1. Importance of QUALITY in manufacture of medicines & regulatory compliances

By Dr. P. V. APPAJI M.Pharm PhD
Former Director, NPPA, Govt of India
Former Director General, PHARMEXCIL, Govt of India

2. India's self-dependency in essential drugs – Present scenario in the domestic market (as on April 2023)

Pharma trade - April 2023.

****

- Indian Pharma domestic trade channel market crosses Rs 2.0 Lakh Crores (perhaps for the first time)! Actual at Rs 2.02 Lakh Crores.

- April 2023 monthly growth : 11.23 % and MAT growth (twelve months to April 2023 : 9.83%

- **********

A. Top five companies:

- Sun , Abbott, CIPLA, Mankind and Alkem.
- Top MAT growth : Alkem : 14.70%

****

B. Top 5 Brands :

- Mixtard, Augmentin, Glycomet GP, Foracort and Lantus.
- Top Growth among five: Augmentin: 36.98%

- **********

C. Top 5 Therapies:

- Cardiac, anti infectives, gastrointestinal, antidiabetic, respiratory.
- Top growth among five: gastrointestinal 12.0%

- Domestic market size Rs 2.02 lakh Crores
- Annual growth 9.83 %
- Top company : SUN Pharma
- Top brand : Mixtard
- Top therapy : Cardiac

3. Indian pharma in Domestic Market – Top 40 Pharma companies

IQVIA

Top Companies in IPM –April'23

RANKING		CORPORATIONS	MONTH April'23			MAT April'23			
MAT	MON		Values in Cr	MS %	Growth %	Values in Cr	MS %	Growth %	EVOL
		IPM	17706.86	100	11.30	202305.16	100	9.83	100
1	1	SUN*	1386.46	7.75	11.42	15504.21	7.66	11.06	101.86
2	2	ABBOTT*	1125.68	6.32	11.42	12515.34	6.18	11.34	101.37
3	3	CIPLA	936.30	5.26	10.44	11006.20	5.44	10.75	100.83
4	4	MANKIND	808.53	4.54	10.48	8958.40	4.43	13.76	103.57
5	5	ALKEM*	712.12	4.00	13.75	8262.19	4.08	14.70	104.43
6	6	LUPIN LIMITED	601.14	3.38	5.59	7001.43	3.46	7.28	97.88
7	8	INTAS PHARMA*	614.47	3.45	11.15	6906.50	3.41	15.76	105.43
8	7	TORRENT PHARMA*	603.80	3.40	7.44	6831.63	3.38	13.18	103.05
9	9	MACLEODS PHARMA	571.95	3.21	10.08	6700.26	3.31	14.57	104.31
10	10	ARISTO PHARMA*	537.41	3.02	19.24	5923.53	2.93	10.05	100.23
11	12	DR REDDYS LABS	486.01	2.73	4.65	5881.21	2.91	4.14	94.82
12	11	ZYDUS CADILA*	519.17	2.92	9.13	5846.45	2.89	8.74	99.01
13	13	GLAXOSMITHKLINE*	433.28	2.43	8.61	5152.27	2.55	7.99	98.33
14	14	EMCURE*	354.94	1.99	6.08	4127.93	2.04	6.30	96.79
15	16	GLENMARK PHARMA	342.08	1.92	10.58	4120.95	2.04	5.71	96.25
16	15	U S V	353.07	1.99	7.11	3999.64	1.93	10.17	100.31
17	17	IPCA LABS	334.63	1.88	9.04	3742.99	1.89	15.22	104.9
18	19	MICRO LABS*	282.73	1.59	6.54	3381.37	1.67	5.42	95.96
19	20	PFIZER*	281.99	1.58	2.15	3319.84	1.64	-1.37	89.8
20	18	SANOFI*	283.21	1.59	4.78	3150.69	1.56	0.77	91.75
21	21	ALEMBIC	266.63	1.50	17.96	3098.23	1.53	10.52	100.63
22	22	FDC	218.13	1.23	8.89	2134.89	1.05	16.48	107.85
23	23	ERIS LIFESCIENCES*	180.69	1.02	8.67	2073.97	1.02	8.76	99.03
24	24	JB PHARMA*	177.90	1.00	17.61	2054.78	1.02	21.97	111.05
25	25	HIMALAYA DRUG	147.94	0.83	0.03	1641.78	0.81	3.73	94.66
26	26	CADILA PHARMA	142.29	0.80	12.62	1529.29	0.76	9.67	97.12
27	27	AJANTA PHARMA	138.09	0.78	14.31	1511.10	0.75	16.59	106.07
28	28	FRANCO INDIAN	123.72	0.70	10.42	1457.76	0.72	4.92	95.53
29	31	INDOCO*	105.60	0.60	11.31	1289.22	0.64	5.20	95.75
30	29	LA RENON HEALTHCA	116.98	0.66	23.73	1261.47	0.62	27.66	110.23
31	35	BLUE CROSS	108.41	0.61	21.93	1240.10	0.61	7.82	98.17
32	33	PROC &GAMB HEALTH	100.58	0.57	-0.58	1142.40	0.56	5.74	97.19
33	32	CORONA REMEDIES	101.20	0.57	20.16	1103.08	0.55	20.94	110.12
34	34	HETERO HEALTHCARE*	96.07	0.55	34.66	1097.33	0.54	1.89	92.58
35	36	SYSTOPIC	90.24	0.51	5.10	1003.08	0.50	8.58	98.86
36	38	MEDLEY PHARMA	88.56	0.50	9.04	998.38	0.49	5.94	96.46
37	37	WIN MEDICARE	78.35	0.44	17.49	911.77	0.45	9.24	99.47
38	39	HEGDE & HEGDE	72.94	0.41	3.37	888.54	0.44	10.99	101.08
39	40	APEX	71.41	0.40	19.42	834.04	0.41	1.96	92.83
40	41	FOURRTS INDIA	71.33	0.40	12.84	831.61	0.41	8.73	99

Top five include :

- ·**Sun Pharma – Rs 15,504 crores**
- **Abbott - Rs 12,515 crores**
- **Cipla – Rs 11,006 crores**
- **Mankind – Rs 8958 crores**
- **Alkem – Rs 8,262 crores**

4. QUALITY - THE CRITICAL REQUIREMENT FOR ANY MEDICINE

Quality management is a critical aspect of the pharmaceutical industry. It ensures that all medicines meant for human consumption are safe, effective, and reliable. The pharmaceutical industry is highly regulated, and quality management is crucial in meeting regulatory requirements. Poor quality management practices can negatively impact patient safety, result in costly product recalls, and tarnish the reputation of a pharmaceutical company. In this article, we will discuss the importance of quality management in the pharmaceutical industry.

