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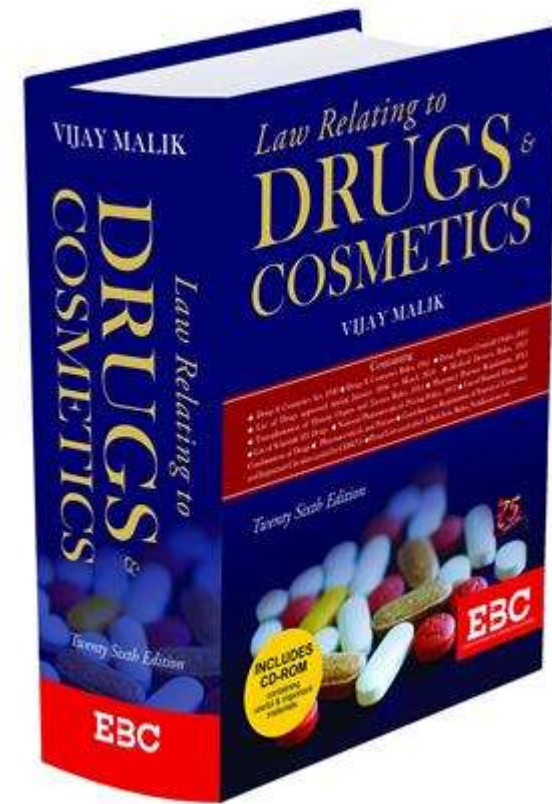
- Graduation from COPS, Trivandrum in 2007, Secured 3rd Rank
- Post Graduation in Pharmaceutics from COPS, Calicut in 2010, Secured 1st Rank
- Provisional Lecturer in Pharmacy, COPS, Calicut in 2010
- Pharmacist in Government Service in 2011
- Joined as Drugs Inspector in 2011
- Served as Technical Assistant to Drugs Controller till 2017
- Served as Drugs Inspector, Kollam (2017-2020)
- Drugs Inspector (Special Intelligence Branch) since 2020

Best Regulatory Practices for Community Pharmacies

Presenter: M.C GEETHA, M.Pharm
Drugs Inspector(Special Intelligence Branch)
DRUGS CONTROL DEPARTMENT
GOVT. OF KERALA

Regulations....

- ▶ Drugs & Cosmetics Act 1940
- ▶ Drug Rules 1945
- ▶ Cosmetics Rules 2020
- ▶ The Medical Device Rules 2017
- ▶ Drugs & Magic Remedies(Objectionable Advertisement) Act 1954 & Rules 1955
- ▶ Drugs Price Control Order 2013(under Essential Commodities Act 1955)
- ▶ Kerala Drugs & other Stores (Unlawful possession Act) 1971
- ▶ Kerala Poison Rules, 1996 issued under the Poison Act, 1919.
- ▶ Kerala Essential Articles Control Act 1986.



Drugs and Cosmetics Act 1940
& Drugs Rules 1945
Cosmetics Rules 2020
Medical Device Rules 2017

Regulations on pharmacies & Role of Community Pharmacist..... ..

- ▶ Service of Registered Pharmacist
- ▶ Maintenance of Records
 - Sales
 - Purchase
- ▶ Maintenance of Registers
 - Schedule H1
- ▶ Stamping of prescription
- ▶ Duplicate copy of prescription
- ▶ No substitution
- ▶ Government sale
- ▶ Storage of drugs- label directions, veterinary drugs
- ▶ Date expired drugs



Schedule H1 drug (Midway between Schedule H and Schedule X)

Why Schedule H1 was implemented?

