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Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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EDITORIAL

Dear Readers,

We are wishing all our reader a very happy Tamil New Year. We are happy to publish the 25th issue of Pharma Web Newsletter for Jan Mar 2015. We regret to inform all the readers the delaying publishing our News letter in time bound manner due to certain legal problem as regard to our Trust premises. We hope to solve the problem at the earliest.

In this issue we are publishing the following articles

a. ***Opportunities & Challenges of Pharma Exports to Rest of the World (Row) Markets*, by Mr. S. V. Veerramani, Chairman & Managing Director, M/s. Fourrts (India), Lab Pvt Ltd, President, IDMA, Mumbai, Chairman, TNPSWT.**

b. ***Position of Indian Manufacturers in WHO Prequalification of Medicines Programme* by WHO Prequalification Team**

c. ***Recent GMP Developments & Trends and Date Integrity & Verification* by Mr. David Churchward, Expert Inspector, MHRA UK**

d. ***Pharmaceutical Patenting In India* by Dr. S. P. Subramaniyan, Asst Controller of Patents & Designs, IPR, Chennai**

e. ***Patenting for Pharmaceuticals* Case study by Dr. K. Gowthamarajan, Prof & Head, Dept of Pharmaceutics, JSS College of Pharmacy, Mysore**

We are also publishing an amendment issued by Government of India, Ministry of Law & Justice to The Drugs & Cosmetics Act (Amendment) Act, 2008.

We are happy to publish the important and relevant Parliament Questions & Answers pertaining to Drugs & Cosmetics items, during the year 2014 2015 for the benefit the readers

Important events as well as news items on various technical issues are highlighted in this issue.

With Best Regards,
R. NARYANASWAMY
Chief Editor

With best compliment from

Tablets (India) Limited

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ARTICLES

OPPORTUNITIES & CHALLENGES OF PHARMA EXPORTS TO REST OF THE WORLD (ROW) MARKETS

By

S. V. Veerramani,

Chairman & Managing Director, Fourrts (India) Laboratories Pvt. Ltd
President, IDMA

(Lecture Delivered on 24th January 2015, during 66th IPC, Hyderabad)

GLOBAL MARKET

- Total global Pharmaceutical market value to reach USD 1.1 trillion* by 2015 and US$ 1.60 trillion** by 2020
- ROW market value is around US$340 billion (opportunity exists for formulations from Analgesics to Bio-similar)

*As per IMS data
** As per Business Monitor International

KEY REST OF WORLD (ROW) MARKETS

The RoW market consists of more than 35 different markets entailing South East Asia, Asia Pacific, Africa and the Middle East.

- AAMLA (Asia Pacific, Africa, Middle East & Latin America
- CIS (Common Wealth of Independent States)

KEY REST OF WORLD (ROW) MARKETS

ROW MARKETS

Key Opportunities

- Continuously growing market – double digit growth compared to single digit growth in developed markets.
- Comparatively less stringent registration formalities
- Entry Barriers are less
- Scope for selling wide range of products

ROW MARKETS

Key Opportunities

- ROW markets are not always on the main radar of MNCs or bigger players due to market fragmentation and comparatively low values
- To cash upon in-experience of multinational companies to play in the 'generic market segment'
- SMEs can step into this market quickly
- JV with African / European companies for expansion of business is possible

COMPARISON OF SPENDING FOR 10 SPECIFIC DISEASES IN DEVELOPED Vs EMERGING MARKETS BY 2017

Developed Market	Sales in 2017 in USD	Emerging Markets	Sales in 2017 in USD
1. Oncology	74 – 84 Billion	1. Pain	22 – 25 Billion
2. Diabetes	34 – 39 Billion	2. Other CNS Drugs	20 – 23 Billion
3. Pain	31 – 36 Billion	3. Antibiotics	18 – 21 Billion
4. Asthma/COPD	31 – 36 Billion	4. Oncology	17 – 20 Billion
5. Hypertension	23 – 26 Billion	5. Hypertension	14 – 17 Billion
6. Derma	22 – 25 Billion	6. Diabetes	10 – 12 Billion
7. Antibiotics	18 – 21 Billion	7. Derma	10 – 12 Billion
8. Antipsychotics	13 – 16 Billion	8. Antiulcerants	9 – 11 Billion
9. Antiulcerants	12 – 14 Billion	9. Asthma/COPD	3 – 5 Billion
10. Antidepressants	10 – 12 Billion	10. Allergy	3 – 5 Billion

ROW MARKET CHALLENGES

- Non uniform healthcare systems
- Fragmented markets
- Cultural and language barriers of each market
- Competition from local manufacturers and global players
- Varied infrastructure facilities in each market
- Market, socio-economic and political dynamic situations (regulatory and other changes occur frequently)
- Necessity to offer 'mixed basket of products viz., latest medicines of generics

ROW MARKETS

Key Challenges

- Lack of harmonization in regulatory requirements
- Absent, New or changing regulations
- Differences in labeling requirements
- Increasing Requirements of local clinical trials / B.E study and related expense in certain markets

LET US TAKE BRIEF VIEW

OF

ROW MARKETS, GEOGRAPHICAL LOCATION WISE

WITH RESPECT TO OPPORTUNITIES,

CHALLENGES & SOLUTIONS

MAJOR AFRICAN MARKETS

AFRICA will be a significant economic force in future and Pharma companies have much to gain

Western Africa
- Nigeria
- Ghana
- Guinea
- Benin

Southern Africa
- South Africa
- Zambia
- Angola
- Mozambique
- Namibia

Eastern Africa
- Kenya
- Tanzania
- Uganda
- Ethiopia
- Mauritius

Northern Africa
- Sudan
- Egypt
- Algeria
- Morocco

Central Africa
- Chad
- Gabon
- Cameroon
- Congo Rep
- Equtl Guinea

INDIA's Top 10 Destination countries of Africa

Value in $ mn

Rank	Country	2013-14	Gr%	Contribution To Total exports
1	South Africa	501.28	13.77	3.33
2	Nigeria	381.97	11.99	2.54
3	Kenya	250.34	-0.54	1.66
4	Ghana	167.23	-9.84	1.11
5	Tanzania Rep	162.43	22.51	1.08
6	Uganda	158.52	27.59	1.05
7	Ethiopia	142.36	63.16	0.95
8	Egypt A Rp	98.04	6.58	0.65
9	Malawi	90.25	41.86	0.60
10	Mozambique	72.43	27.05	0.48
Total Africa		2867	11.87	19.06

Source: Pharmexcil

MAJOR THERAPEUTIC SEGMENTS IN AFRICA

- Anti Malarial
- Anti Tubercular
- Anti HIV
- Anti Microbial
- Haematanics
- Gastro-Intestinal
- Cardio-Vascular
- Anti Diabetes
- Dermatology
- Anti Fungal

OPPORTUNITIES

- Appeal of Africa lies not in its size but in the dynamics that drive sustainable growth
- By 2016, Pharma spending in Africa is expected to reach US$30 billion
- In Algeria, the chronic medicine to essential medicine ratio is increased by 72%. A similar trend is likely to emerge in other countries, such as Kenya and Botswana, where Non Communicable Diseases have been declared a national priority
- African markets are still poorly understood: information on medicine consumption is not systematically collected, resulting in fragmented and patchy data.
- Fastest growing are Nigeria (CAGR 2011-16 = 13%), Kenya (CAGR 2011-16 = 17%) and Botswana (CAGR 2011-16 = 12%)

CHALLENGES

Marketing and Commercial

- Payments
- Pricing
- Inadequate market coverage due to local influencing factors
- "Made in India" labels from China

Regulatory Aspects

- Lack of available dossier standards.
- Regulations for registering a drug vary significantly. Rwanda can take only 2 weeks to register a product. Kenya and Nigeria can take 6 to 12 months. Tanzania and Ghana take more than 1 year.

LATIN AMERICAN MARKETS

OPPORTUNITIES

- The Latin American pharmaceutical market is now worth USD 45 billion. This region represents a growing consumer base for the drug industry as by 2020 population may be as high as 687 million.
- Argentina +36.1% and Venezuela +23.6% experience fast increase in medicine sales
- Mexico by +9.3%, Brazil +8.8%, Colombia +7.4%, Peru +7.2% and Chile +7.2%
- Seven major Latin American markets are - Brazil, Mexico, Venezuela, Argentina, Colombia, Chile and Peru
- A number of countries are working to introduce universal healthcare coverage which in turn could create excellent long term opportunities

INDIA's Top 10 Destination countries of LAC

Value in USD mn

Rank	Country	2013-14	Gr%	Contribution To Total exports
1	Brazil	315.55	-3.82	2.10
2	Mexico	119.96	-13.10	0.80
3	Venezuela	85.24	20.43	0.57
4	Colombia	82.80	10.08	0.55
5	Chile	45.00	-4.01	0.30
6	Peru	44.74	19.95	0.30
7	Argentina	44.48	-1.00	0.30
8	Dominic Rep	26.40	8.51	0.18
9	Guatemala	24.10	9.30	0.16
10	Ecuador	17.23	22.90	0.11
Total LAC		917.6	-0.43	6.10

Source: Pharmexcil

LATIN AMERICAN MARKETS

CHALLENGES

- Intellectual Property: Laws on intellectual property are not enforced in a number of countries, leading to legally ambiguous products on the market.
- Regional governments are making serious attempts to encourage the use of generics and Indian companies in particular have made headway into the major markets.
- Political Situation: Political shift to the LEFT in some countries.

LATIN AMERICAN MARKETS

REGULATORY ASPECTS

- The regulatory regime in LATAM countries can be divided into three categories
- A - Countries with established regulations like Brazil, Mexico, and Venezuela to demonstrate efficacy, safety through clinical trials or BE studies with the innovator's product in the drug approval process.
- B - Countries such as Argentina, Chile, Columbia, Ecuador, and Paraguay also have the regulations for registration of new or generic drug but are less stringent.
- C - The last category of countries Guatemala, Barbados, Bolivia, Nicaragua and Peru have less stringent drug regulations for the approval of drugs.

LATIN AMERICAN MARKETS

INFERENCE

- Epidemiological and demographic shifts will increase overall demand for pharmaceuticals
- Increased government investment in healthcare and expenditure on pharmaceuticals through 2019
- Increased insurance coverage
- Likely shift to reference pricing

ASIAN MARKETS

OPPORTUNITIES

- Pharma market in Asia is exceptionally heterogeneous and expected to reach USD 97 billion in 2016. China's contribution is 75%
- The Pharmaceutical industry is in a state of transition and the generic drug market is slowly gaining more attention
- Outsourcing of manufacturing is the current trend

ASIAN MARKETS

OPPORTUNITIES

Major markets in Asia includes

- Bangladesh
- China
- Hong Kong
- Indonesia
- India
- South Korea
- Malaysia
- Myanmar
- Philippines
- Pakistan
- Singapore
- Sri Lanka
- Thailand
- Taiwan
- Vietnam

** JAPAN not considered as it is grouped under DEVELOPED market

IDMA's Top 10 Destination countries of Asean

Value in USD mn

Rank	Country	2013-14	Gr%	Contribution To Total exports
1	Vietnam Soc Rep	216.51	6.57	1.44
2	Philippines	140.84	11.38	0.94
3	Myanmar	138.44	12.91	0.92
4	Singapore	119.61	-35.96	0.80
5	Thailand	119.61	-16.13	0.80
6	Malaysia	75.13	9.46	0.50
7	Indonesia	66.65	4.01	0.44
8	Cambodia	35.65	31.94	0.24
9	Lao Pd Rp	1.86	44.19	0.01
10	East Timor	0.58	-25.64	0.00
Total Asean		915	-3.02	6.08

Source: Pharmexcil

ASIAN MARKETS

CHALLENGES

- Malaysia, Singapore expect supplies from PICs country approved facility
- Vietnam market slowly tilting towards PICs approved facility and also need to support dossier with in-use stability data
- For registration in Vietnam Packing Material supplier to be GMP certified
- Thailand require BE studies to be carried out locally

ASIAN MARKETS

Regulatory Aspects

- Regulatory requirements ranges from Minimal documentation with supportive BE data for specific product category to CTD level documentation
- Philippines require supplier COA for API and excipients and also Chromatograms from formulation manufacturer

CIS MARKETS

OPPORTUNITIES

- CIS market in 2013 was USD 30 to 35 billion; Russia was USD 19 to 21 billion
- Pharma market in CIS region is dominated by branded generics
- Expected growth rate of the pharmaceutical markets: 14 - 17% through 2014

CIS MARKETS

OPPORTUNITIES

The CIS region was part of erstwhile USSR (United Soviet Socialist Republic) now become several independent countries:

- Armenia
- Azerbaijan
- Belarus
- Kazakhstan
- Kyrgyzstan
- Moldova
- Russia
- Tajikistan
- Turkmenistan
- Ukraine
- Uzbekistan
- Georgia

INDIA's Top 10 Destination countries of CIS

Value in $ mn

Rank	Country	2013-14	Gr%	Contribution To Total exports
1	Russia	545.69	-4.70	3.63
2	Ukraine	111.44	-28.33	0.74
3	Kazakhstan	58.87	4.75	0.39
4	Uzbekistan	47.57	17.98	0.32
5	Turkmenistan	20.61	52.89	0.14
6	Tajikistan	19.08	49.53	0.13
7	Belarus	15.83	13.80	0.11
8	Georgia	8.52	18.83	0.06
9	Kyrghyzstan	6.55	2.18	0.04
10	Moldova	5.81	15.97	0.04
	Total CIS	845	-5.62	5.62