Quality of a product is highly essential. It provides assured patient safety and effectiveness of medications. Quality can be achieved through enforcement of effective Quality Management Systems.

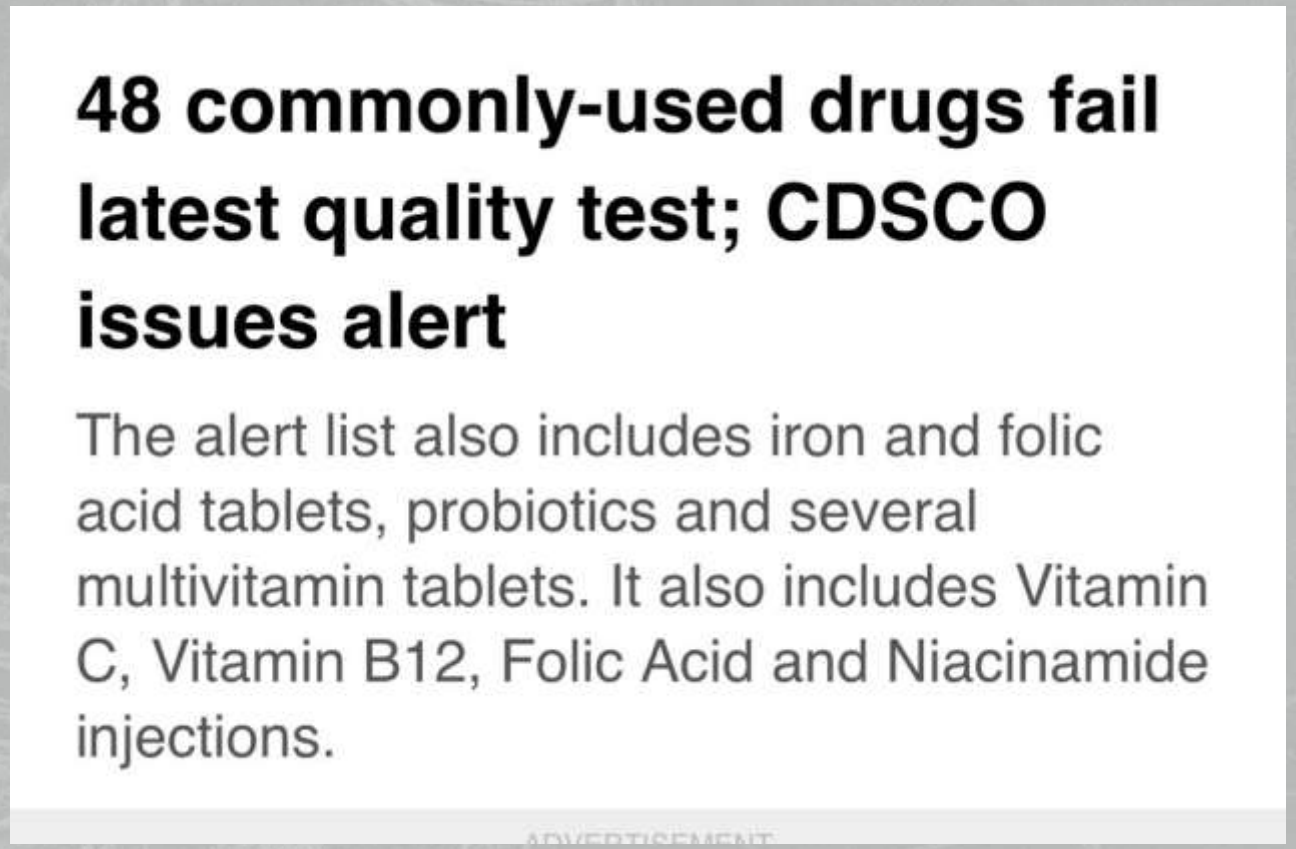
5. Quality – Importance of Quality Management Systems (QMS)

Pharmaceutical companies have a responsibility to ensure that their products are safe for human consumption. Quality management practices ensure that each step in the process, from research and development to manufacturing, distribution, and post-market surveillance, is carried out with the highest level of safety in mind. Quality management systems establish controls that help to identify and manage risks associated with the use of pharmaceutical products.

QMS :

- **achievable by setting proper SOPs**
- **ensures patient safety.**
- **ensures waste reduction & process improvements.**
- **enable withstanding competitive environment.**
- **ensures consistent high quality**