- Central Drugs Standard Control Organization (CDSCO) implemented Schedule H1 in India starting March 1, 2014
- 47 drugs were placed under the Sch.H1 list. (Antibiotics, Anti TB drugs and Habit forming Drugs)
- H1 list includes **24 antibiotics**, such as third- and fourth-generation cephalosporins, carbapenems, antituberculosis drugs, and newer fluoroquinolones

Schedule H1 drug

(e) if it contains a drug substance specified in Schedule H1, the drug formulation shall be labelled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and shall also be labelled with the following words, in a box with a red border:

SCHEDULE H1 DRUG - WARNING:
- It is dangerous to take this preparation except in accordance with the medical advice.
- Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Schedule H1 drug

"SCHEDULE H1"

(SEE RULES 65 AND 97)

- | | |
|----------------------|---------------------------------|
| 1. Alprazolam | 24. Doripenem |
| 2. Balofloxacin | 25. Ertapenem |
| 3. Buprenorphine | 26. Ethambutol Hydrochloride |
| 4. Capreomycin | 27. Ethionamide |
| 5. Cefdinir | 28. Feropenem |
| 6. Ceftiditoren | 29. Gemifloxacin |
| 7. Cefepime | 30. Imipenem |
| 8. Cefetamet | 31. Isoniazid |
| 9. Cefixime | 32. Levofloxacin |
| 10. Cefoperazone | 33. Meropenem |
| 11. Cefotaxime | 34. Midazolam |
| 12. Cefpirome | 35. Moxifloxacin |
| 13. Cefpodoxime | 36. Nitrezepam |
| 14. Ceftazidime | 37. Pentazocine |
| 15. Ceftibuten | 38. Prulifloxacin |
| 16. Ceftizoxime | 39. Pyrazinamide |
| 17. Ceftriaxone | 40. Rifabutin |
| 18. Chlordiazepoxide | 41. Rifampicin |
| 19. Clofazimine | 42. Sodium Para-aminosalicylate |
| 20. Codiene | 43. Sparfloxacin |
| 21. Cycloserine | 44. Thiactazone |
| 22. Diazepam | 45. Tramadol |
| 23. Diphenoxylate | 46. Zolpidem |

Register for Schedule H1 drugs

Sl no.	Bill no. and Date	Name of the drug sold	Batch no.	Quantity sold	Name of the patient	Name and address of the Doctor

Signature of Reg Pharmacist



To be maintained for 3 years

Punitive actions....

▶ Departmental

- Suspension
- Cancellation

▶ Prosecution

Offences vs Case laws...

- ▶ NSQ
- ▶ Without Service of RP
- ▶ Without Drugs Licenses
- ▶ Substitutions- Inj.DMPA Kannur- Paracetamol
- ▶ Stocking drugs with inscription “Government Sale Only”
- ▶ Manufacturing products with misleading claims
- ▶ Sale of date expired drugs
- ▶ Non maintenance of records

Current trends in Misuse...

- ▶ Prescription misuse
- ▶ Online purchase- 1MG, India Mart, Net Med
- ▶ Courier- Mephenteramine, Tapentadol
- ▶ Photo frame- Pregabalin

Penalties related to Manufacture



OFFENCES

PENALTIES

Manufacture of any spurious drugs

- a) NLT 10 years imprisonment – life & Rs.10 Lakhs fine
- b) NLT 7 years imprisonment –life & Rs.3 lakhs Fine

Manufacture of adulterated drugs

- a) NLT 10 years imprisonment – life & Rs.10 Lakhs fine
- b) NLT 3 years-5 years imprisonment & Rs.1 lakh Fine

Manufacture / sale- Without Valid Drug licence

- a) NLT 3 years-5 years imprisonment & Rs.1 lakh Fine

Manufacture of misbranded drugs
Or in contravention of the provisions

- a) NLT 1 year-2 years imprisonment & NLT Rs.20,000 Fine

1.

OPERATION AMRITH

**(ANTIMICROBIAL
RESISTANCE INTERVENTION FOR TOTAL HEALTH)**

- Effective implementation of preventing the sale of antibiotics without prescription

IMPACT- reduction of Rs 1,000 crore in the sale of antibiotics was observed in the state. Substantiate data for 300 crore with DCD

- Posters with statutory warning designed and being printed



LEGAL WARNING

Sale of drugs including antibiotics falling under Schedule H and H1 without Doctors prescription is an offense and is punishable under Drugs and Cosmetics Act.