Source: Pharmexcil

CIS MARKETS

CHALLENGES - Regulatory Aspect

- CIS region with common historical roots, has many similarities in regulatory practice
- Yet, it would be a mistake to approach every member country the same way
- For a new medicine to be registered in Russia it has to go through local clinical trials, even if the international ones are available. Every country has its own regulation
- Registration procedures for national producers is complicated and time consuming
- Cost of registration is very high and not consistent. Official and other expenses are almost equal
- Tedious and time consuming as certain parts of the dossier needs to be translated into local language
- PICs approved facility mandatory for Ukraine market

CIS MARKETS

CHALLENGES – Marketing / Commercial

- Reliable and dependent importing/distribution and marketing partner/s
- Language is a MAJOR communication barrier
- Packing Material to be exactly to approved version in text and color else the goods will not be approved for sale
- Timely receipt of payments
- Increasing trend to encourage local manufacturing

ROW MARKETS

Key Strategy

- Test waters in one specific geographical location/selected country. Africa can be the first choice.
- While stabilizing in chosen market plan for next destination country
- Select few single molecule/s for registration with complete data as per guidelines
- Take this experience as Stepping stone which will help in developing other markets
- Local market knowledge is advantageous
- Existing Exporters can try and source few formulations locally in markets with such requirement for ease of registration

EXPORT ASSISTANCE SCHEMES

- **Focus Market Scheme**
  For 77 countries
- **New Focus Market Scheme**
  For 36 countries
  (for the above 2 schemes, claims to be filed through JDGFT)
  Entitlement is 3% of FOB value of Exports made
- **Special Focus Market Scheme**
  For 50 countries
  (claims to be filed through JDGFT)
  Entitlement is 4% of FOB value
- **Incremental Exports Incentive For Year-Over-Year Performance** (claims to be filed through JDGFT)
  Entitlement is 2% of FOB value of increment

EXPORT ASSISTANCE SCHEMES

- **Duty Drawback Scheme** (claims will be received through Customs)
  Duty Drawback is given on the basis of either
  (a) All Industry Rate or (b) Brand Rate
- **Market Access Initiative** (MAI) Scheme – For Registration Reimbursement (claims to be filed through Pharmexcil)
  Maximum claim value up to Rs.1.00 Crore per Financial Year. Out of this, 50% will be the reimbursement.
- **Market Development Assistance** (MDA) Scheme (claims to be filed through Pharmexcil)
  To assist Exporters for export promotion activities abroad, including Travel. Exporters up to an Export Turnover of Rs.30.00 Crores will be eligible under this scheme.

POSITION OF INDIAN MANUFACTURERS IN WHO PREQUALIFICATION OF MEDICINES PROGRAMME

By
WHO Prequalification Team

Regional Workshops for Indian Pharmaceutical Manufacturers

Update on Good Manufacturing Practices (GMP)

focused on Production of Active Pharmaceutical Ingredients and Oral Solid Dosage Forms

Organized on collaboration of WHO and GOI with expert support of MHRA,

February 2015, Mumbai, Chennai

Position of Indian manufacturers in WHO Prequalification of Medicines Programme

PREQUALIFICATION OF MEDICINES PROGRAMME
A UNITED NATIONS PROGRAMME MANAGED BY WHO
World Health Organization

PQP QUALITY MEDICINES FOR EVERYONE

Categories of medicines invited for WHO prequalification

- **Primary categories of medicines:**
  - **HIV/AIDS**
  - **Malaria**
  - **Tuberculosis**
- **Later added:**
  - Reproductive health
  - Influenza
  - Acute diarrhoea
  - Neglected tropical diseases
- Potentially other categories of products, if there is the need
- **Prequalification also applicable for APIs!**
- **Published in invitations for Expression of Interest (EOI) on Prequalification website**

http://www.who.int/prequal/

PREQUALIFICATION OF MEDICINES PROGRAMME
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Regional GMP Strengthening Workshop for Manufacturers February 2015
2
PQP QUALITY MEDICINES FOR EVERYONE

Two prequalification routes

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3
PQP QUALITY MEDICINES FOR EVERYONE

Standards

- WHO standards as defined in WHO guidelines and International Pharmacopoeia are applied in prequalification process
- If these not exist, ICH guidelines are applied
- In case of need, guidelines of stringent regulatory authorities, which are involved in ICH process

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PQP QUALITY MEDICINES FOR EVERYONE

Frequent misunderstandings

- Manufacturers/manufacturing sites are prequalified
- PQP issues WHO GMP certificates
- PQP provides direct financial support
- Prequalification gives right to succeed in tenders
- PQ status is national authorization (registration) in recipient countries
- All medicines used in treatment of HIV/AIDS and tropical diseases are invited for PQ
- Prequalified medicines may bear WHO logo

NO

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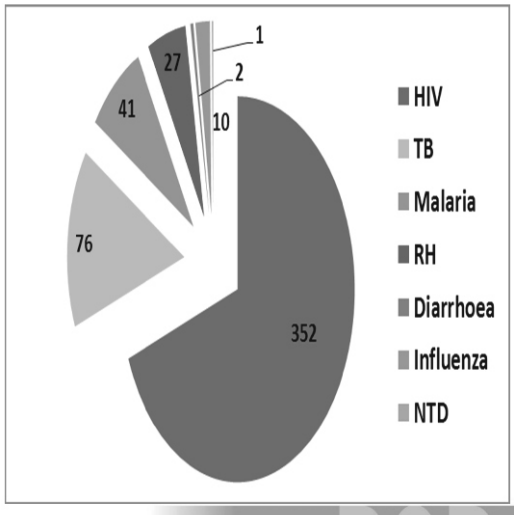
509 Medicines Prequalified and Listed by WHO
February 2015



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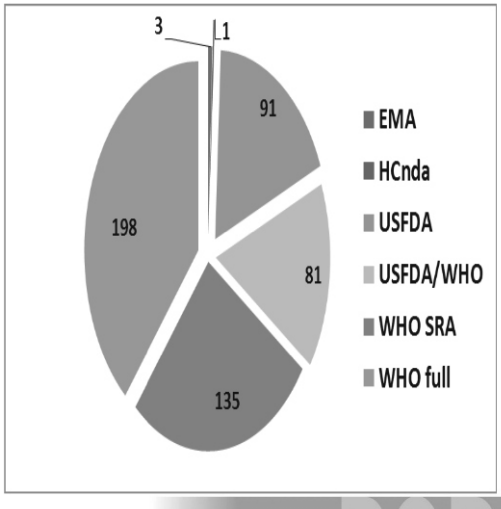
Routes of prequalification/listing



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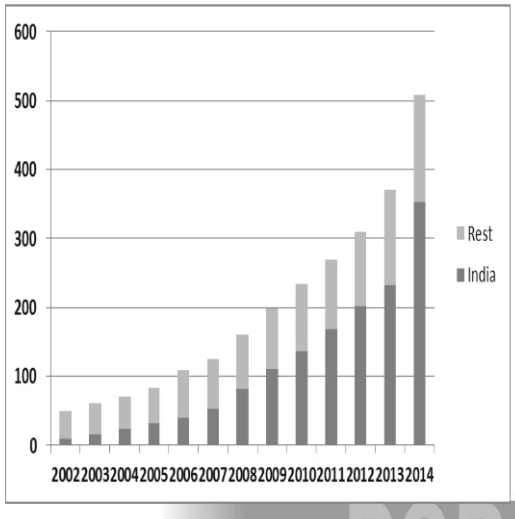
Growing share of medicines produced in India on prequalification list



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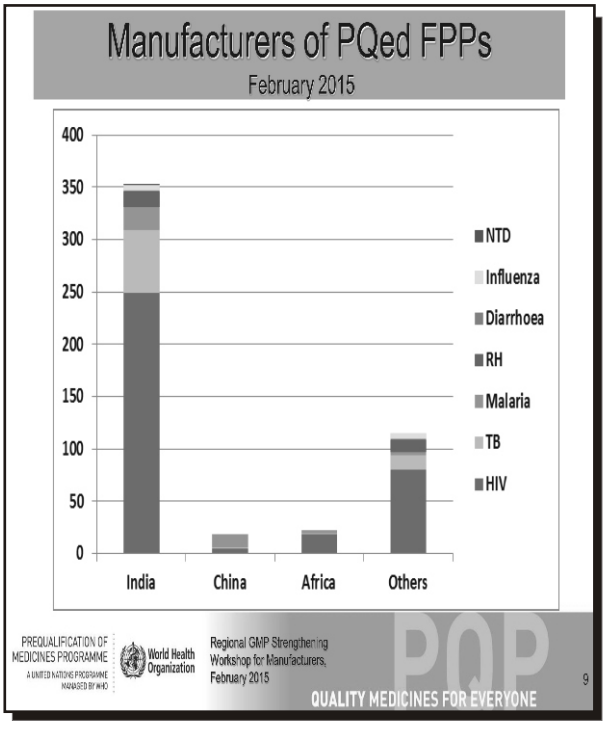
Manufacturers of PQed FPPs
February 2015
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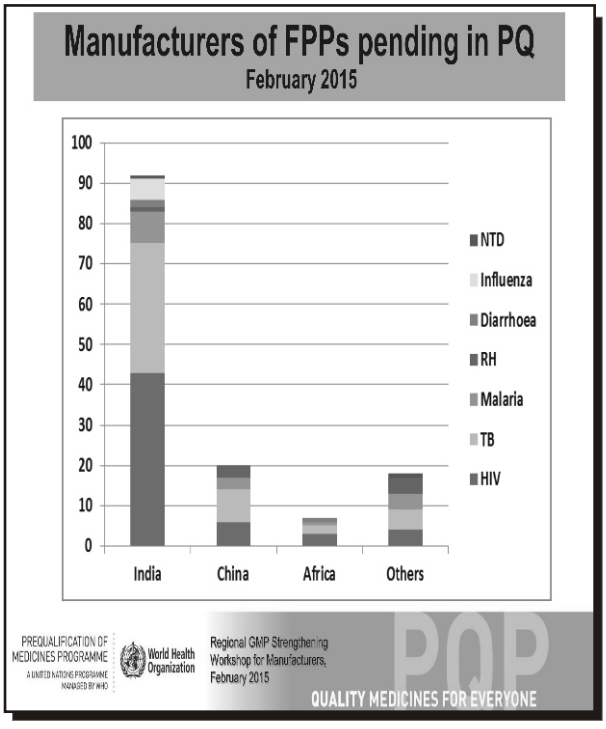
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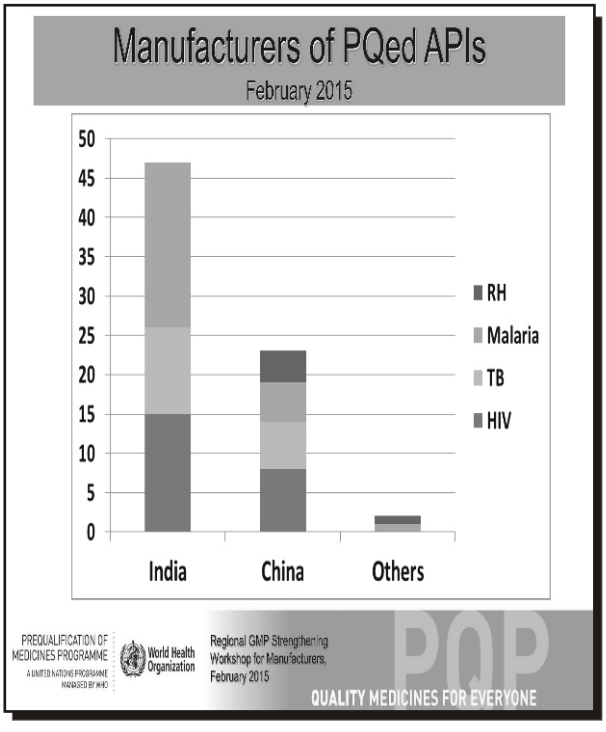
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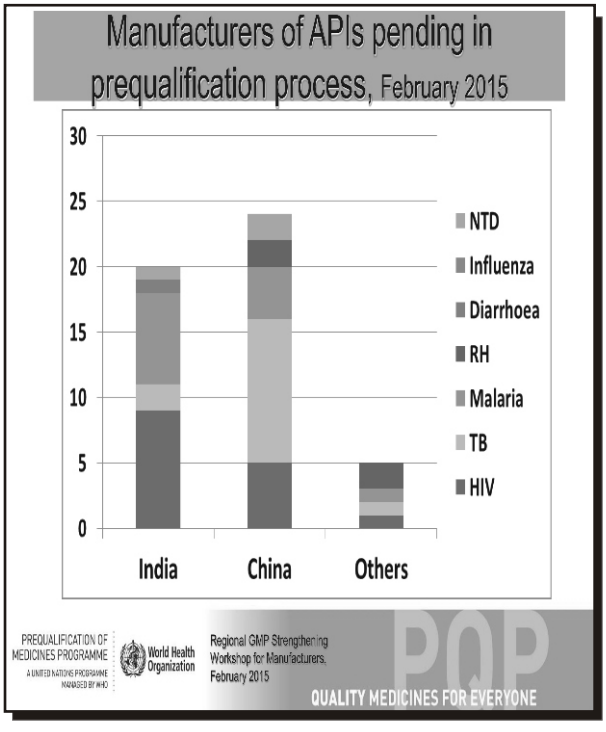
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QUALITY MEDICINES FOR EVERYONE

Strengths of Indian manufacturers from PQP perspective

- Access to APIs
- Technical capability
- Available infrastructure
- Pro-export policy and interest in developing markets
- Representation in and experience from developing countries
- Big internal market contributing to economy of scale
- Favourable cost of workforce
- Capacity to quickly develop and produce new formulations
- Language

Registration in countries by WHO-PQT collaborative registration process

23 participating NMRAs from 22 countries

Africa

- Botswana
- Burkina Faso
- Cameroon
- DR Congo
- Ethiopia
- Ghana
- Ivory coast
- Kenya
- Madagascar
- Malawi
- Mozambique
- Namibia
- Nigeria
- Sierra Leone
- Tanzania
- Uganda
- Zambia
- Zanzibar
- Zimbabwe

Europe/Asia

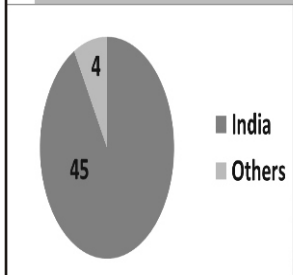
- Armenia
- Georgia
- Kyrgyzstan
- Ukraine

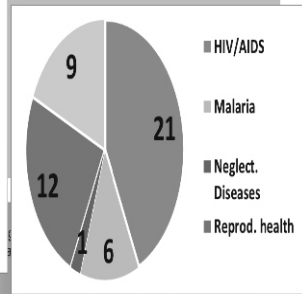
Fig. 1 Map of Africa with highlighted countries participating in the WHO Collaborative Registration Procedure (A, light-blue) and those countries where FPPs according to this CRP has already been authorised (B, dark-blue) (January 2015). The grey-coloured countries due to definition do not belong to the WHO African Region, but to the WHO Eastern Mediterranean Region.