6. Quality issues – manufacture of sub-standard drugs



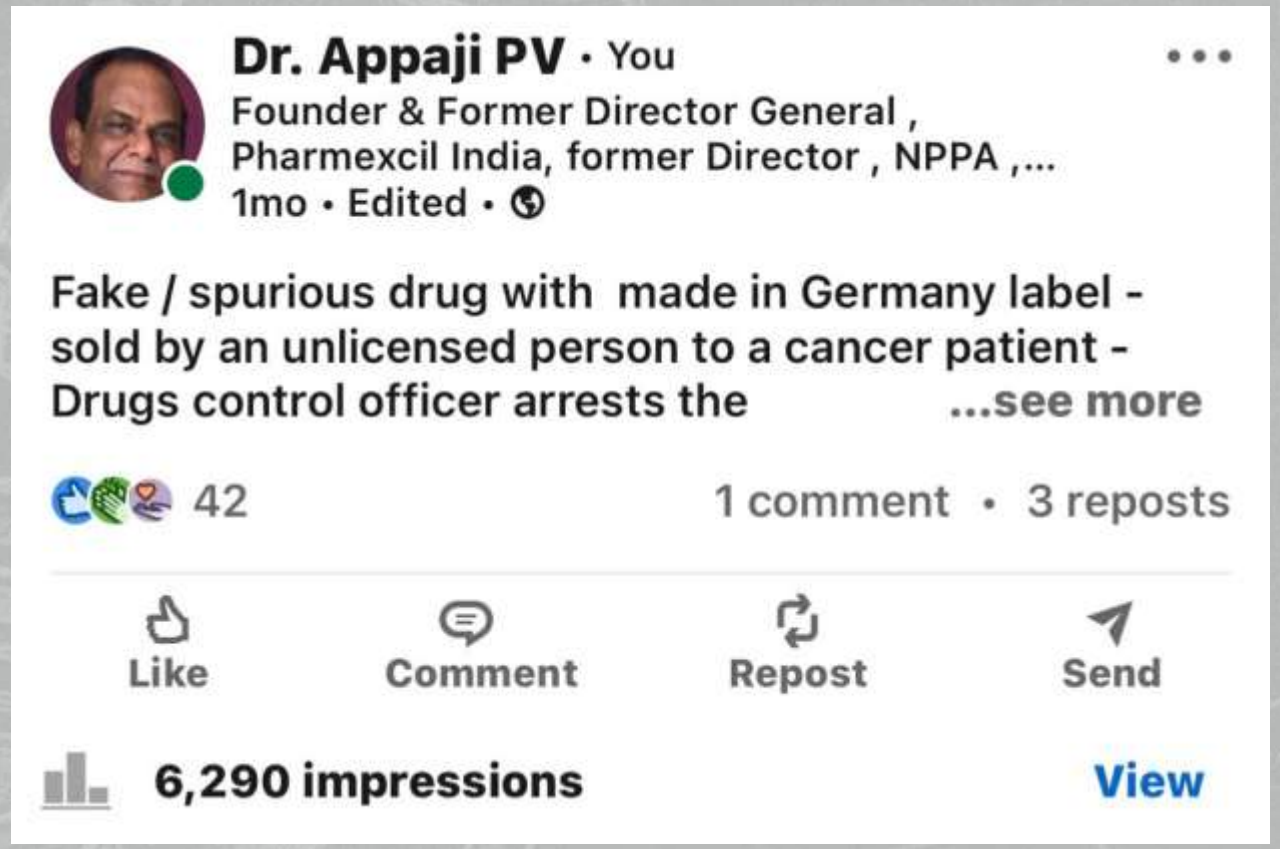
48 commonly-used drugs fail latest quality test; CDSCO issues alert

The alert list also includes iron and folic acid tablets, probiotics and several multivitamin tablets. It also includes Vitamin C, Vitamin B12, Folic Acid and Niacinamide injections.

ADVERTISEMENT

- **Drug regulators regularly pick up samples all over the country & publish test reports.**

7. Quality issues - Menace of fake / spurious drugs



Fake /spurious anti-cancer drugs with imported made in Germany label are also found. Quality completely compromised.

8. Quality issues : cough syrups containing toxic contaminants

Gambia. Dr Appaji on re... Done

ETHealthworld.com Search

Exclusive

Gambia cough-syrup deaths a 'wake-up call' to streamline pharma regulatory system: Expert

The government's decision to impose barcoding on the top 300 medicines sold in the country is very appropriate and it should start soon and can be expanded later informed Dr Appaji PV, Founder & Former Director General, Pharmexcil India, Former Director, NPPA, Govt of India, Ex-officer, Drugs Control Department, GOVT of AP /Telangana, following the Gambia cough-syrup related deaths.

ETHealthWorld • October 14, 2022, 16:12 IST

New Delhi: In the wake of the Gambia cough-syrup-related deaths, the Indian regulatory apex body Central Drugs Standard Control Organisation (CDSCO) has initiated an investigation into the matter. Sonepat-based Maiden Pharmaceuticals, the manufacturer and exporter of the cough syrups in question has been directed by the CDSCO and Haryana State Drugs Controller to stop all activities on grounds of deficiencies found in the preliminary investigation.

The Ministry of Health & Family Welfare has appointed a four-member committee for further investigation. The committee will, after examining and analysing adverse event reports, causal relationships and all related details shared by the World Health Organisation (WHO), suitably advise and recommend Drug Controller General of India (DCGI) about the further course of action. The committee may co-opt any other technical expert as deemed necessary. The four-member committee comprises the following technical experts: Dr YK Gupta, Vice Chairperson, Standing National Committee on Medicines (Chair), Dr Pragya D Yadav, NIV, ICMR, Pune, Dr Arti Bahl, Division of Epidemiology, NCDC, New Delhi and AK Pradhan, JDC(I), Central Drugs Standard Control Organisation (CDSCO).

Some cough syrups made in India have reportedly caused deaths in Gambia – DCGI said that adequate data was not provided by WHO

9. Quality Issues – Cough syrups made in Indonesia (toxic contaminants)

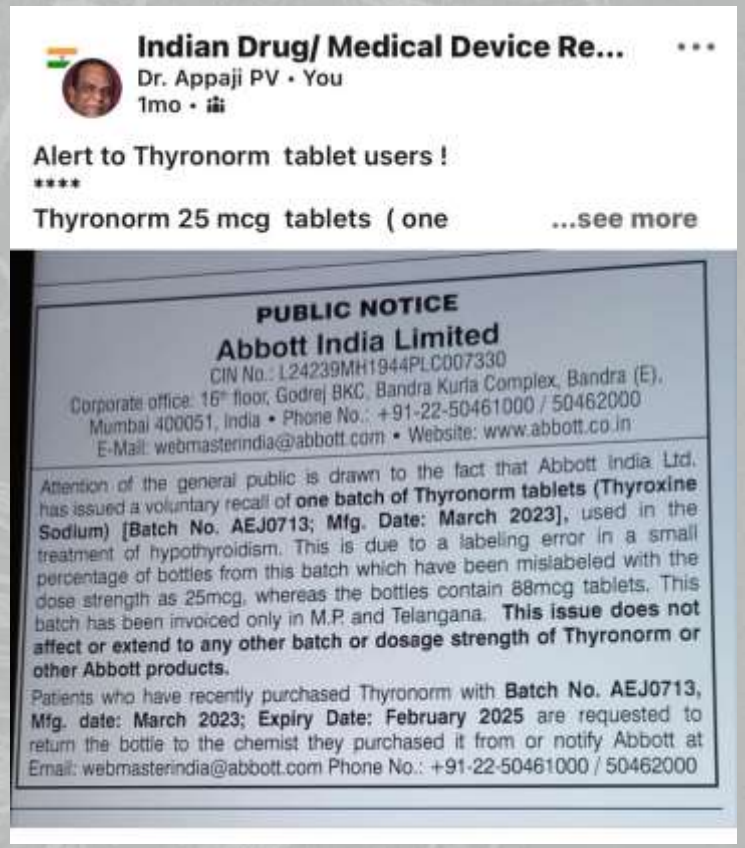
Al Arabiya English
https://english.alarabiya.net › world

Cough syrup deaths: Indonesia finds local trader guilty of forging ingredient ...

