised to process cases for issuance of registration letters except for cases of restraining orders from any court.”

DRAP Registration/MA does not act as defense to trademark Infringement

2017 C L D 1136 [Sindh] Division Bench Judgment (NOVARTIS AG Vs. NABIQASIM INDUSTRIES (Pvt.) LIMITED)

At Page 1138 2nd Paragraph

..... contending that mere registration of a drug name under Drug law does not give right to the registrant to sell the said drug in the market, as with regards to products being sold in the market place under a particular mark, the Trade Mark laws govern such use of the drug's name

At Page No. 1139

“The case at hand is of two medicines used for the treatment of different ailments as mentioned earlier, and whose generic names are also different. For LESCOL it is Fluvastatin and for DESCOL it is Atorvastic. While the first one is used for the treatment of diabetes, the second is used as lipid-lowering agent for the prevention of cardio vascular diseases, meaning thereby used in cases of heart attack, therefore, a small mistake could be fatal for the user and no possibility of deception could be allowed.”

Eli Lilly etc Vs. Atco Pharmaceutical

Order:

“Relying upon the material placed on record, in the meanwhile, respondents/defendants No.1 & 3 are restrained from importing, exporting, manufacturing, formulating, stocking, advertising and selling defendant No’s.1 infringing “Baricitinib” products either alone or in combination with any other product or in any salt form of “Baricitinib” under any trade mark/name in infringement of Patent Nos.142331 and 142333 and restraining the defendant No.1 from perusing and/or obtaining marketing, authorizing from DRAP for “Baricitinib” products and also restrained defendant No.2 from processing defendant Nos. 1 application for registration of “Baricitinib” products”

Eli Lilly etc Vs. Atco Pharmaceutical

Order:

“ 17.Defendants No.1 and 3 are restrained from importing, exporting, manufacturing, advertising and selling Baricitinib products alone or in combination with any other product in any salt form, and Defendant No. 1 is restrained from pursuing and obtaining marketing authorization from DRAP for Baricitinib products while Defendant No. 2 is restrained from processing Defendant No. 1's applications for registration of Baricitinib products till the final decision of the Suit.”

- Publication of agenda (names only)
- Early action to prevent launch.
- Restraining order against Gx and DRAP (possibly).
- Unjust enrichment.
- Online Pharmacies.