Courtesy of Stefanie Haas

Current experience with the process

- 49 registrations in 11 countries:
- 30 different prequalified products for treatment of HIV/AIDS, TB, malaria and contraceptives
- 10 companies involved, 7 from India
- 60% of registrations granted within 90 days





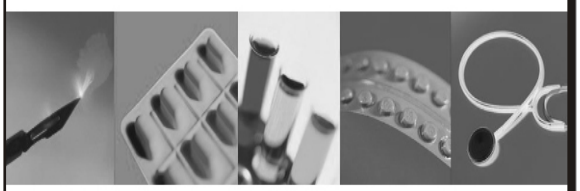
RECENT GMP DEVELOPMENTS AND TRENDS

By
David Churchward
Expert GMP Inspector, MHRA UK

MHRA
Regulating Medicines and Medical Devices

Recent GMP Developments and Trends

David Churchward
Expert GMP Inspector, MHRA UK



Medicines and Healthcare Products Regulatory Agency

Objectives

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- International trend: risk based GMP
  - Challenges of implementation
- Recent and future changes in GMP and EU legislation with international impact
- International regulatory collaboration initiatives.

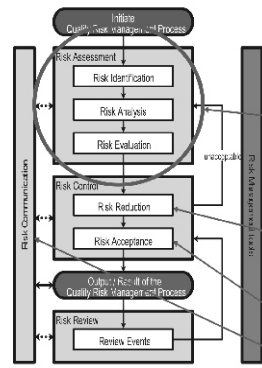
Risk based GMPs

MHRA

- Probably the most significant overall change in recent years
- Places even greater reliance on an effective quality system
  - Understanding of process
  - Understanding of product
    - Variables which impact quality
- Quality Risk Management (ICH Q9) principles
  - Encourages focus on higher risk / impact areas.

Quality Risk Management

MHRA

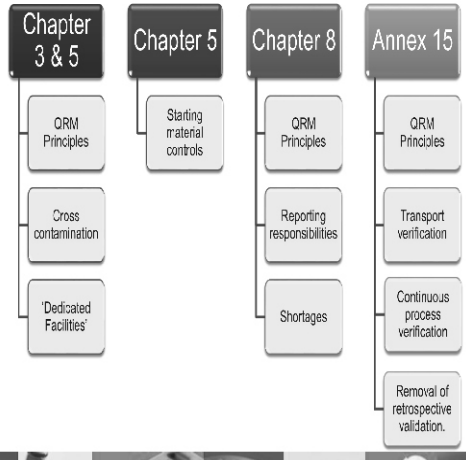


Key elements to implement risk based GMPs

- Not 'risk justification'!
- Information-based
- Effective mitigating measures
- Commensurate with risk / quality impact
- Understanding residual risk
- Review & communication.

EU GMPs – recent changes

MHRA



EU GMPs – Future change

MHRA

Annex 1 (Sterile Products)

- Complete revision
- ICH principles
- New technologies
- WFI manufactured by technologies other than distillation
- Align with international requirements.

Future EU legislative change

MHRA

GDP for API (FMD Art 46f)

- Section 17 of revised GMP Part II links to GDP for APIs
- Based on GDP for dosage form

GMP for Excipients (FMD Art 46f)

- Appropriate GMP determined by manufacturer, based on risk
- Document what GMP is needed
- Establish and maintain a control strategy

'Safety features' – packaging (FMD Delegated Act)

- Verify the authenticity, ID individual packs, alert to tampering
- Harmonised across EU; 2-D barcode & tamper evident seal
- Supply chain check in/out, database managed by stakeholders.

International

MHRA

- Regulatory collaboration and convergence in standards
  - PIC/S
    - Training and capacity building among participating authorities
    - Convergence in international GMPs
    - Global PIC/S participating authorities influencing change
- 'Regulatory partnerships'
  - International Coalition of Medicines Regulatory Authorities (ICMRA)
  - Transatlantic Trade and Industry Partnership (TTIP)
  - Information and workload sharing
    - Impact to inspections
- Early Compliance Management intervention by regulators
  - Avoid serious non-compliance
  - Maintain supply.

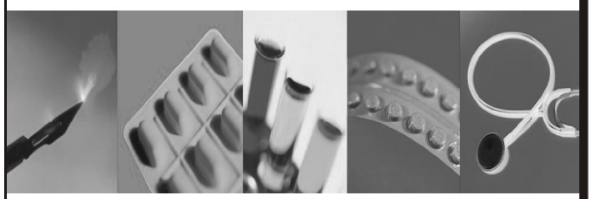
DATA INTEGRITY AND VERIFICATION

By
David Churchward
Expert GMP Inspector, MHRA UK

MHRA
Regulating Medicines and Medical Devices

Data Integrity and Verification

David Churchward
Expert GMP Inspector, MHRA UK



Medicines and Healthcare Products Regulatory Agency

Objectives

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- Outline basic data integrity expectations
- Impact of organisational behaviour on data governance
- How to build data integrity into the existing PQS
- Identifying and preventing bad practice.

So….. what's data integrity?

MHRA

- The extent to which all data are complete, consistent and accurate throughout the data lifecycle*

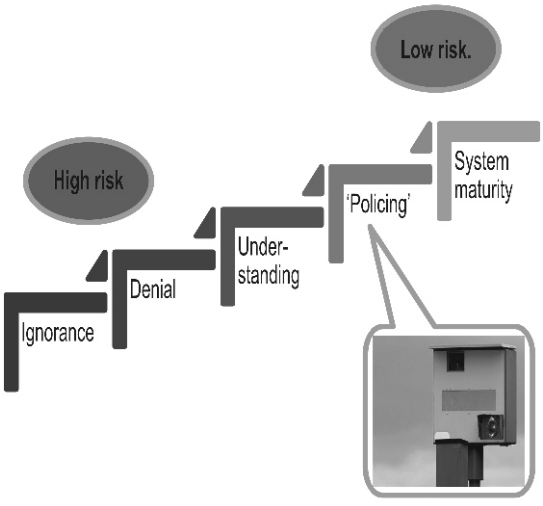
* from initial data generation and recording, through processing (including transformation or migration), use, retention, archiving and retrieval.

MHRA

Impact of organisational behaviour, risk awareness and leadership

Data Integrity: Risk awareness

MHRA



Data Lifecycle

MHRA

- Does the company understand the data lifecycle concept?
  - All phases in the life of the data (including raw data), from initial generation and recording, through processing (including transformation or migration), use, retention, archiving and retrieval
- Important when reviewing DI risks as a whole.

System maturity

MHRA

- Depth of understanding which does not just focus on the obvious
  - Not just about HPLC systems or 'trial injections'
- Quality Risk Management approach to data integrity
  - On-going risk review
  - What is their approach to mitigating these risks?
  - Awareness of residual risk
    - Is this managed to an acceptable level?
  - Do they understand the potential impact of these risks?.

MHRA

Encouraging the right behaviours at all levels in the organisation

Encouraging the right behaviours

MHRA

- Clear understanding of importance of data integrity at all levels
  - How do staff react to DI system weaknesses?
  - Is there evidence of non-contemporaneous recording?
- Internal reporting is encouraged
  - Can staff give their supervisor 'bad news' without fear?
- Senior management approach to data integrity which is not based on fear
  - 'zero tolerance' – what does that mean?.

MHRA

Designing systems to comply with Data Integrity principles

Design *paper* systems which reduce opportunities for falsification

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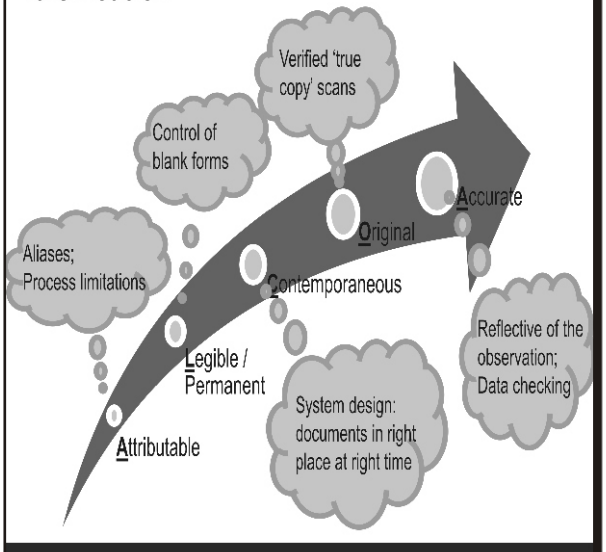

Design *electronic* systems which reduce opportunities for falsification

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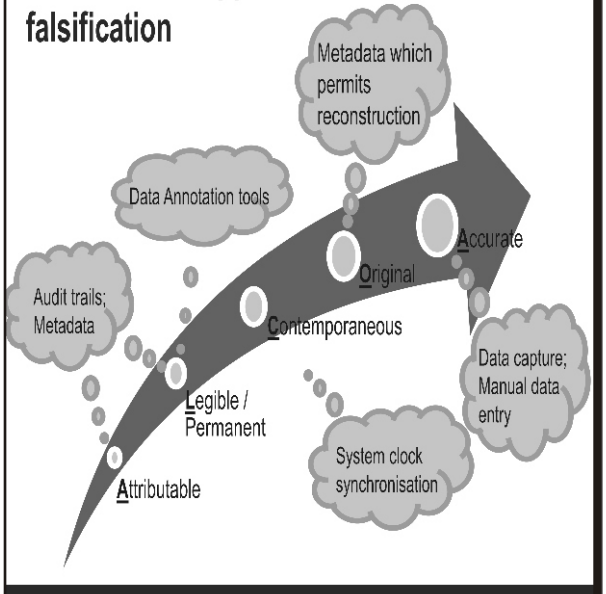

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Data review and system monitoring

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Data and system review

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- Data Review
  - Paper
  - Electronic – source data (not the paper)
  - Non-contemporaneous review is OK (unless verifying an observed value)
- Iterative data governance system review
  - QRM-type approach
  - Self inspection.

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Applying DI principles to supply chain management

15

Supply Chain Management

MHRA

- Data governance can't be just about a single site
- Contractor-generated data can have significant impact (raw material suppliers, laboratories)
- Can the CG trust paper reports?
  - Audit scope - focus on data integrity
  - Paper can be reviewed off line.

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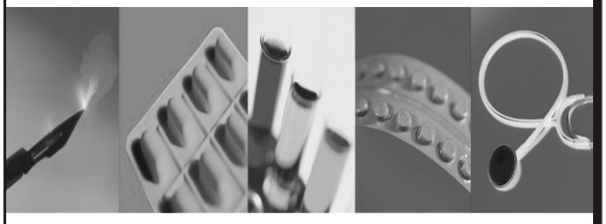
Regulating Medicines and Medical Devices

Interactive Session: Data Integrity & Verification



Medicines and Healthcare Products Regulatory Agency

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Workshop material to be provided

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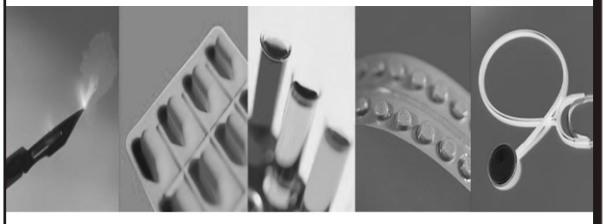
Regulating Medicines and Medical Devices

Top global data integrity failures: Identifying and preventing bad practice



Medicines and Healthcare Products Regulatory Agency

Top data integrity deficiencies: Global View

MHRA

- Analytical 'trial injections'
- Data traceability
  - Re-processing / re-testing into compliance
  - Miss-reporting / fabrication of data
- Recreating original documents

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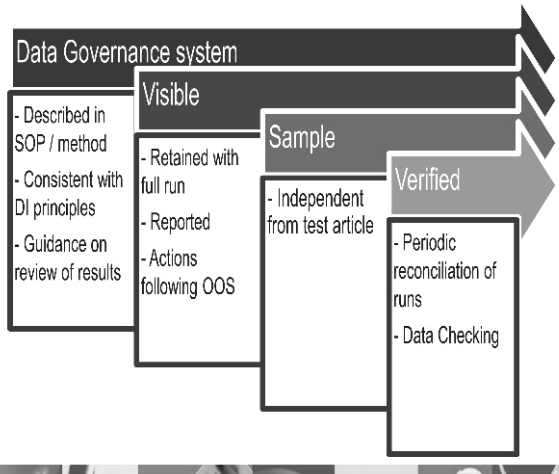
Trial Injections

Analytical 'trial injections'

MHRA

Analytical 'trial injections': Addressing DI issues

MHRA



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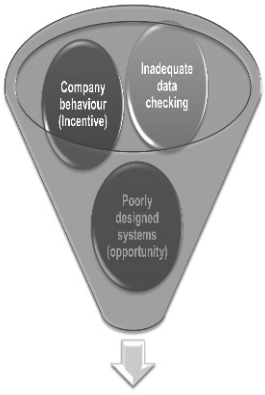
Data Traceability: Checking Raw Data

Raw data verification: why is it so important?