30-Jan-2023 — Indonesian police said on Monday a local trader of industrial-grade chemicals sold them as pharmaceutical-grade, leading to heir use in ...

Toxic contaminants present in cough syrups made by in Indonesian industry have reportedly caused Children's deaths.

10. Quality issues – Product recalls



Indian Drug/ Medical Device Re...
Dr. Appaji PV • You
1mo •

Alert to Thyronorm tablet users !
****
Thyronorm 25 mcg tablets (one ...see more

PUBLIC NOTICE

Abbott India Limited

CIN No.: L24239MH1944PLC007330
Corporate office: 16th floor, Godrej BKC, Bandra Kurla Complex, Bandra (E), Mumbai 400051, India • Phone No.: +91-22-50461000 / 50462000
E-Mail: webmasterindia@abbott.com • Website: www.abbott.co.in

Attention of the general public is drawn to the fact that Abbott India Ltd. has issued a voluntary recall of **one batch of Thyronorm tablets (Thyroxine Sodium) [Batch No. AEJ0713; Mfg. Date: March 2023]**, used in the treatment of hypothyroidism. This is due to a labeling error in a small percentage of bottles from this batch which have been mislabeled with the dose strength as 25mcg, whereas the bottles contain 88mcg tablets. This batch has been invoiced only in M.P. and Telangana. **This issue does not affect or extend to any other batch or dosage strength of Thyronorm or other Abbott products.**

Patients who have recently purchased Thyronorm with **Batch No. AEJ0713, Mfg. date: March 2023; Expiry Date: February 2025** are requested to return the bottle to the chemist they purchased it from or notify Abbott at Email: webmasterindia@abbott.com Phone No.: +91-22-50461000 / 50462000

Thyronorm is a widely used drug by several thyroid patients. Due to an error in labelling of strength of the tablets (25mcg as 88 mcg), the manufacturer has made very effective efforts for recall of the product.

11. Quality issues – Common observations by USFDA

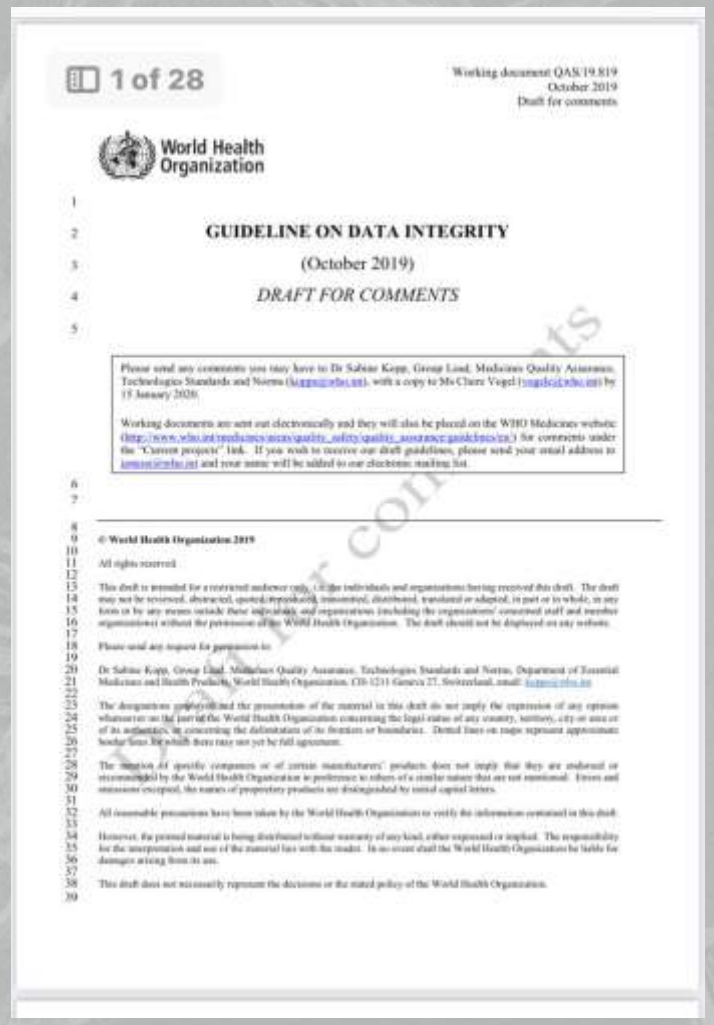
FY 2018 Top FDA Observations

DRUG INSPECTION OBSERVATIONS SUMMARIES

CFR REFERENCE	SHORT DESCRIPTION
21 CFR 211.22(d)	Procedures not in writing, fully followed
21 CFR 211.160(b)	Scientifically sound laboratory controls
21 CFR 211.192	Investigations of discrepancies, failures
21 CFR 211.100(a)	Absence of Written Procedures
21 CFR 211.67(a)	Cleaning / Sanitizing / Maintenance
21 CFR 211.68(b)	Computer control of master formula records
21 CFR 211.67(b)	Written procedures not established/followed
21 CFR 211.110(a)	Control procedures to monitor and validate performance
21 CFR 211.68(a)	Calibration/Inspection/Checking not done
21 CFR 211.165(a)	Testing and release for distribution

- **Procedures not followed**
- **Issues with laboratory controls**
- **Inadequate investigations**
- **Incomplete / absence of written procedures**
- **Cleaning & maintenance related issues**
- **Improper computer control systems**
- **Inadequate validations**
- **Improper calibrations / inspections**

12. Quality issues – Importance of Data Integrity



1 of 28

Working document QAS/19.819
October 2019
Draft for comments

World Health Organization

GUIDELINE ON DATA INTEGRITY

(October 2019)

DRAFT FOR COMMENTS

Please send any comments you may have to Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (kopps@who.int), with a copy to Ms Claire Vogel (vogelc@who.int) by 15 January 2020.

Working documents are sent out electronically and they will also be placed on the WHO Medicines website (http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/) for comments under the "Current projects" link. If you wish to receive our draft guidelines, please send your email address to jamesi@who.int and your name will be added to our electronic mailing list.