Drugs Controller

Always use antibiotics with a valid prescription from a Registered Medical Practitioner.

Antibiotics resistant infections can lead to longer hospital stays, higher medical costs and more death.

www.dc.kerala.gov.in | dc.drugs@kerala.gov.in | 0471 2471886

**Issued in Public Interest
Drug Control Department**

Sl.No	ACTIVITIES	ACTION TAKEN
1.	OPERATION DOUBLE CHECK	<ul style="list-style-type: none">• Devised to Monitor the movement of NSQ & Antibiotics
2.	OPERATION VETBIOTICS	<ul style="list-style-type: none">• To tackle use of antibiotics in veterinary feeds Inspections- 73, Prosecutions-02 Value of drugs seized- 2 Lakhs
3.	PACKAGING REGULATIONS	<ul style="list-style-type: none">• Blue Envelop implementation-Part of the ongoing ROAR program, to curb the unscientific and excessive use of antibiotics.



Operation Vetbiotics

- ▶ Initiative launched to tackle sale of adulterated veterinary feeds that contain antibiotics.
- ▶ Initiated prosecutions

Govt acts against unauthorised sale of veterinary antibiotic medicines

Onmanorama Staff

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Representational Image. Photo: AFP

In a move to curb the unregulated use of antibiotics, the Drugs Control Department has seized medicines worth Rs 1.28 lakhs and taken legal action against two shops that sold veterinary antibiotics.

ലൈസൻസില്ലാതെ വിറ്റ വെറ്ററിനറി മരുന്നുകൾ പിടിച്ചെടുത്തു

മാനന്തലൂർ ▶ ലൈസൻസില്ലാതെ വില്പന നടത്തിയ വെറ്ററിനറി ആന്റിബയോട്ടിക് മരുന്നുകൾ പിടിച്ചെടുത്തു. തൃശ്ശൂർ-പാറയിൽ പ്രവർത്തിക്കുന്ന മരുന്നുകടയിൽ നിന്നാണ് വെള്ളിയാഴ്ച ഡ്രഗ്സ് സ്പെഷ്യൽ ഇൻലിജൻസ് വിഭാഗത്തിന്റെ നേതൃത്വത്തിൽ ഇത് കണ്ടെത്തിയത്.

കാപ്പറേഷൻ വെറ്റ് ബയോട്ടിക് പരിശോധനയിലാണ് ക്രമക്കേട് കണ്ടെത്തിയത്. അനിമൽ ഫീഡ് സൂപ്പിമെന്റ് എന്ന വ്യാജേന ബെംഗളൂരുവിൽ പ്രവർത്തിക്കുന്ന കമ്പനി വിതരണം ചെയ്യുന്ന ആന്റിബയോട്ടിക് മരുന്നുകളാണ് പിടിച്ചെടുത്തത്. ഈ മരുന്ന് ഉപയോഗിക്കുന്നതിലൂടെ ആന്റിമൈക്രോബിയൽ റെസിസ്റ്റൻസ് എന്ന അപകടകരമായ സാഹചര്യം ഉണ്ടാകുമെന്ന് കണ്ടെത്തി



▶ തൃശ്ശൂർ-പാറയിൽ വെറ്ററിനറി മരുന്ന് വില്പന നടത്തുന്ന സ്ഥാപനത്തിൽ ഡ്രഗ്സ് സ്പെഷ്യൽ ഇൻലിജൻസ് ഉദ്യോഗസ്ഥർ പരിശോധന നടത്തുന്നു

യിട്ടുള്ളതിന്റെ അടിസ്ഥാനത്തിലാണ് പരിശോധനകൾ കർശനമാക്കിയതെന്ന് ഉദ്യോഗസ്ഥർ പറഞ്ഞു. ഡ്രഗ്സ് ഇൻസ്പെക്ടർ എം.സി.ഗീത, ചീഫ് ഇൻസ്പെക്ടർ വി.വിനോദ്, ഇൻസ്പെക്ടർമാരായ

എസ്.അജി, മൈമൂൺ ഖാൻ, എം.ശ്രീപ്രവിൺ എന്നിവരുടെ നേതൃത്വത്തിൽ നടത്തിയ പരിശോധനയിൽ ഒരു ലക്ഷത്തോളം രൂപ വിലയുള്ള മരുന്നുകളാണ് പിടിച്ചെടുത്തത്.