MHRA



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Raw data check: why is it so important?

MHRA

- Summary reports don't tell the whole story
  - Re-processing / re-testing into compliance?
  - Amending / fabricating data?
- Traceability from raw data to final report
- Verifying that all data is accounted for
- Reviewer needs access to:
  - All raw data and metadata
  - SOP for data checking
  - Validated reports (if database systems used).

Raw data check: why is it so important?

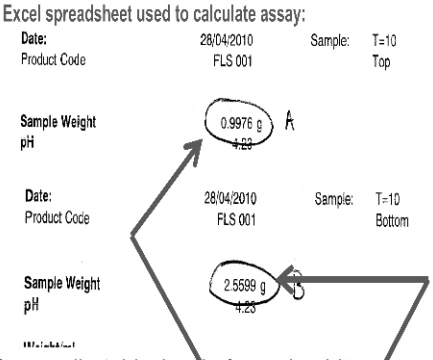
MHRA

- Is it necessary to check raw data from 'validated systems'?
- Yes!
  - Human interface and decision making
  - Influence over what is reported
  - Shows undisclosed data amendments, deletions, re-runs, re-processing, hidden fields, withheld data.

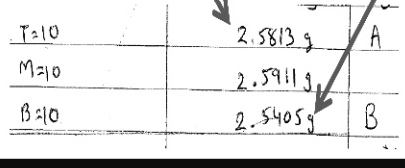
Raw data check: why is it so important? - Examples

MHRA

Excel spreadsheet used to calculate assay:



Corresponding Lab book entries for sample weights:



Raw data check: why is it so important? - Examples

MHRA

Sample name	Acquisition time	Filename
Acet.@250 REP 1	17:13:19	090811-003.rst
Acet.@250 REP 2	17:17:10	090811-004.rst
Acet.@250 REP 5	17:28:19	090811-007.rst
Acet.@250 REP 5	17:34:07	090811-007-20110809-173718.rst
Acet.@250 REP 6	17:37:58	090811-008.rst
Acet.@250 inj acc	17:41:58	090811-009.rst

- Where are REP 3 and REP 4? We have an 11 minute gap and the .005 & .006 datafiles are missing
- Why has REP 5 been reinjected?
- Why does the 6th injection have a different sample name?

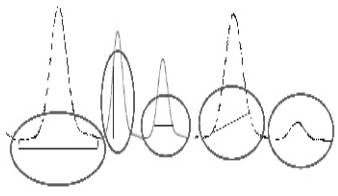
Raw data check: why is it so important? - Examples

MHRA

- On viewing the electronic data the missing results (REP 3 & 4) had been run at ~17:21 and ~17:25
- The results had been disregarded
- The HPLC 'passed' the Performance Qualification (PQ) RSD requirement using the amended data set
- The HPLC would have failed the PQ RSD requirement using the original results.

Raw data check: why is it so important? - Examples

MHRA



- Over-estimate assay
- Under-estimate impurity
- Turn off integration to ignore 'problem' peaks
- **All this may not be visible without ability to expand baseline from raw data**

Raw data check: why is it so important? - Examples

MHRA

Inspection deficiency:

Nine-month stability results for Product A were reported in the product quality review

- *No raw data (in either hard copy or electronic format) could be located to verify the authenticity of these results.*

MHRA

Recreating original documents

Recreating documents: Justification

MHRA

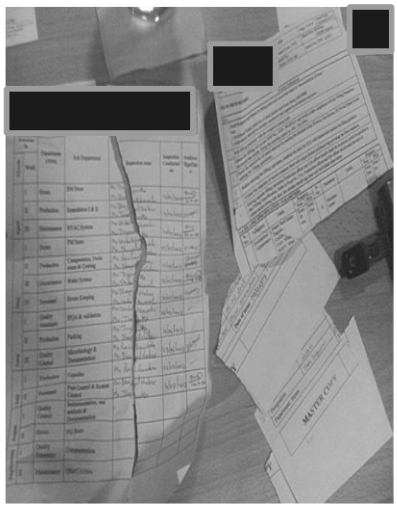
x	9
Undesirable data	Unusable original
Minor damage	Major damage / spillage
'Tidying' documents	Uncorrectable entry error

Recreating documents

MHRA

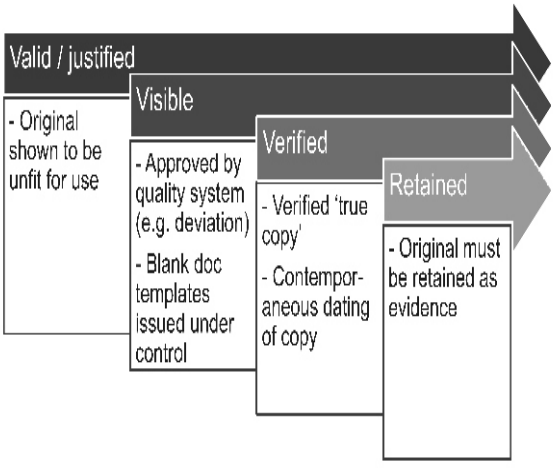
Recreating documents: Example

MHRA



Recreating documents: Addressing DI issues

MHRA



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Global regulatory actions

MHRA

- Stakeholder information resources
  - WHO guidance
  - MHRA GMP definitions & expectations for data integrity
  - Guidance from other regulators
- Impact on inspections
  - Part of routine scope
  - Verifying Data Governance throughout the PQS.

Challenges

MHRA

Industry

- Organisational behaviour
- Understanding the data lifecycle
- Risk prioritisation
- Supply chain

Regulators

- Distinguishing between 'intent' and 'bad practice'
- Encouraging industry self-reporting of data integrity failure

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Data Integrity & Verification: Summary

MHRA

- Data Governance: holistic approach to maintain data integrity throughout the lifecycle
- Not just about fraud, not limited to labs and IT
- Culture: led from the top; empowered from below
- Embedding within PQS: ALCOA principles
- Requirements are already defined in international GMPs
- Review of global 'top issues' to help in implementing compliant systems.

PHARMACEUTICAL PATENTING IN INDIA

By

Dr. S.P. Subramaniyan

Asst. Controller of Patents & Designs, IPR, Chennai

(Lecture delivered on 27th February 2015, during the workshop on IPR & Patents at Vinayaka Missions College of Pharmacy, Salem)

Patent is a statutory and monopoly right granted by the Government for an invention for a limited period of time to the innovator in lieu of full disclosure of his invention which excludes others from making, using, selling, and importing the patented product or process for producing that product. Patent is an intangible property that can be exploited unlike other property throughout the world at the same time. Inventions relating to either a product or process that is new, involving inventive step and capable of industrial application and also fulfilling the requirement of categories incorporated in section 3 of the Act can be applied for patent.

At the time of Independence, both product and process patent was prevailed for drugs in India which was governed by the Patents and Designs Act, 1911. It was designed in such way to benefit foreigners than Indians. As a result, there was no growth in scientific research and industrialization in the country and curbed the innovativeness and inventiveness of Indians.

After independence Government of India constituted a committee under the chairmanship of Justice (Dr.) BakshiTek Chand, a retired judge of the Lahore High Court in 1949 to review the working of 1911 Act. The Committee submitted the final report in 1950 making recommendations for prevention of misuse or abuse of patent rights in India with special emphasis to food and medicine and surgical and curative devices which need to be made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee. The Act was amended to provide compulsory license in respect of food and medicines, insecticide, germicide or fungicide, and a process for producing substance or any invention relating to surgical or curative devices.

Another committee have been appointed under the chairmanship of Justice N. RajagopalaAyyangar in 1957, to further amend the patent law which meets the requirement of the country. The committee observed that the grant of patents to Indians and foreigners was roughly in the ratio of 1:9 during the period 1930-37 and the same was remained even number of institutions for post-graduate training and several national laboratories were established to encourage a rapid growth of scientific education immediately after independence.

The committee recommended to retain the patent system and excluded product patents for substances intended for use and capable of being used as food or as medicine or drug. The term of the patent was also brought down from 14 years to five 5 years from the date of sealing of the patent or 7 years from the date of patent whichever was earlier. India was dependent on imports of many essential bulk drugs and the prices of the drugs also very high till early 1970s. After enactment of Patents Act, 1970 many Indian companies started manufacturing bulk drugs in large scale. During the period 1970-1994, the Indian pharmaceutical industry became nearly self-sufficient and one of the largest exporters of generic medicines. A large number of developing countries depend upon the supply of cheaper generic medicines from India. Because of product patent regime, Indian generic companies have steadily become the "pharmacy of the developing world".

TRIPs allowed a ten years transition period for developing countries to introduce product patents under Article 65. To meet the international agreements such as WTO and TRIPS, patent applications claiming pharmaceuticals, food and agrochemicals product were allowed to file in India under section 5(2) which was bifurcated from section 5 of the Patents Act, 1970 as 'WTO application' or 'Mail-box application'. Exclusive Marketing Rights (EMR) were made available for such applications u/s Article 70.8 subject to certain conditions for a term of five years from the date of grant of such rights or till the grant or rejection of patents claiming such products.

The Patents Act 1970 was amended in a phase-wise manner in 1999, 2002 and in 2005 in conformity with the TRIPs agreement. After the introduction of product patenting in 2005, mail-box and EMR provisions [Section 5 and Chapter IVA of the Patents Act 1970] were deleted and consequently product patents have been made available for inventions related to pharmaceuticals, agrochemicals, foods and products of chemical reactions since 01.01.2005. While introducing the amendments, utmost care was taken to protect the public health and nutrition. Also, provisions for both pre- and post-grant oppositions were engrafted in the Patents Act.

Following subject matters relating to drugs are acceptable in India;

(1) New Chemical Entity (drug per se)
(2) Process or method of preparing a drug
(3) Composition
(4) Combination

Synthetic medicines shall fulfil the provisions laid down in section 3(d), 3(e) and 3(i); and herbal medicines 3(c), 3(d), 3(e), 3(i) and 3(p) in addition to section 2(1)(j) and 2(1)(j)(a) of the Patents Act. Section 3 (d) stipulates additional proviso to prevent ever greening patent and clear intention to grant good patent.

Traditional herbal medicines are gaining momentum not only in India but also around the globe. Even though indications for many traditional herbs are known in the art, safety and efficacy, dose and dosage regimen for the active ingredients separated from a plant, novel combination of plant materials or extracts are need to be studied using pharmacological techniques for human consumption. For filing patent application either for synthetic or natural product, detailed clinical trial reports of pharmacological studies such as pharmacokinetic and pharmacodynamic results is not at all mandatory, but there shall be convincing proof for the activity of said products or improved effect over the known substance or combination(s). Preliminary *in vitro* or *in vivo* test results are sufficient to protect the invention by filing a patent application.

India is signatory to various international agreements other than the WTO and TRIPs agreement, these include Paris Convention (since 1998), Patent Cooperation Treaty (since 1998) and Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (since 2001), Convention on Biological Diversity 1992 (CBD). The amendments of the Patents Act 1970 were also calibrated to recognize India's accession to these treaties.

The ministerial conference of WTO adopted 'The Doha declaration on TRIPS and Public Health' (2001) in the wake of the public health crisis afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. The Doha declaration provided a mechanism for compulsory licensing to supply medicines to countries with insufficient or no-manufacturing capacities. The declaration also explicitly stressed that the TRIPs Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. Consequently, a provision (Section 92A) was introduced in the Patents Act for Compulsory Licensing for the purpose of export of pharmaceuticals products to any country having insufficient or no manufacturing capacity.

Convention of Biological Diversity (CBD) acknowledged the sovereign right of the nations on their genetic resources and mandated that the access to the genetic resources and any intellectual property derived there from should be subject to the benefit sharing accrued from such access. The CBD also warranted that the member states should protect their traditional and indigenous knowledge. In consequence of the CBD, India passed the Biological Diversity Act, 2002 which provides a mechanism for access to the genetic resources and benefit sharing accrued there from. Section 6 of the Biological Diversity Act came into force on 1st July 2004, and prescribes that obtaining IPRs from the utilization of biological resources in India is subject to the approval of the National Biodiversity Authority (hereinafter referred to as NBA). To facilitate this access and benefit sharing and in order to prevent any unauthorized use of the

biological resources of India, in 2005 suitable amendments were made in Section 10 of the Patents Act, 1970, wherein disclosure of the source and geographical origin of the biological material was made mandatory in an application for patent when the said material was used in an invention.

Pharmaceutical patenting in India is therefore, an extremely important and sensitive issue and also essential for promoting innovation and technological development in the country. Further, many of the issues related to the product patenting in the field of pharmaceuticals e.g., section 3(d) are now becoming clear through the judgements of the Courts. India amended various provisions in the Patents Act by utilizing flexibilities provided in the International Agreements to safeguard public health and also to meet international obligation. Thus, new provisions introduced and amendments made to the Patents Act are well within the international commitments and also complied with regulations of all the said agreements.