Data integrity is a major observation in many of the USFDA audits of Indian companies. USFDA / WHO / ICH etc regularly issue updated guidelines for compliance.

13. Importance of quality – WHO guidelines / audit of national regulatory authorities

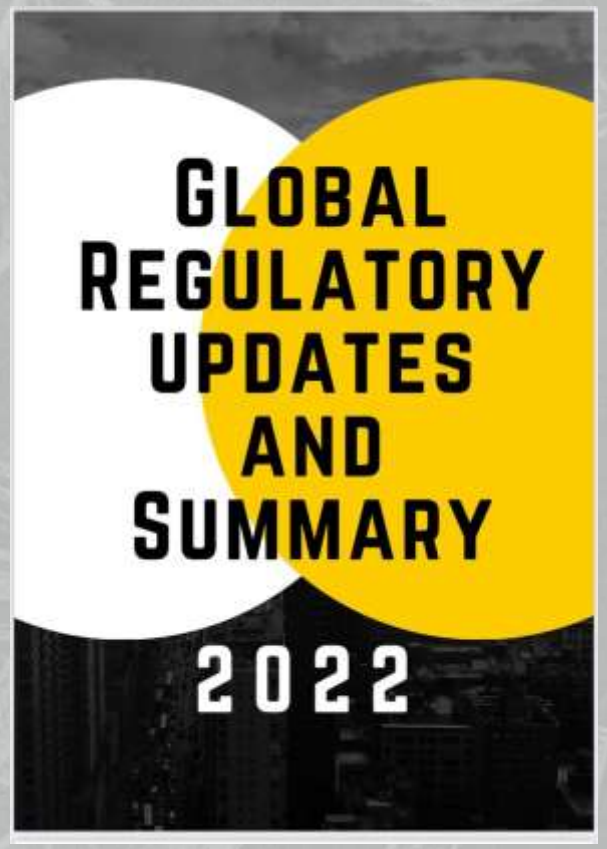
Annex 13

WHO guideline on the implementation of quality management systems for national regulatory authorities

Abbreviations

WHO in its periodical audits of national regulators, verifies the quality management systems being adopted by various national regulatory authorities and gives them grading. Our regulator received good grading in vaccine regulations etc.

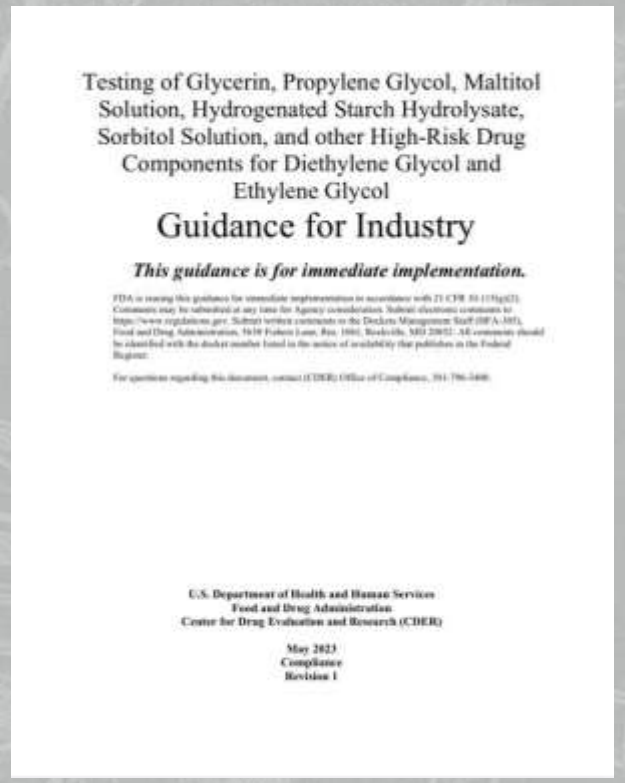
14. Ensuring quality products – Ongoing actions by country regulators



In order to ensure quality (safety and efficacy) of drugs in the market, national regulators are vigilantly taking appropriate and times actions. Some such decisions taken in 2022 include :

- **Titanium dioxide no longer considered as safe**
- **Guidelines for medical devices cybersecurity**
- **Guidelines by WHO for evaluation of biosimilars**
- **Guidelines on excipients in the labelling and package leaflet**

15. Quality issues due to toxic contaminants – USFDA issues guidance for industry.



Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol

Guidance for Industry

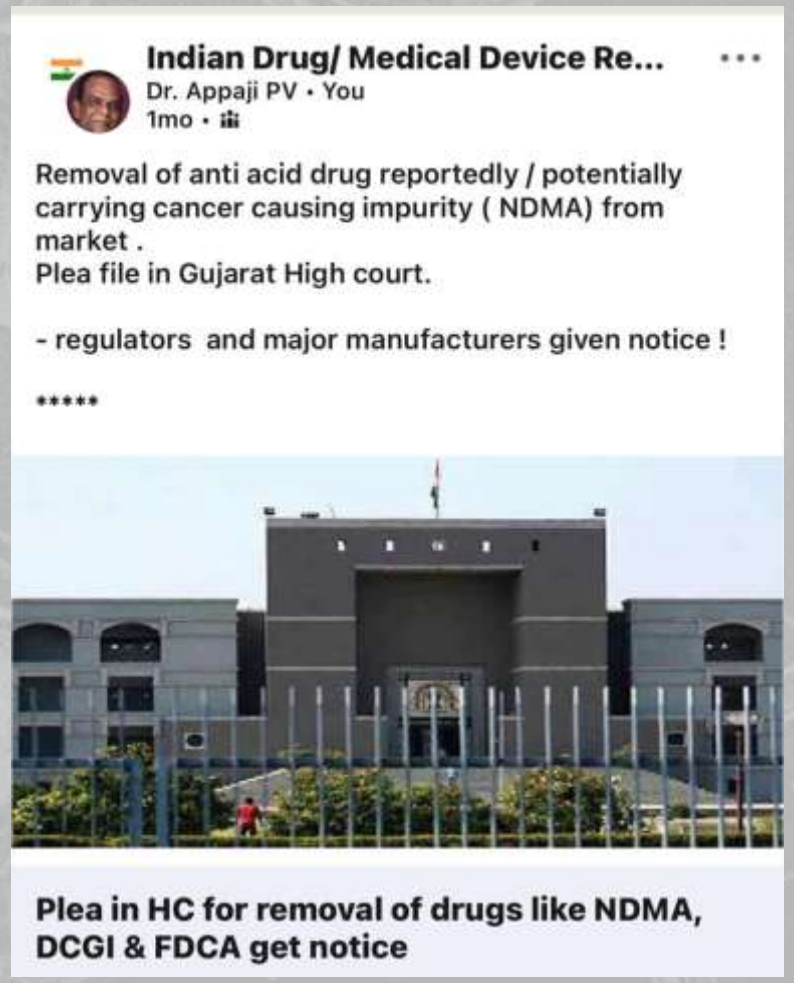
This guidance is for immediate implementation.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