Packaging Regulations

- ▶ Part of the ongoing ROAR (Rage on Antimicrobial Resistance) program
- ▶ Implementation of blue envelopes for the sale of Antibiotics
- ▶ curb the unscientific and unethical use of antibiotics.



MEDICINE POUCH MODEL

CAUTION - ANTIBIOTIC



മരുന്ന്/Medicine.....

രോഗിയുടെ പേര്/Patient Name.....

Age..... F M Others

രാവിലെ Morning	ഉച്ചക്ക് Afternoon	വൈകിട്ട് Evening	രാത്രി Night
			

.....വീതം.....മണിക്കൂർ ഇടവിട്ട് കഴിക്കുക
ഭക്ഷണത്തിന്.....മണിക്കൂർ മുൻപ്/ശേഷം
(.....hour before food/after food)

ആന്റിബയോട്ടിക് കഴിക്കുമ്പോൾ ശ്രദ്ധിക്കേണ്ട കാര്യങ്ങൾ

- ഡോക്ടറുടെ നിർദ്ദേശ പ്രകാരം, കുറിപ്പിടയോടുകൂടി മാത്രം ആന്റിബയോട്ടിക്കുകൾ വാങ്ങി ഉപയോഗിക്കുക.
- ഒരു വ്യക്തിയായി ഡോക്ടർ നൽകുന്ന കുറിപ്പിയിൽ മറ്റുള്ളവർ മരുന്നുകൾ വാങ്ങി ഉപയോഗിക്കാതിരിക്കുക.
- ഉപയോഗശൂന്യമായതോ കാലാവധി കഴിഞ്ഞതോ ആയ ആന്റിബയോട്ടിക്കുകൾ നമ്മുടെ പരിസരങ്ങളിലോ ജലാശയങ്ങളിലോ വലിച്ചെറിയരുത്.

ആന്റിമൈക്രോബിയൽ പ്രതിരോധം എന്ന
മഹാവിപത്തിനെ നമുക്ക് ഒന്നിച്ച് നേരിടാം

പൊതുജന താൽപ്പര്യം - ഡ്രഗ്സ് കൺട്രോൾ വകുപ്പ്, കേരള സർക്കാർ

Issued in Public Interest - Drugs Control Dept., Govt. of Kerala

RAIDS	PURPOSE	ACTION TAKEN
<p>OPERATION SHAREERA SOUNDARYA</p> <p>DECEMBER 2024</p>	<p>Curb illegal sale of steroidal preparations being used for body building in Gymnasiums and Fitness Centers across the state.</p>	<ul style="list-style-type: none">• Busted illegal stocking and sale of steroid drugs in Gymnasiums and Fitness Centers• Prosecutions- 2• Value of Steroids seized 1.2 Lakhs



CAMPAIGN	PURPOSE	ACTION TAKEN
<p>Antibiotic literacy campaign</p> <p>SPAARK- SOUKHYAM SADA</p> <p>Drugs Control Department in association with VHSE- NSS</p> <p>DECEMBER 2024</p>	<p>Aimed to create awareness on risks and dangers associated with irrational use of antibiotics and other habit forming drugs.</p>	<ul style="list-style-type: none">•Organized an antibiotic literacy campaign in 343 panchayat in the state to create awareness against indiscriminate use of Antibiotics- New stepping stone to battle against AMR

Disposal of unused Antibiotics.....

- ▶ Discarded drugs litter the lanes of Bhagirath Palace, the largest wholesale market of drugs in the country.....