TARIFF FOR ADVERTISEMENTS

The members of the Tamilnadu Pharmaceutical Science Welfare Trust desire to accept and publish important advertisements in Pharma Web, from Pharma and allied industries, Pharmacy colleges, etc. The following are the tariff :

Back Cover	**Rs. 6,000/-**
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Note: 20% discount on the above rates for four consecutive issues.

PATENT FILING FOR PHARMACEUTICALS –CASE STUDY

By

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Professor & Head, Department of Pharmaceutics, JSS College of Pharmacy, Mysore

(Lecture delivered on 27th February 2015, during the workshop on IPR & Patents at Vinayaka Missions College of Pharmacy, Salem)

Patent Prosecution refers to the entire process of getting a patent grant, starting from the filing of the patent application to its grant. It includes all the communications to and from the Patent Office, from the time of filing the patent application to its grant. There are many issues that go into a grant of a patent. Many technical and legal requirements need to be fulfilled while filing a patent application. It includes the steps of filing information disclosure statements, assignments and proper payment of fees.

After filing a patent application with all the necessary documents, the prosecution of the patent will start. This phase can take 3-4 years to complete from the date of filing of the application. After 18 months from the date of filing, the patent application shall be published. The patent application is reviewed by competent Patent Examiners. If there are any discrepancies, the Patent Examiner informs the applicant, whereupon appropriate action is taken. These may include amendment of claims, or classification or drawings that the Examiner feels should be amended. This 'office action' and 'response to office action' may occur several times before a patent is finally allowed (or rejected).

It should be noted that Indian patent law allows two kinds of opposition, pre-grant opposition and post-grant opposition. Pre-grant opposition can be anytime after the publication of the patent until its grant. Only when a patent is successful in its pre-grant opposition proceedings can it be considered for grant. Also, after the patent is allowed to be published in the Patent Journal, there can be a post-grant opposition. This opposition decides whether the patent should be maintained or not.

Pharmaceutical patenting in India is therefore, an extremely important and sensitive issue since, while a bad patent is a burden to society, good patents are also essential for promoting innovation and technological development in the country. Quality, consistency and uniformity of examination and grant of patents thereafter are, therefore, the top most priority concerns for the Patent Office. In order to achieve these targets the Patent Office is continuously upgrading its internal resources. Apart from updating its physical resources like revamping its internal work modules or its public interfaces, the Office, in an attempt to bring in quality, consistency and uniformity, has introduced

guidelines for examination in certain key areas like traditional knowledge and biotechnology. Further, many of the issues related to the product patenting in the field of pharmaceuticals are now becoming clear through the decisions of the Courts. Therefore there is a need to develop guidelines for examination of pharmaceutical patents, incorporating the analysis of the Courts, with the objective that the guidelines will help improve the examination standard and will introduce harmonious practice amongst the technical Officers of the system. Claims of Pharmaceutical Inventions

The details of wording of claims, clarity, support and sufficiency of the disclosure are discussed under appropriate headings. However, for better understanding of the issues related to novelty and inventive step and other patentability criteria, a preliminary reference is made hereunder on claims of pharmaceuticals and allied inventions which are usually filed in patent applications of the relevant fields. Generally, applications pertaining to pharmaceutical and allied subject-matters comprise the claims relating to the following subject matters, but not limited to:

I. Product claims:

i. Pharmaceutical product:

a. New Chemical Entities;

b. Formulations/Compositions; Combinations/ dosage/dose;

d. New forms of known substance such as: Salts, Ethers and Esters; Polymorphs; Solvates, including hydrates; clathrates; Stereoisomers; Enantiomers; Metabolites and pro-drugs; Conjugates; Pure forms; Particle size; Isomers and mixtures thereof; Complexes; Derivatives of known substances; and

ii. Kits;

iii. Product-by-process.

II. Claims for process/method of manufacturing;

III. Claims related to new property, new use of known substance or use claims, including second indications;

IV. Claims for method of treatment and/or diagnosis of human beings and animals;

V. Claims related to selection inventions (relating to product and process)

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From Bench to Beside-Perceptional Change in a Pharmacist's role

By

B. Jenifer

Periyar College of Pharmaceutical Sciences, Trichy

Note: This article was awarded First Prize in the Essay Competition conducted by our Trust

The role of the pharmacist's has changed immensely over the past decade. The practice of Pharmacy is evolving from a profession that dispenses pharmaceutical products and best use of medicaments to patients.

The November 1999, Institute of medicine report on medical error's recognized that "the Pharmacist's has become an essential resource" and patient safety demand that access to the pharmacist's expertise must be possible at all times.

The Pharmacist's working in collaboration with other health care professionals, to increase their participation in patient care services. The initiation of drug therapy, educating and counseling patient on the effective use of the drug therapy, identifying and correcting actual drug-related problems and anticipating and preventing potential drug related problems.

Pharmacist' have the ultimate responsibility for ensuring the"3R's".

- Right drug
- Right patient
- Right dose

Pharmacist's are offering expanded health care services in the retail settings and are also ideal locations to raise disease awareness and deliver educational information at multiple points of contact. These include that over the counter (OTC) and personal care aisles, the Pharmacy counter, in specialist publications and prescriptions pick up areas.

One significant example is in the dramatic increase in the number of Pharmacist trained to deliver vaccination up from 40,000 to 1, 50,000 between 2007 to 2011.

Now Pharmacist's are devoting more time and attention to offering a wide spectrum of services, screening tests, wellness programmes, vaccination, clinics.

In older days, a Pharmacist's are focused only to dispensing a drug, compounding so they are called as "compounders".

But now-a-days it is perceptionally changed. Pharmacist's may offer consultation services for the management of complex diseases, such as diabetes or give general advice on diet and exercise. Pharmacists also educate other health care professionals such as physicians or nurses about pharmacology related issues are medication management. They may need to complete insurance forms, document their communication with patients and physicians or record medications they have dispensed pharmacists are often supervisors as well. Pharmacist's must be instructed on a proper use and potential side effects of medications to a patient.

Pharmacist are learned to check for possible harmful interaction among different drugs patients take under the supervision of licensed Pharmacist, also get practice in record-keeping duties and the completion of insurance forms.

Counseling patients involves more than information about adverse reactions and interactions with other medications, foods, alcohol, and other beverages like grape fruit juice. Counseling includes training patient how and when to take doses following up with patients to see if medication are working, sharing tips on how to minimize side effects while maximizing benefits and listening to all of a patient concerns.

Now-a-days, Pharmacist's are helping patient to heal and avoid getting sick by sharing advice on using non prescription remedies, taking health supplements such as vitamins using herbal and nature health product, exercising and maintaining a good diet. Pharmacist's are continuing education courses to maintain and renew their licenses, keeping the data on drug approval, product recalls and changes to medications, indications, warning and make sure they comply with federal and state laws regulating pharmacy.

There are changes in the Pharmacist's role and in the Community Pharmacy are impacting health care delivery and these trends will continue to accelerate in this rapidly transitioning environment.

Fifty years ago, the primary role of Pharmacist was solely to dispense prescription, they were not permitted to discuss medications with patients and had to refer them back to their physicians when question arose. Over time Pharmacists began to supply some very basic information about prescription. But, today circumstances are very different. Retail Pharmacist's role is providing advice about health issues, symptoms,medications is possible to customer enquiries, recruiting , training and managing staff, processing and dispensing medicines, ordering, selling and controlling medicines and other stocks, meeting medical representatives, managing budgets, keeping statistical and financial record, preparing publicity material, displays, marketing services.

Formal collaborative care models between Pharmacists and Physicians establish clear channel for Pharmacist's to deliver the services above with positive clinical effects.

Now-a-days, Pharmacists have developed improved skills such as maturity, attentiveness, responsibility, excellent interpersonal skills, confidence, and commercial awareness. Pharmacist's are known for "low threshold ", meaning that patient, families are health professional can always freely ask for advice and assistance.

"From advice to device, the Pharmacist's have always represented a first line of defence for health information and wellness".

There has been a growing need for community Pharmacist's around the world to have a greater professional role in the delivery of primary care for patients. Pharmacists are highly trusted health care professionals with extensive knowledge of pharmacotherapy and the management of chronic diseases, so it makes sense for health care stake holders, including government and policy makers, insurance and consumers, to use their expertise.

Conclusion:

Together with the other members of the team that is formed around a patient is need to palliative care, the Pharmacist has a well-defined and unique role in order to guarantee maximum comfort, based on the rational and optimal use of medication and other specific products.

Editorial Policy and Disclaimer

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This issue of Pharma Web is also available online at the Trust website www.pictrust.com

भारत का राजपत्र
The Gazette of India
असाधारण
EXTRAORDINARY
भाग II — खण्ड 1
PART II — Section 1
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं॰ 35] नई दिल्ली, शुक्रवार, दिसम्बर 5, 2008/अग्रहायण 14, 1930
No. 35] NEW DELHI, FRIDAY, DECEMBER 5, 2008 / AGRAHAYANA 14, 1930

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE

(Legislative Department)

New Delhi, the 5th December, 2008/*Agrahayana* 14, 1930 *(Saka)*

The following Act of Parliament received the assent of the President on the 5th December, 2008, and is hereby published for general information:—

THE DRUGS AND COSMETICS (AMENDMENT) ACT, 2008

No. 26 OF 2008

[*5th December,* 2008.]

An Act further to amend the Drugs and Cosmetics Act, 1940.

BE it enacted by Parliament in the Fifty-ninth Year of the Republic of India as follows:—

Short title and commencement.

1. (*1*) This Act may be called the Drugs and Cosmetics (Amendment) Act, 2008.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint:

Provided that different dates may be appointed for different provisions of this Act and any reference in any such provision to the commencement of this Act shall be construed as a reference to the commencement of that provision.

Insertion of new section 17E.

2. After section 17D of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), the following section shall be inserted, namely,—

Adulterated cosmetics.

"17E. For the purposes of this Chapter, a costmetic shall be deemed to be adulterated,—

(*a*) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(*b*) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(*c*) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(*d*) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(*e*) if it contains any harmful or toxic substance which may render it injurious to health; or

(*f*) if any substance has been mixed therewith so as to reduce its quality or strength.".

Amendment of section 18.

3. In section 18 of the principal Act, in cluase (*a*) , for sub-clause (*ii*), the following sub-clause shall be substituted, namely,—

"(*ii*) any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;".

Amendment of section 26A.

4. In section 26A of the principal Act, for the word "prohibit", the words "regulate, restrict or prohibit" shall be substituted.

Insertion of new section 26B.

5. After section 26A of the principal Act, the following section shall be inserted, namely,—

Power of Central Government to regulate or restrict, manufacture, etc., of drug in public interest.

"26B. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug.".

Amendment of section 27.

6. In section 27 of the principal Act,—

(*i*) in clause (*a*),—

(*A*) for the figures, letter and words "17B or which", the figures, letter and words "17B and which" shall be substituted.

(*B*) for the words "punishable with imprisonment for a term which shall not be less than five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees;", the words "punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more:" shall be substituted.

(*C*) the following provisos shall be inserted, namely:—

"Provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation, to the person who had used the adulterated or spurious drugs referred to in this clause:

Provided further that where the use of the adulterated or spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed on and realised from, the person convicted under this clause, shall be paid to the relative of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause.

Explanation.—For the purposes of the second proviso, the expression "relative" means—

(*i*) spouse of the deceased person; or

(*ii*) a minor legitimate son, and unmarried legitimate daughter and a widowed mother; or

(*iii*) parent of the minor victim; or

(*iv*) if wholly dependent on the earnings of the deceased person at the time of his death, a son or a daughter who has attained the age of eighteen years; or

(*v*) any person, if wholly or in part, dependent on the earnings of the deceased person at the time of his death,—

(*a*) the parent; or

(*b*) a minor brother or an unmarried sister; or

(*c*) a widowed daughter-in-law; or

(*d*) a widowed sister; or

(*e*) a minor child of a pre-deceased son; or

(*f*) a minor child of a pre-deceased daughter where no parent of the child is alive; or

(*g*) the paternal grandparent if no parent of the member is alive;";

(*ii*) in clause (*b*),—

(*A*) for the words "not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees", the words "not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(*B*) in the proviso, for the words "less than one year and of fine of less than five thousand rupees", the words "less than three years and of fine of less than one lakh rupees" shall be substituted;

(*iii*) in clause (*c*),—

(*A*) for the words "not be less than three years but which may extend to five years and with fine which shall not be less than five thousand rupees", the words "not less than seven years but which may extend to imprisonment for life and with fine which shall not be three lakh rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(*B*) in the proviso, for the words "less than three years but not less than one year", the words "less than seven years but not less than three years and of fine of less than one lakh rupees" shall be substituted;

(*iv*) in clause (*d*), for the words "and with fine", the words "and with fine which shall not be less than twenty thousand rupees" shall be substituted.

Amendment of section 27A.

7. In section 27A of the principal Act, for clauses (*i*) and (*ii*), the following clauses shall be substituted, namely,—

(*i*) any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the cosmetics confiscated, whichever is more;

(*ii*) any cosmetic other than a cosmetic referred to in clause (*i*) in contravention of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees, or with both.".

Amendment of section 28.

8. In section 28 of the principal Act, for the words "with fine which may extend to one thousand rupees or with both", the words "with fine which shall not be less than twenty thousand rupees or with both" shall be substituted.

Amendment of section 28A.