May 2023
Compliance
Revision 1

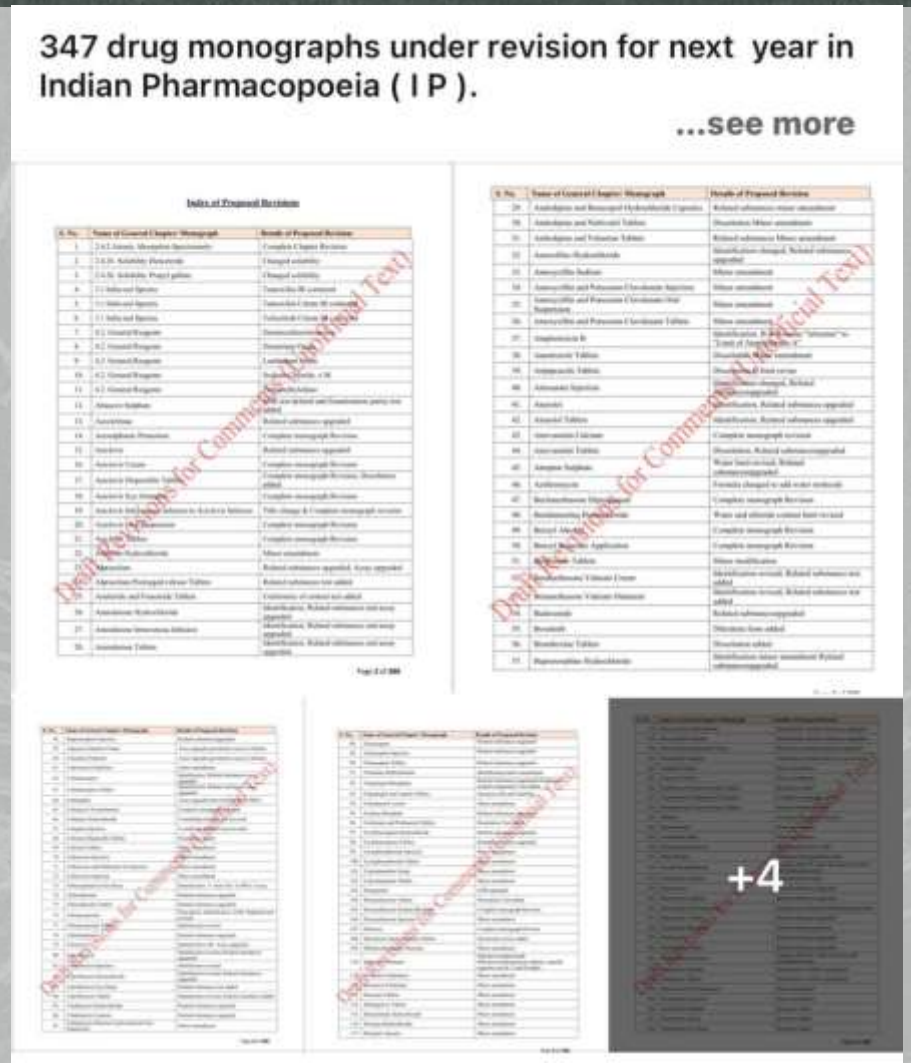
National Regulators are vigilant to quality issues. USFDA issued guidance paper for detection of toxic contaminants like DEG & EG in some commonly used solvents.

16. Quality through effective control of impurities in drug products



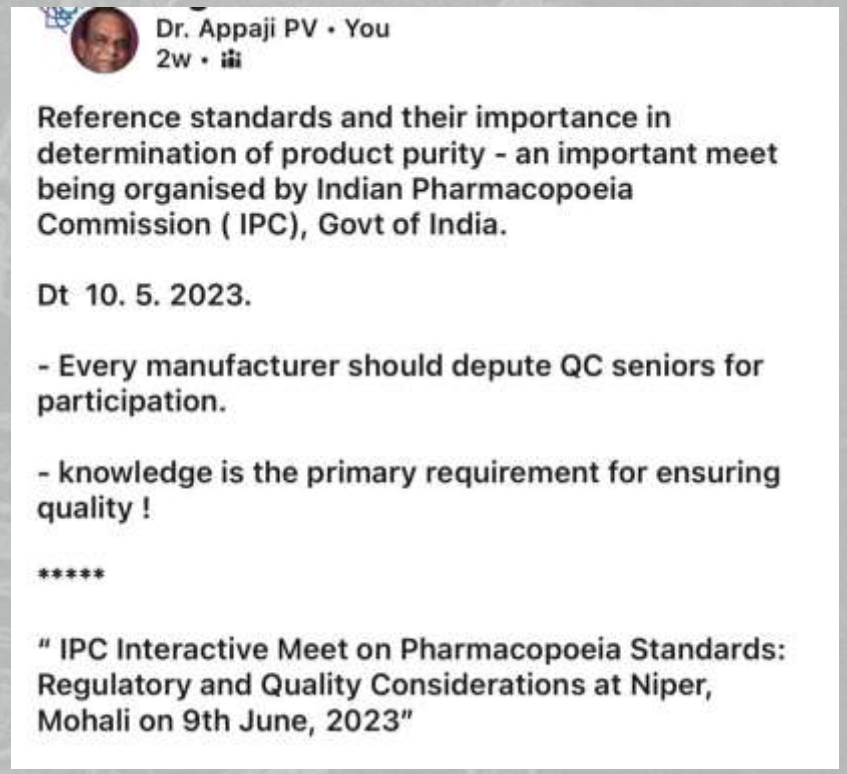
NDMA, a potentially cancer causing impurity, is recently found in Drugs like Ranitidine etc. All Regulatory agencies thoroughly studied about this new impurity molecule and published general paragraphs for detection & estimation to ensure presence of NDMA within limits. Some NGO's have recently filed petitions for banning drugs reportedly containing NDMA impurity.