PROUD

(Programme on Removal of Unused Drugs)

- ▶ Used antibiotics which are often disposed of carelessly seeps into the soil and water bodies, eventually affecting human life. In an effort to tackle the unsafe disposal of unused drugs, the State Drugs Control Department and All Kerala Chemists and Druggists' Association (AKCDA) have jointly launched PROUD in the district on a pilot basis.
- ▶ set to introduce the initiative across all districts in the state.



- ▶ 100 safe drug collection boxes have been kept at selected places, including medical shops in TVM city where people can drop expired or unused drugs from their houses.
- ▶ About 21 tonnes of unused drugs from the city have been collected so far, segregated and handed over to Ramky Energy and Environment Ltd in Mangaluru for incineration.



nPROUD.....

- ▶ Pilot Study- Calicut
- ▶ Haritha Karma Sena
- ▶ KEIL -Kerala Enviro Infrastructure Ltd

nPROUD (Programme for Removal of Unused Drugs) Project.

Identified 160 collection sites in Kozhikkode Corporation & 25 sites in Ulliyeri Panchayat

Permanent Collection Sites identified and the list of PCS published in departmental website.

nPROUD Project was inaugurated by the Hon. Minister on 22.2.2025 at Kozhikkode

Sorting Center



The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954



Need to monitor advertisements:

- ▶ Scientific & ethical advertisements help the public
- ▶ But unethical and misleading advertisements are immensely dangerous to the society.
- ▶ Hence, it become necessary to control them and save the public.



- ▶ Drugs & Magic Remedies (Objectionable Advertisement) Act 1954
Rules 1955
- ▶ ACT NO. 21 OF 1954
- ▶ 1st April, 1955
- ▶ OBJECTIVE
 - To prevent objectionable and unethical advertisement of drugs
 - To prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities.

-Real objective of the Act was to prevent the menace of self medication and self treatment rather than preventing any morale or social menace.



The original included schedule contained a list of 54 diseases and conditions:

- ▶ Appendicitis
- ▶ Arteriosclerosis
- ▶ Blindness
- ▶ Blood poisoning
- ▶ Bright's disease
- ▶ Cancer
- ▶ Cataract
- ▶ Deafness
- ▶ Diabetes
- ▶ Diseases and Disorders of brain
- ▶ Diseases and Disorders of the optical system
- ▶ Diseases and Disorders of the uterus
- ▶ Disorders of menstrual flow
- ▶ Disorders of the nervous system
- ▶ Disorders of the prostatic gland
- ▶ Fits
- ▶ Form and structure of the female bust
- ▶ Gall stones, kidney stones and bladder stones
- ▶ Gangrene
- ▶ Glaucoma
- ▶ Goitre
- ▶ Heart diseases
- ▶ High/low blood pressure
- ▶ Hydrocele
- ▶ Hysteria
- ▶ Infantile paralysis
- ▶ Insanity
- ▶ Leprosy
- ▶ Leucoderma
- ▶ Lockjaw
- ▶ Paralysis
- ▶ Plague
- ▶ Pleurisy
- ▶ Pneumonia
- ▶ Rheumatism
- ▶ Ruptures
- ▶ Sexual impotence
- ▶ Smallpox
- ▶ Stature of persons
- ▶ Sterility in women
- ▶ Trachoma
- ▶ Tuberculosis
- ▶ Tumours
- ▶ Typhoid fever
- ▶ Ulcers of the gastro-intestinal tract
- ▶ Venereal diseases,

Drugs Price Control Order 2013 (Essential Commodities Act 1955)



Drugs Price Control Order 2013 (under Essential Commodities Act 1955)

- ▶ Made under under Essential Commodities Act 1955
- ▶ Came into force on 15th May 2013
- ▶ to ensure that the essential drugs are available in the market at affordable prices for the general public.
- ▶ pricing of essential medicines based on market based policy.
- ▶ National Pharmaceutical Pricing Authority (NPPA) -Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers- responsible for the implementation of DPCO 2013.





Thank
You