9. In section 28A of the principal Act, for the words "with fine which may extend to one thousand rupees or with both", the words "with fine which shall not be less than twenty thousand rupees or with both" shall be substituted.

Amendment of section 29.

10. In section 29 of the principal Act, for the words "five hundred rupees", the words "five thousand rupees" shall be substituted.

Amendment of section 30.

11. In section 30 of the principal Act,—

(*a*) in sub-section (*1*),—

(*i*) in clause (*a*),—

(*A*) for the words "not be less than two years but which may extend to six years and with fine which shall not be less than ten thousand rupees", the words "not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees" shall be substituted;

(*B*) in the proviso, for the words "less than two years and of fine of less than ten thousand rupees", the words "less than seven years and of fine of less than one lakh rupees" shall be substituted;

(*ii*) in clause (*b*), for the words "shall not be less than six years but which may extend to ten years and with fine which shall not be less than ten thousand rupees", the words "shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees" shall be substituted;

(*iii*) in clause (*c*), for the words "five thousand rupees", the words "fifty thousand rupees" shall be substituted;

(*b*) in sub-section (*2*), for the words "ten years, or with fine, or with both", the words "two years, or with fine which shall not be less than ten thousand rupees or with both" shall be substituted.

Amendment of section 32.

12. In section 32 of the principal Act, for sub-sections (*1*) and (*2*), the following sub-sections shall be substituted, namely:—

"(*1*) No prosecution under this Chapter shall be instituted except by—

(*a*) an Inspector; or

(*b*) any gazetted officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government; or

(*c*) the person aggrieved; or

(*d*) a recognised consumer association whether such person is a member of that association or not.

(*2*) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter.".

Insertion of new section 32B.

13. After section 32A of the principal Act, the following section shall be inserted, namely:—

Compounding of certain offences.

"32B. (*1*) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any offence punishable under clause (*b*) of sub-section (*1*) of section 13, section 28 and section 28A of this Act (whether committed by a company or any officer thereof), not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the institution of any prosecution, be compounded by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government, on payment for credit to that Government of such sum as that Government may, by rules made in this behalf, specify:

2 of 1974.

Provided that such sum shall not, in any case, exceed the maximum amount of the fine which may be imposed under this Act for the offence so compounded:

Provided further that in cases of subsequent offences, the same shall not be compoundable.

(*2*) When the accused has been committed for trial or when he has been convicted and an appeal is pending, no composition for the offence shall be allowed without the leave of the court to which he is committed or, as the case may be, before which the appeal is to be heard.

(*3*) Where an offence is compounded under sub-section (*1*), no proceeding or further proceeding, as the case may be, shall be taken against the offender in respect of the offence so compounded and the offender, if in custody, shall be released forthwith.".

Amendment of section 33.

14. In section 33 of the principal Act, in sub-section (*2*),—

(*i*) after clause (*dd*), the following clause shall be inserted, namely,—

"(*dda*) prescribe under clause (*d*) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring;";

(*ii*) in clause (*p*), the word "and" occurring at the end shall be omitted;

(*iii*) in clause (*q*), the word "and" shall be inserted at the end;

(*iv*) after clause (*q*), the following clause shall be inserted, namely,—

"(*r*) sum which may be specified by the Central Government under section 32B.".

Amendment of section 33-I.

15. In section 33-I of the principal Act,—

(*a*) in sub-section (*1*),—

(*i*) for clause (*a*), the following clause shall be substituted, namely:—

"(*a*) any Ayurvedic, Siddha or Unani drug—

(i) deemed to be misbranded under section 33E,

(ii) deemed to be adulterated under section 33EE, or

(iii) without a valid licence or in violation of any of the conditions thereof, as required under section 33 EEC,

shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more;";

(*ii*) in clause *(b)*, for the words "five thousand rupees", occurring at both the places, the words "fifty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(*iii*) after clause *(b)*, the following clause shall be inserted, namely:—

"(*c*) any Ayurvedic, Siddha or Unani drug in contravention of the provisions of any notification issued under section 33EED shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees or three times the value of the drugs confiscated, whichever is more.";

(*b*) in sub-section (*2*), for the words "three months and with fine which shall not be less than five hundred rupees", the words "six months and with fine which shall not be less than ten thousand rupees" shall be substituted.

Amenment of section 33J.

16. In section 33J of the principal Act,—

(*a*) in clause (*a*), for the words "two thousand rupees", the words "fifty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(*b*) in clause *(b)*, for the words "five thousand rupees" occurring at both the places, the words "one lakh rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(c) in clause *(c)*, for the words "six months and with fine which shall not be less than one thousand rupees", the words "one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted.

Insertion of new sections 33KA and 33KB.

17. After section 33K of the principal Act, the following sections shall be inserted, namely,—

Disclosure of name of manufacturer, etc.

"33KA. Every person, not being the manufacturer of any Ayurvedic, Siddha or Unani drug or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the Ayurvedic, Siddha or Unani drug.

Maintenance of records and furnishing of information.

33KB. Every person holding a licence under clause *(c)* of section 33EEC shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.".

Amendment of section 33N.

18. In section 33N of the principal Act, in sub-section (*2*),—

(i) in clause (*gga*), the word "and" occurring at the end shall be omitted;

(ii) after clause (*gga*), the following clause shall be inserted, namely,—

"(*ggb*) prescribe the records, registers or other documents to be kept and maintained under section 33KB; and".

Amendment of section 36A.

19. In section 36A of the principal Act, for the words "all offences under this Act", the words, brackets, figures and letters "all offences (except the offences triable by the Special Court under section 36AB or Court of Session) under this Act" shall be substituted.

20. After section 36A of the principal Act, the following sections shall be inserted, namely:— Insertion of new sections 36AB, 36AC, 36AD and 36AE.

'36AB. (*1*) The Central Government, or the State Government, in consultation with the Chief Justice of the High Court, shall, for trial of offences relating to adulterated drugs or spurious drugs and punishable under clauses (*a*) and (*b*) of section 13, sub-section (*3*) of section 22, clauses (*a*) and (*c*) of section 27, section 28, section 28A, section 28B and clause (*b*) of sub-section (*1*) of section 30 and other offences relating to adulterated drugs or spurious drugs, by notification, designate one or more Courts of Session as a Special Court or Special Courts for such area or areas or for such case or class or group of cases as may be specified in the notification. Special Courts.

Explanation.—In this sub-section, "High Court" means the High Court of the State in which a Court of Session designated as Special Court was functioning immediately before such designation.

(*2*) While trying an offence under this Act, a Special Court shall also try an offence, other than an offence referred to in sub-section (*1*), with which the accused may, under the Code of Criminal Procedure, 1973, be charged at the same trial. 2 of 1974.

36AC. (*1*) Notwithstanding anything contained in the Code of Criminal Procedure, 1973,— 2 of 1974. Offences to be cognizable and non-bailable in certain cases.

(*a*) every offence, relating to adulterated or spurious drug and punishable under clauses (*a*) and (*c*) of sub-section (*1*) of section 13, clause (*a*) of sub-section (*2*) of section 13, sub-section (*3*) of section 22, clauses (*a*) and (*c*) of section 27, section 28, section 28A, section 28B and sub-sections (*1*) and (*2*) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be cognizable.

(*b*) no person accused, of an offence punishable under clauses (*a*) and (*c*) of sub-section (*1*) of section 13, clause (*a*) of sub-section (*2*) of section 13, sub-section (*3*) of section 22, clauses (*a*) and (*c*) of section 27, section 28, section 28A, section 28B and sub-sections (*1*) and (*2*) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be released on bail or on his own bond unless—

(*i*) the Public Prosecutor has been given an opportunity to oppose the application for such release; and

(*ii*) where the Public Prosecutor opposes the application, the court is satisfied that there are reasonable grounds for believing that he is not guilty of such offence and that he is not likely to commit any offence while on bail:

Provided that a person, who, is under the age of sixteen years, or is a woman or is sick or infirm, may be released on bail, if the Special Court so directs.

(*2*) The limitation on granting of bail specified in clause (*b*) of sub-section (*1*) is in addition to the limitations under the Code of Criminal Procedure, 1973 or any other law for the time being in force on granting of bail. 2 of 1974.

(*3*) Nothing contained in this section shall be deemed to affect the special powers of the High Court regarding bail under section 439 of the Code of Criminal Procedure, 1973 and the High Court may exercise such powers including the power under clause (*b*) of sub-section (*1*) of that section as if the reference to "Magistrate" in that section includes also a reference to a "Special Court" designated under section 36AB. 2 of 1974.

Application of Code of Criminal Procedure, 1973 to proceedings before Special Court.

36AD. (*1*) Save as otherwise provided in this Act, the provisions of the Code of Criminal Procedure, 1973 (including the provisions as to bails or bonds), shall apply to the proceedings before a Special Court and for the purposes of the said provisions, the Special Court shall be deemed to be a Court of Session and the person conducting the prosecution before the Special Court, shall be deemed to be a Public Prosecutor: 2 of 1974.

Provided that the Central Government or the State Government may also appoint, for any case or class or group of cases, a Special Public Prosecutor.

(*2*) A person shall not be qualified to be appointed as a Public Prosecutor or a Special Public Prosecutor under this section unless he has been in practice as an advocate for not less than seven years, under the Union or a State, requiring special knowledge of law.

(*3*) Every person appointed as a Public Prosecutor or a Special Public Prosecutor under this section shall be deemed to be a Public Prosecutor within the meaning of clause (*u*) of section 2 of the Code of Criminal Procedure, 1973 and the provisions of that Code shall have effect accordingly. 2 of 1974.

Appeal and revision.

36AE. The High Court may exercise, so far as may be applicable, all the powers conferred by Chapter XXIX or Chapter XXX of the Code of Criminal Procedure, 1973, on a High Court, as if a Special Court within the local limits of the jurisdiction of the High Court were a Court of Session trying cases within the local limits of the jurisdiction of the High Court.'. 2 of 1974.

T. K. VISWANATHAN,
Secy. to the Govt. of India

EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 1235] नई दिल्ली, सोमवार, अगस्त 10, 2009/श्रावण 19, 1931
No. 1235] NEW DELHI, MONDAY, AUGUST 10, 2009/SRAVANA 19, 1931

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 10 अगस्त, 2009

का.आ. 2076(अ).—केन्द्रीय सरकार, औषध और प्रसाधन सामग्री (संशोधन) अधिनियम, 2008 (2008 का 26) की धारा 1 की उप-धारा (2) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, एतद्द्वारा 10 अगस्त, 2009 को उस तारीख के रूप में नियत करती है, जिसको उक्त अधिनियम की धाराओं में अन्तर्विष्ट उपबंध प्रवृत्त होंगे ।

[फा. सं. एक्स. 11014/04/2009-डीएफक्यूसी]

देबाशीष पण्डा, संयुक्त सचिव

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 10th August, 2009

S.O. 2076(E).—In exercise of the powers conferred by sub-section (2) of Section 1 of the Drugs and Cosmetics (Amendment) Act, 2008 (26 of 2008), the Central Government hereby appints the 10th August, 2009 as the date on which the provisions contained in the Sections of the said Act shall come into force.

[F. No. X. 11014/04/2009-DFQC]

DEBASISH PANDA, Jt. Secy.

INFORMATION

M.Pharm & Pharm D Scholarships 2014-15 awarded by TNPSWT
Profile of 1st Rank Projects

PHARMACEUTICS

Name: Mr. E.Surendra

Project Title: Synthesis & Characterization of lipid conjugated raloxifene hydrochloride carbon nanotubes for targeted drug delivery to human breast cancer cells

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. N. Jawahar

PHARMACEUTICAL CHEMISTRY

Name: Mr. T. Ananthakumar

Project Title: Determination of Melamine Residue in Raw milk, Pasteurized milk, & milk related product by UV – Visible Spectroscopy and ultra-performance liquid chromatography

College:Madras Medical College, Chennai

Guide's Name: Dr. (Mrs) V. Niraimathi

PHARMACEUTICAL ANALYSIS

Name: Mr.AvendraYadav

Project Title: Impurity profiling on Diacerein with Genotoxicity Approach by LCMS and AMES test

College: JSS College of Pharmacy, Ooty

Guide's Name:Mr.M.R.Jeyaprakash

PHARMACOLOGY

Name: Mr.V.Gopi

Project Title: Novel method for validation of serum Matrix Metalloproteinase 1 (MMP1) in lung cancer prognosis

College: Madras Medical College, Chennai

Guide's Name:Mrs. R.Indhumathy

PHARMACOGNOSY

Name: Mr.G.Arunkumar

Project Title:
Development,Standardisation and Pharmacological Evaluation of Anti Diabetic activity for polyherbal formulation

College: Madras Medical College, Chennai

Guide's Name: Dr.R.VijayaBharathi

PHARMACY PRACTICE

Name: Mr.M.Ananthan

Project Title: Improving Glycemic Controlled of Inadequately controlled Type 2 DM patient initiated to add on therapy of long acting basal analogue an open label study Trichy Diabetes specialty centre

College: Annai JKK SampooraniAmmal College of Pharmacy, B.Komarapalayam

Guide's Name: Mr.S.Kannan

PHARM D- PHARMACY PRACTICE

Name: Ms.DhanuJosey, Ms.Divya Ann Jetto, Ms.Evelyn Harold, Ms. Mabel Elizabeth V.K.

Project Title: Dosage adjustments of potentially hepatotoxic medications in patients with liver dysfunction

College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Mrs. A.S.Manjula Devi

PHARM D- CLINICAL PHARMACY

Name: Ms.G.Charushma Devi, M.Gayathri,CH.DivyaSree, Mohammed Rafi

Project Title: Urotensin-IIlevels and its association with oxidative stress in early diabetic nephropathy.