17. Ensuring quality through good Quality Control procedures – initiatives of Indian Pharmacopoeia commission (IPC)



Indian Pharmacopoeia commission has been actively updating Drug monographs. It has recently announced review of 347 Drug monographs.

18. Ensuring quality through good Quality Control procedures – initiatives of Indian Pharmacopoeia commission (IPC)



Dr. Appaji PV • You
2w •

Reference standards and their importance in determination of product purity - an important meet being organised by Indian Pharmacopoeia Commission (IPC), Govt of India.

Dt 10. 5. 2023.

- Every manufacturer should depute QC seniors for participation.

- knowledge is the primary requirement for ensuring quality !

*****

" IPC Interactive Meet on Pharmacopoeia Standards: Regulatory and Quality Considerations at Niper, Mohali on 9th June, 2023"

IPC has proposed and interactive meet with industry on Pharmacopoeia standards: Regulatory & Quality considerations at NIPER Mohali on 9th June 2023

19. Quality issues – Risk based inspections initiated by Central and State Drug Regulators

With increasing reports of Quality failures of Indian made medicines in domestic and overseas markets, Govt has initiated a scheme of preparing a list of risk based companies, conducting regular inspections throughout the country and has been stopping / suspending / cancelling manufacturing activities.

20. Quality issues – Recent actions by drug regulators for non-compliances

The Tribune

Home Trending New Cricket Videos Nation World Sport

Solan, May 25

The Drugs Control Administration (DCA) has ordered 11 pharmaceutical firms located in the industrial hub of Baddi-Barotiwala-Nalagarh, and Sirmaur and Kangra districts to stop manufacturing after critical observations were detected in its functioning during risk-based inspections done recently. Navneet Marwaha, State Drugs Controller, said, "As many as 29 firms were inspected in the second phase of the inspections undertaken jointly by the state DCA and the Central Drugs Standard Control Organisation in the last two months."

"While 11 have been told to shut manufacturing operations owing to critical flaws pertaining to Schedule M of the Good Manufacturing Practices (GMP) of the Drugs and Cosmetics Act, 1940, show-
ise notices have been issued to the

- **29 Firms inspected - jointly**
- **Closure of 11 pharmaceutical firms**

21. Quality issues – Govt holds a brainstorming session of drug regulators for better compliance

Business Standard

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Home / Current Affairs / News / National / Go...

Govt to organise 'Chintan Shivir' with focus on drug quality regulation

The Chintan Shivir will be held for two days from February 26- 27, 2023 at Shanti Vanam in Hyderabad

ANI General News

A brainstorming session was held under the chairmanship of honourable Minister, Sri Mansukh Mandaviya with senior officers Of State and Central Drug Control Organizations & several Decisions were made for improving Quality Systems through effective regulatory mechanisms.

22. Quality issues – Govt's mandate to test all exported cough syrups

Indian Regulatory Affairs Profe...
Dr. Appaji PV • You
1w •

Exporters of Cough syrups to get them tested in central Govt drug testing labs and NABL accredited state Govt labs. CoA copies to be ...see more

(To be published in the Gazette of India Extraordinary Part-II, Section - 3,Sub-Section (ii))

Government of India
Ministry of Commerce & Industry
Department of Commerce
Directorate General of Foreign Trade
Vanijya Bhawan, New Delhi

Notification No. 04 /2023
New Delhi, Dated: 23rd May, 2023

Subject: Amendment in Export Policy of Cough Syrup.

S.O. (E) In exercise of powers conferred bySection 3 read with Section 5 of the Foreign Trade (Development &Regulation) Act, 1992 (No. 22 of 1992), as amended, read with Para1.02 and 2.01 of the Foreign Trade Policy, 2023, the Central Government hereby makesfollowing amendment in Chapter 30 of the Schedule 2 of the ITC (HS) Export Policy related to export of Cough Syrup w.e.f. 1st June, 2023:

Sl. NO.	ITC HSCodes	Description	Existing Export Policy	Revised Export Policy
84 A	3004	Cough Syrup	Free	Cough Syrup shall be permitted to be exported subject to the export sample being tested and production of Certificate of Analysis (CoA) issued by any of the following laboratories: Indian Pharmacopoeia Commission, Ghaziabad, Uttar Pradesh • CDL, Kolkata, West Bengal • CDTL, Chennai, Tamil Nadu • CDTL, Mumbai, Maharashtra • CDTL, Hyderabad, Telangana • RDTL, Chandigarh • RDTL, Guwahati, Assam • Any NABL accredited State Drugs Testing Laboratory

2. Effect of this Notification:

The export of "Cough Syrup" under ITC (HS) Codes falling under the Heading 3004 shall be permitted subject to the export sample being tested and production of Certificate of Analysis (CoA) issued by any of the laboratories as mentioned in Para-1 above, with effect from 1st June 2023.

(Santosh Kumar Sarangi)

Govt has issued a notification on 22nd May 2023 for testing all syrups for exports for toxic contaminants .

23. Regulatory compliances – Procedure for testing Cough syrups for exports.

Cough syrups for exports : DCGI notifies procedure and documents to be submitted by manufacturers / exporters - Also provide format for CoA / analysis report to be given by Govt Lab.

DEG / EG content : not more than 0.1%.

Dt 25.05.2023.

*****

Documents / samples to be submitted:

- Covering letter from the manufacturer/exporter on letter head addressed to concerned laboratory.

- Manufacturing license of the product for export purpose.

- Export order

- Representative sample from the export consignment.

- Thrice the quantityrequired for performing complete analysis of the sample.

- Qualitative composition of product including excipients.

- Certificate of analysis by the manufacturer of the particular batch and method of analysis (STP).

- Reference/working standard (with traceability certificate) and Placebo as applicable.

DCGI has circulated procedure to be followed for submission of samples of Cough syrups, intended For export markets.

24. Quality issues – Govt's initiative to strengthen regulatory systems

In order to ensure uniform and effective regulatory mechanism for the whole country, Government is proposing to make central regulator as authority for issue of manufacturing licenses. The bill needs to be approved in the Parliament.

25. Quality issues; The menace of fake drugs – Govt's proposal for mandatory barcodes on top selling medicines

ThePrint

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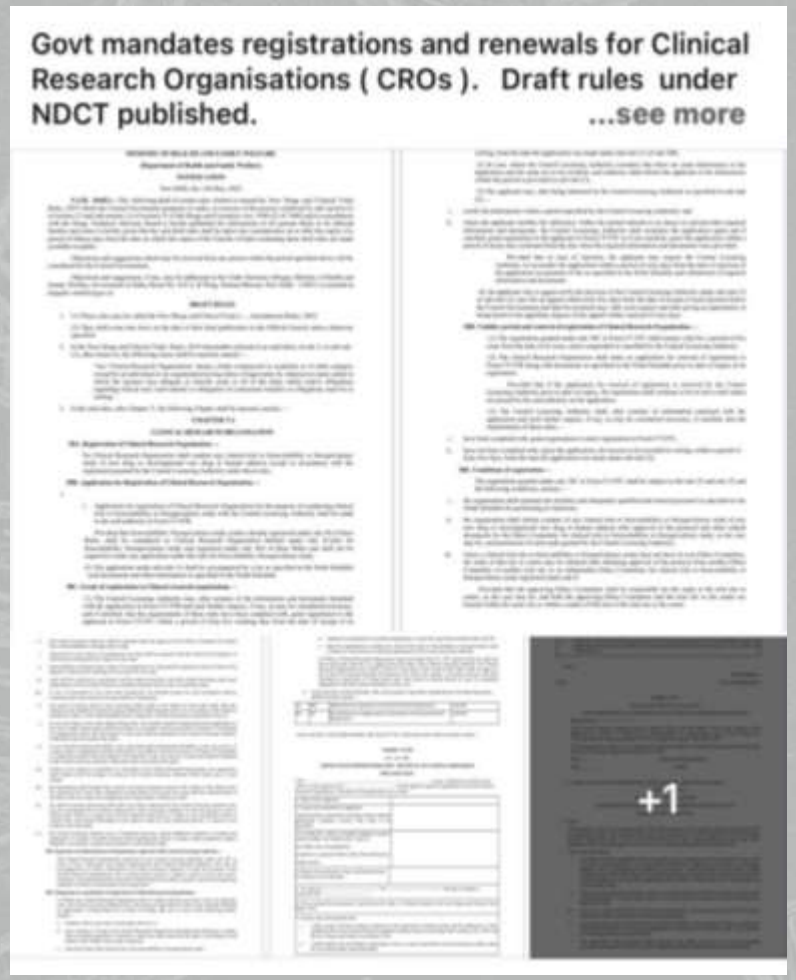
India

Soon 300 drug formulations to have mandatory bar codes on packages

New Delhi, Nov 5 (PTI) To curb the menace of spurious medicines, the government is finalising the process of mandating pharmaceutical companies to print bar code on the packages of 300 drug formulations so that information such as manufacturing licence and batch number can be accessed upon scanning. The amendments to Drugs and Cosmetic Rules, [...]

Keeping in view the large number of regular reports on presence of fake drugs in the market and the difficulties for total vigilance of all drugs in the market, Govt has mandated for barcoding for 300 top selling brand named products where authenticity of the product can be verified by scanning the barcode. Implementation date extended to 1st August 2023.

26. Importance of BA/BE data – Govt proposes registration of Clinical Research Organizations (CRO)



Clinical data plays an important role in establishing efficacy of a drug product. Keeping in view several complaints from overseas regulators, Govt has initiated regulatory controls on CROs

27. Quality issues in exported formulations – Govt's initiative for track and trace barcoding

Track & trace bar coding for exported formulations : implementation date extended upto 1st August 2023.

***

- Govt had introduced this proposal long time before (about Year 2012) .

- it was mainly proposed to make India's image in overseas countries as a trusted supplier of quality generics.

- I was DG , Pharmexcil during that time and explained the benefits and problems of this scheme to Govt and industry.

- Due to strong opposition from MSME sector on account of huge costs involved in barcoding and parent child relation linkage (serialisation) , the part relating to parent child maintenance is getting postponed continuously for last several years.

- as the problem is still not resolved, Govt has again extended the implementation date to 1st Agust 2023.

There were instances of fake drugs and quality faliures in exported formulations in the past also. Govt , through PHARMEXCIL had initiated implementation of Track & Trace barcoding in the year 2011 itself. However due to genuine issues raised by MSME companies, it is implemented partially at present. Implementation of serialization is extended up to 1st Aug 2023.

28. Quality of medicines – Importance of APIs

QR Codes on active pharmaceutical ingredients mandatory vide Drugs (Amendment) Rules, 2022

On January 18, 2022, the Ministry of Health and Family Welfare has notified the Drugs (Amendment) Rules, 2022 to further amend the

Bhumika Indulia

1 year ago

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On January 18, 2022, the Ministry of Health and Family Welfare has notified the Drugs (Amendment) Rules, 2022 to further amend the Drugs Rules, 1945. The amendment makes QR codes mandatory on every active pharmaceutical ingredients. The Amendment Rules will come into

APIs play a significant role in the quality of manufactured medicines. Keeping in view several reports of movement of fake APIs in the market, Govt has initiated QR code requirement on the labels of APIs marketed by manufacturers. It has come into force since 1st January 2023

29. Making country self-sufficient with important drugs – Govt's initiative under PLI schemes.

The goverment launched the PLI scheme for pharmaceuticals in 2021 with a financial outlay of ₹15,000 crore over a period of six years. So far, 55 applicants have been selected under the scheme, including 20 Micro, Small & Medium Enterprises (MSMEs). 22-Feb-2023

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Sales incentives worth ₹165.74 crore released to four pharma companies ...

While India is self-dependent for over 90% of domestic requirements of medicines, the situation is not the same the case of API's which are crucial inputs for medicines. Govt has encouraged Production of such API's and other drugs through PLI (Production Linked Incentive) schemes. Govt recently disbursed 165.74 crores rupees to four companies.

30. DCGI notifications & circulars - compilation

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Good amount of data is available on DCGI website & nicely compiled regularly by Mr Rakesh Dahiya, Drug Licensing Authority of Haryana.

31. THANKS FOR YOUR ATTENTION .

LET US ALL UPDATE REGULARLY ABOUT QUALITY RELATED REGULATIONS AND IMPLEMENT THEM SINCERELY IN OUR UNITS – Quality is the first requirement in making of medicines.