College:SRM College of Pharmacy, Chennai

EVENTS

Workshop on Intellectual Property Rights & Patents

The One day Workshop on Intellectual Property Rights and Patents was conducted on 28.02.2015 at Vinayaka Mission's College of Pharmacy, Vinayaka Missions University in Association with Indian Pharmaceutical Association –Tamil Nadu branch sponsored by TANIPA & Tamil Nadu Pharmaceutical Sciences Welfare Trust. The Workshop was inaugurated by Dr. Prof. K. Chinnaswamy, President, Tamil Nadu Pharmacy Council as chief guest. Dr.Y.Abraham, Registrar, Vinayaka Missions University, Salem presided over the function, Mr. A. KrishnaDev, Chairman, TANIPA Trust, Chennai and Former Deputy Drugs Controller, Govt. of India, Mr. J. Jayaseelan, Secretary, Indian Pharmaceutical Association –Tamil Nadu branch, Managing Director, Delvin Pharmaceuticals, Chennai, Thiru. N. Sreenivasen, Hon. General Secretary, Tamil Nadu Pharmaceutical Welfare Trust, Mr.R. Narayanaswamy, Coordinator, Pharma Knowledge and Training Institute and Mr.R.Sabapathi, Executive Director, Medopharm, Chennai felicitated the function. Dr.B.Jaykar, Principal, Vinayaka Mission's College of Pharmacy, Salem welcomed the gathering.

Total 235 delegates from Vinayaka Mission's College of Pharmacy and various Institutions in and around of Salem attended the workshop. The scientific sessions was started after the inauguration. Dr. S.P.Subramaniyan, Asst. Controller, Intellectual Property Rights Office, Chennai delivered a Lecture on Patent Systems in India. He elaborated about the prevailing of Patent Systems in India. He emphasized on TRIPS, Doha declaration and the importance of Pharmaceutical patents in India. In the second session, Mr. J. Jayaseelan, M.D, Delvin Formulations delivered a lecture on impact of patents on Indian Pharma Industries. He enlighted the delegates about the product and

process patenting systems. The positive and the negative aspects of patents on Indian Pharma companies and the importance of Intellectual Property rights to the Pharmaceutical Industries. The last lecture delivered by Dr. K. Gowthamarajan, Prof& Head, J.S.S. College of Pharmacy, Ooty. He has given the clarity on how to file the patents and narrated the method of filing the patents. Prof. K. Chinnaswamy, President, Tamil Nadu State Pharmacy Council distributed the participation certificates to the delegates. The workshop was concluded by National Anthem.

Career Opportunities for Pharma Graduates

Faculty of Pharmacy, Sri Ramachandra University (SRU), organized a seminar on "Career Opportunities for Pharma Graduates" in association with Indian Pharmaceutical Association (IPA), Tamilnadu branch and Tamilnadu Indian Pharmaceutical Association Trust (TANIPA) ChennaiI on 17th February 2015, at SRU. Dr. D. Chamundeeswari, Principal, Faculty of Pharmacy, SRU, welcomed the gathering. Mr. A. Krishnadev, Chairman, Tamilnadu Indian Pharmaceutical Association Trust, Chennai was the guest of honor and he delivered the inaugural address. Dr. S. P. Thyagarajan, Professor of Eminence and Dean (Research) delivered the keynote address. Mr. M. M. Yousuf, President, IPA (TN), Secretary, TANIPA Trust, released the scientific proceedings. Dr. K. V. Somasundaram, Dean of

M/s. Delvin Formulations Pvt. Ltd. / Saimirra Innopharm Pvt. Ltd. / Nuray Chemicals Pvt. Ltd., Secretary, IPA (TN), launched the dedicated email id pharmaplacement.org@gmail.com created by placement cell, Faculty of Pharmacy, SRU, in collaboration with IPA (TN) and TANIPA. Dr. K. Chitra, Vice Principal, Faculty of Pharmacy, SRU proposed the vote of thanks. The scientific sessions were held from 11:00 am to 4:00 pm on various topics including "Roadmap to a Pharma Entrepreneur" by Mr. J. Jeyaseelan, "Industries' expectation from fresh graduates" by **Mr. Sanjay Das Mohapatra,** President, Technical and Operations, Medopharm Pvt. Ltd., Chennai, "Soft skills training" by **Mr. K. Gurunath,** Tri E empowerment, Chennai, and "An overview on intellectual property rights in pharmaceutical industry" by Mr. M. Narendira Kumar, Head- Quality Assurance, Orchid Healthcare, Chennai. A panel discussion was held between 4:30 to 5:30 pm with Mr. M. M. Yousuf, Mr. K. Gurunath andMr. M. Narendira Kumar as panelists and Dr. D. Chamundeeswari as the moderator. The program ended with vote of thanks by Dr. K. Sujatha, Professor, Department of Pharmaceutical Chemistry, Faculty of Pharmacy, SRU. Around 300 students from pharmacy colleges in Chennai were benefitted.

NEWS

Centre Likely to Lift Limits on Swine Flu Drug Sale

The government is mulling lifting restrictions on stocking and selling of Oseltamivir Phosphate or Tamiflu, an oral antiviral drug used to treat swine flu. The move will allow over 4,80,000 chemists across the country to sell the drug and comes at a time when, according to official estimates, 812 people have lost their lives to the virus in India this year, the highest in the last five years.

More than 13,000 others have been infected by the virus so far in 2015. "We are cons"We are considering a move to shift the drug from Schedule X to Schedule H1," an official told ET. If this shift is carried out, chemists across the country will be able to sell the drug, provided the buyer produces a doctor's prescription. They would also have to ensure that details of such sale are recorded in a separate register and maintained for three years.
At present, which has resulted in shortages of the drug in some regions. Tamiflu has so far been tightly regulated to prevent its incessant use, which could make the virus immune to the drug.

The matter was deliberated last week at a meeting of the drug technical advisory board, the apex body on drug safety, people present in the meeting told ET.
"At least one set of experts now believe that this drug has been in use in the developed countries for years now and there is no compelling evidence to cite that such resistance can develop so quickly.
Moreover under Schedule H1, its usage can be closely monitored," said an official, adding that the decision can always be reviewed once the outbreak subsides.

The drug, however, will not be available over the counter. Schedule H1 category was introduced in the drug law in 2013 to combat concerns of antibiotic resistance.

The list contains third and fourth generation antibiotics, select habit forming drugs and anti-TB medicines, and mandates the chemist to not only sell it against a prescription but preserve details like name and address of the prescriber, name of the patient, name of the drug and the quantity supplied for three years. Unlike this, to sell drugs clubbed under Schedule X (under which Oseltamimir Phosphate is classified), the chemist needs a special licence, besides maintaining records of every unit sold for at least two years.

The distribution of Schedule X licence holder pharmacies across states and districts is uneven. For instance, Sikkim has over 60 such stores but Bihar has just four, despite being over 150 times more populous. Also, not every such store has ready stock of the swine flu drug. Besides Swiss innovator Roche, several leading domestic Pharma companies such as Cipla, Hetero and Strides Arcolabs produce Oseltamivir.

A senior executive at one such drug firm, who did not wish to be named, said that at full capacity, his firm can churn out over 600,000 tablets and over six tonne of bulk drugs in a single day.

Source: *The Economic Times, 24th February 2015*

Canadian Co Valeant to Buy Salix in All-Cash $ 10 billion Deal

(Reuters) - Canada's ValeantPharmaceuticalsInternational Inc agreed to acquire gastrointestinal drugmaker Salix Pharmaceuticals Ltd in an all-cash deal valued at about $10.1 billion, the two companies said on Sunday.

The deal for Salix, known for its irritable bowel syndrome drug Xifaxan, was approved by the boards of directors of bothcompanies, the companies said in a news release.

The companies said the deal had an enterprise value of $14.5 billion, which would include Salix's debt and any cash on hand. Valeant will pay $158.00 a share, valuing the all-cash transaction at about $10.1 billion.

The merger is expected to yield more than $500 million in annual cost savings within six months, the release said.

The transaction is expected to close in the second quarter of 2015, and is subject to customary closing conditions and regulatory approval.

The deal is the largest ever for Laval, Quebec-based Valeant, which lost a takeover contest for AllerganInc last year. The usually acquisitive Valeant slowed its buying pace dramatically while it pursued Allergan, and Chief Executive Michael Pearson said last month that it would focus on buying smaller, private companies in 2015.

Pearson said in the release that Salix, based in Raleigh, North Carolina, was an "ideal strategic fit" for Valeant.

Source: *The Economic Times, 24th February 2015*

Pfizer to Buy Hospira for $15 b to Boost Copycat Drug Business

Largest deal since its failed takeover attempt of AstraZeneca

Drugmaker Pfizer Inc on Thursday said it would buy HospiraInc for about $15 billion to boost its portfolio of generic injectible drugs and biosimilars, or copies of biotech drugs.

Pfizer offered $90 per share in cash, a 39 per cent premium to Hospira's closing stock price on Wednesday. Hospira soared 35 per cent to near $88 before the bell on Thursday, while Pfizer was up 3.6 per cent.

For Pfizer, the deal is the largest since its failed takeover attempt of AstraZeneca Plc , which rebuffed its $118-billion approach last year, but has remained a subject of takeover speculation.

Pfizer said the latest move showed its commitment to deploy capital and deliver revenue and earnings per share growth in the near term. The deal is expected to add 10 cents to 12 cents per share to Pfizer's earnings in the first full year after the deal closes, it said.

The move will increase Pfizer's business in established drugs, or those no longer covered by patents. Hospira makes generic versions of injectible drugs that are widely used in hospitals and sells several biosimilars overseas. It has other biosimilars in development.

Drugmakers are racing to develop biosimilars, which typically cost 20-30 per cent less than the original, as big-ticket patents on biotech drugs expire and cash-strapped healthcare systems cut costs.

There are no approved biosimilars in the United

States yet. A U.S. regulatory panel endorsed the first one in January from Novartis AG, a copy of Amgen Inc's blockbuster cancer drug Neuopogen, but it has not yet been approved.

Biosimilars are expected to account for about one-quarter of the $100 billion in sales from off-patent biological drugs by the end of the decade, according to a study compiled by Thomson Reuters BioWorld.

Hospira is seeking approval from the U.S. Food and Drug Administration to market a copy of J&Jarthritis treatment Remicade.

Source: *The Hindu, 6th February 2015*

Double-Action Drugs:One Key Opens Two Locks

In the history of medicine, the hunt for drugs has been an empirical one. Substances from plant, marine and even animal sources have been tried and, over the years, several useful substances have emerged as medications against chosen illnesses as well as for specific medical conditions. More often than not, many of these are general-purpose ones used as tonics, such as gingko biloba or green tea in the Orient, Ashwagandha in Indian Ayurveda, or ZindaTilismat in the Unani system. But in some ones such as the cinchona bark against malaria, or leaves from the periwinkle plant, used in traditional medicines against cancer, the 'active' principles have been confirmed by modern organic chemistry to contain quinine, and vincristine respectively. Yet all these attempts have been empirical, trial and error methods that have taken centurries to grow.

With advances in chemistry, it has become possible to separate individual molecules from such mixtures and synthesise them in pure form in the laboratory — a branch that bears the name natural products chemistry, an area that has been a fertile and focused field in India since the 1950s.

At the same time, advances in the medical sciences, particularly in the field of pathology, have led us to focus on the organ, tissue and cells which are affected and malfunction. And advances in biology have allowed us to get an idea of what has gone wrong at the molecular or cellular level during the malfunction, thus leading to the era of cellular and molecular medicine.

For example, the disorder diabetes is caused by abnormally high levels of sugar in the body. While sugar is essential since it is the fuel for the maintenance and growth of cells and tissue, excess levels of it go to “choke” the metabolism by modifying the chemical structure (and therefore the function) of several proteins' molecules. One example is the chemical reaction between sugar and the oxygen-transport protein, haemoglobin. This reaction modifies the structure of haemoglobin in a manner that its ability to carry and transport oxygen to cells is affected. Once this choking action had been understood, researchers have developed drug molecules (such as metformin) that level down the production of sugar in the liver to acceptable limits.

Note that the drug that the researcher 'designs' should fit the relevant molecules/cell component specifically like a glove on hand or a key on a lock. That way, the specific step(s) are affected without disturbing other components in the cellular machinery in any manner, so that there are no side effects.

It happens occasionally that the “side effects” may not only be harmless, but may prove helpful elsewhere in the body for some other malfunction, purely by happenstance. Aspirin is one such double-action drug. Introduced first as a pain-

reliever, it has also been found to help dissolve clotting of blood. Its analgesic action is on the nervous system while its clot-dissolving action is through its action on platelet cells in blood. Aspirin is thus a master key that appears to open more than one lock. And it is not just a single example — there are others.

The molecule termed ELQ 300 is an antimalarial, which acts against the malaria parasite both in the liver stage and when the parasite has already entered the bloodstream as well, making it a double-action drug. Likewise the peptide M5 that DrAnandRanganathan has come out with (described in our last column of January 29, 2015, < http://www.thehindu.com/sci-tech/health/building-a-molecular-lego-to-fight-malaria-and-tb/article6830912.ece), promises to be effective against TB and malaria.

Source: *The Hindu, 12th February 2015*

Govt to Monitor Prices of Medical Devices

In a serious bid to monitor prices of exorbitantly-priced medical devices like cardiac stents and implants, the government seems to be cracking the whip on medical device companies by issuing them a show-cause notice for not having revealed their prices.

In a communication dated February 9 this year, drug pricing regulator NPPA first directed all medical device companies including Abbott, Johnson and Johnson and Medtronic to submit prices at which they import, and sell the devices to distributors, and their maximum retail prices, sources told TOI. This was immediately followed up by a show-cause issued on February 16 to those in the industry who had not submitted these details.

Sources said the government is keen to monitor prices of medical devices so as to prevent patients being over-charged, and has set a deadline of two weeks for the details to be submitted.

This comes in the wake of concerns of overcharging and over-pricing of cardiac stents, as prices of medical devices are not regulated, or even monitored by the government.

This is the first time that the government has issued such a show-cause notice to medical device companies, after its directive on submitting prices was apparently ignored by certain manufacturers.

Typically, patients are charged almost three to four times of the landed cost (price at which these are imported) in terms of certain devices.

Last year, a Maharashtra Food and Drug Administration report to the government said that drug-eluting stents (manufactured by Abbott) imported at Rs 40,710 and sold to distributor at Rs 73,440, while the company-listed MRP was Rs 1.5 lakh, a mark-up of over 250%.

Also, DES manufactured by Medtronics, imported at Rs 30,848 and sold to distributor for Rs 67,000. MRP marked as Rs 1.62 lakh, a mark-up of more than 400%.

"We will be submitting the price details to the government soon. While we and the distributors, earn a margin of about 15-20% each, it is the hospitals which are marking up the price and selling it to the patients. Now with these details, the pricing structure will become transparent. The government should look at ways to regulate the hospitals which seem to be over-charging patients," an executive with an industry player told TOI.

The distributor or wholesaler charges hospitals

generally a mark-up of 15-20% on the device, which is then sold by hospitals to patients at a price which may be nearly double or triple at which it was imported.

The notice mentions all 22 devices classified as "drugs" under the Drugs and Cosmetic Act, 1940, including cardiac stents, drug-eluting stents, orthopaedic implants, heart valves, internal prosthetic replacements and in-vitro diagnostic devices for HIV, HBsAg and HCV.

Source: *The Times of India, 23rd February 2015*

Deadly Malaria Strain May Reach India Very Soon

A deadly strain of malaria that has become resistant to artemisinin, the best available drug to fight the vector-borne disease, has been found 25 km from the Indian border.

On Friday the Mahidol-Oxford Tropical Medicine Research Unit in Thailand confirmed that resistant parasites have been found in Homalin, Sagaing Region of Myanmar, near the Indian border. The researchers examined parasite samples collected at 55 malaria treatment centres across Myanmar and found they carried mutations in specific regions of the parasite's kelch gene (K13) — a known genetic marker of artemisinin drug resistance.

Resistance to artemisinin has been detected in Cambodia, Laos, Thailand, Vietnam and Myanmar. WHO had earlier launched a $175 million annual plan to contain and prevent the global spread of the artemisinin-resistant parasite beyond the Mekong region. The Mekong Delta region is where chloroquine first began to fail in the 1950s before it moved westwards and lost effectiveness in Africa.

The study published in Lancet Infectious Diseases reports that artemisinin resistance threatens to follow the same historical trajectory from Southeast Asia to the Indian subcontinent as seen in the past with other antimalarial medicines.

The collection of samples from across Myanmar and its border regions was led by DrKyawMyoTun of the Defence Services Medical Research Centre, Napyitaw, Myanmar. The team obtained the DNA sequences of 940 samples of malaria infections from across Myanmar and neighbouring border regions in Thailand and Bangladesh between 2013 and 2014. Of those 940 samples, 371 (39%) carried a resistance-conferring K13 mutation.

Professor Philippe Guerin, director of the Worldwide Antimalarial Resistance Network and co-author of the study, said: "The identification of the K13 markers of resistance has transformed our ability to monitor the spread and emergence of artemisinin resistance. However, this study highlights that the pace at which artemisinin resistance is spreading or emerging is alarming."

Professor Mike Turner, head of Infection and Immunobiology at the Wellcome Trust, said: "Drug-resistant malaria parasites in the 1960s originated in Southeast Asia and from there spread through Myanmar to India, and then to the rest of the world where it killed millions of people. The new research shows that history is repeating itself with parasites resistant to artemisinin drugs, the mainstay of modern malaria treatment, now widespread in Myanmar. We are facing the imminent threat of resistance spreading into India.

Source: *The Times of India, 21st February 2015*

WHO Okays 15-Min Test to Detect Ebola

The World Health Organization has approved the first rapid test for Ebola in a potential breakthrough for ending an epidemic that has killed almost 10,000 people in West Africa, it said on Friday.

The test, developed by US firm Corgenix Medical Corp , is less accurate than the standard test but is easy to perform, does not require electricity, and can give results within 15 minutes, WHO spokesman TarikJasarevic said. 'It's a first rapid test. It's definitely a breakthrough,' he said. The standard laboratory test has a turnaround time of 12-24 hours. While the Corgenix test is not failsafe, it could quickly identify patients who need quarantine and make it much easier to verify rapidly any new outbreaks. Procurement and roll-out of the test kits will not begin immediately because the company is still working out costing and needs a week or two more to finish administrative procedures with the U.S. Food and Drug Administration, Jasarevic said. The health charity Medecins Sans Frontieres, which has been at the forefront of the fight against Ebola, had expressed an interest, he said. The so-called ReEBOV Antigen Rapid Test involves putting a drop of blood on a small paper strip and waiting 15 minutes for a reaction in a test tube. It is able to correctly identify about 92 percent of Ebola infected patients and 85 percent of those not infected with the virus, the WHO said.

Source: *The Times of India, 21st February 2015*

Top Drug Cos in Race to Bid for Sun Pharma's 7 Brand

Cipla, Hyderabad based Natco& US-based Mylan keen to buy select chronic therapy drugs estimated to be close to Rs 137 crore

Mumbai –based Cipla Pharma, Hyderabad's Natco and Us drug maker Mylan are among the companies in the fray toBuy select brands of Sun Pharma that have been put up for sale by the companies as per an order of the CompetitionCommission of India.

The total value of the seven drugs is estimated to be close to Rs 137 crore, according to data available with the All IndiaOrganisation of Chemists and Druggists Association. These drugs are in the category of chronic therapy ranging from anti-depressants to heart disease drugs. Other interested players include IntasPharma and Emcure. A consultant closely involved with the sale process said the deal could be completed in a month.

A Cipla spokesperson declined to comment on specifics but said it continues to look for assets to expand itsbusiness."As a pharmaceutical company, we are constantly in discussions with multiple parties on potentialcollaboration opportunities – in line with our aspiration to drive access and ensure availability of high quality, affordable medicines".

A Sun's spokesperson said the divestment process is under way. "The divestment process is currently in progressas per the CCI order. However, it will be premature to discuss specific details", it added. Mylan officials could not be reached for a comment.

A Natco official, who did not wish to be quoted, said the company was in talks to buy Sun's brands, but there Could be an added complication in the form of a personal investment by DilipShanghvi, the managing director of Sun in Natco. The official said it is unsure if CCI will allow them to buy the brands.

Sun Pharma last year announced the acquisition of Ranbaxy Pharma for $3 billion, making it the largest Drug-maker in India with a total sales of nearly Rs 9,000 crore in the Rs 80,000 crore industry.

The competition watchdog, while examining the deal, for the first time invoked the 'public scrutiny' process as the combined entity might create a monopoly situation in certain life-saving drugs. It gave the company six months to complete the transaction. The diversification does not impact Sun as these brands account for less than 1% of the total sales. In the quarter-ended December 2013, the India sales revenue of Sun was at Rs 1,150 crorewith a 21% growth. Sun Pharma shares fell 2% to Rs 915 on Monday after its earnings missed estimates on Saturday.

Source: *The Economic Times, 17th February 2015*

Lupin's MP Plant Comes Under US FDA Scanner

Concerns raised over output processes at co'sPithampur plant where oral contraceptives are made

The U.S. Food and Drug Administration (FDA) has raised concerns over production processes at a plant that makes oral contraceptives operated by Lupin Ltd(LUPN.NS), India's fourth-largest generic drug manufacturer by sales.

The FDA inspected the plant in January this year, after which it issued the company a so-called Form 483, listing six observations on the manufacturing processes at the plant, Lupin said in a statement on Monday.

Lupin didn't disclose the nature of the observations. Once a Form 483 is issued by the FDA, a company has 15 days to respond before the FDA takes further action.

The FDA's concerns come as India's generic drugmakers continue to face close regulatory scrutiny on their products. In recent months, local plants of firms including Sun Pharmaceutical Industries Ltd (SUN.NS), Dr Reddy's Laboratories Ltd (REDY.NS), and Cadila Healthcare Ltd (CADI.NS) have all come under the FDA's scanner due to production quality issues.

The Lupin plant, at Pithampur in Madhya Pradesh, produces both oral contraceptives and treatments for eye diseases for sale in the United States. The U.S. oral contraceptives market, in which Lupin is a leading supplier, is valued at about $5 billion and the firm has filed for approval of close to 36 products in that segment so far.

Lupin, which started selling oral contraceptives in the U.S. in 2011, said that since the FDA audit it has won U.S. approvals to launch one new drug and transfer production of two existing medicines to the same plant. The company also said it had received FDA approval for a generic version of Allergan Inc's (AGN.N) Lumiganopthalmic solution, which was filed from its Pithampur plant.

The FDA regularly audits plants that export products to the United States. When it issues a Form 483, it outlines conditions or practices at the plant that it believes may cause the products made there to be in violation of its standards.

The Pithampur plant is Lupin's second-largest manufacturing facility exporting to its largest market, the United States. The FDA letter could impact approvals of new drugs made at the plant, analysts at brokerage MotilalOswal said in a note.

Source: *The Economic Times, 24th February 2015*

Gets FDA Nod for Ophthalmic Solution

"Lupin has received approval to market its generic bimatoprost ophthalmic solution in the US Market.

The company said it has received the final approval for its product, a generic version of Allergan's LumiganOpthalmic Solution, from the USFDA.

“Lupin Pharmaceuticals, the company's US subsidiary would commence marketing the product shortly, it added.

The company said filing for the product with the FDA was made from its Indore facility which was audited in January 2015.

Two Lupin facilities, the Lupin Bioresearch Centre, Pune (LBC) and its manufacturing facility at Pithampur, near Indore were audited by the US FDA in November, 2014 and January, 2015, respectively.

The Mumbai-based company's product is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension. Its shares closed 2.5% lower at Rs 1,648.7 a piece on the BSE.

Source: *The Economic Times, 24th February 2015*

Boehringer Wants to Make Drugs Accessible in India

BoehringerIngelheim is weighing several options to make its drugs affordable to patients in India,

where the sensitive subjects of patent protection and affordable access to lifesaving medicines have put multinational pharmaceutical companies against authorities .

“We have to acknowledge that we have to have lower prices in India,” chairman Andreas Barner told ET in

an interview. “However we also have to navigate through the fact that in India, you have very high affluent

population whose income levels can be comparable to that in Germany.”

Thus a section of the population can easily access anyhealthcare facility but the vast majority can’t

afford even the basic requirements.It is to resolve this contradiction that companies like Boehringer

Ingelheimare exploring innovative ways, while protecting their intellectual property rights.

The privately held company said it wants to look at various financing options for patients with different income brackets. It is also considering tie- ups with organisations for financing possibilities. “Apart from absolute amount of money , there is also an issue of cash flow exercise for a patient, whether I pay the entire amount now, or spread it in instalments.

So,we are not restricting ourselves to say that we will only lower the prices,“ said SharadTyagi, its India head. Over the coming months, BoehrinBoehringerIngelheim is expected to launch two drugs in India: Afatinib, used as a first-line treatment against metastatic non-small cell lung cancer, and diabetic drug Jardiance. Cancer drugs are among the most expensive and unaffordable for a majority of Indians. India had issued a compulsory licence to domestic drug manufacturer Natco Pharma two years ago to make and sell a cheaper version of kidney cancer drug Nexavar, a move that had raised concerns among MNCs. While they continue to accuse India of undermining their patents, they are also trying to make their products more affordable through financing options and discounts in developing nations

BoehringerIngelheim, which currently sells only five products in the India said it never had any negative views on the country.

“We never shared the pessimism of other companies; there is an intrinsic value of democracy and India. Therefore, while then I was not too pessimistic, now I won't be too optimistic and say everything is perfect“ saidBarner.

Source: *The Economic Times, 24th February 2015*

Govt Looks to Plug Holes in Swine-flu Drug Distribution

The government is trying to fix the glitches in the fiddly and fragmented drug distribution system of the country that is leading to cases of shortage of swine-flu drugs (Oseltamivir) in pockets, despite the sufficient manufacturingcapacity of Indian drugmakers.

After a meeting with the Drug Controller General of India on Tuesday the All India Organisation of Chemists and Druggists (AIOCD) is now telling thousands of chemists with a valid licence (to stock tightly regulated swine-fluDrugs enlisted in schedule X of the drug law) to procure directly from company appointed distributors and agents to save time, said the drug trade body's general secretary Suresh Gupta.

This means doing away with the link of stockiest in the four-layered drug supply chain and speeding up the delivery of the drug from Pharma units to retailers who are entitled to sell it.

"We are also governed by the Essential Commodities Act and in emergency situation, we will do anything possible within law to make the drug available. We are also urging stakeholders to use fast courier services to deliver the drug " said Gupta.

The drug regulator is also identifying districts where there is no valid licence holding chemist and talking to the states and local administrations to fast-track the grant of schedule X licences in those areas to make the drug available according to people familiar with the move.

There are over 2,800 valid schedule X licence holder pharmacies in the country but their distribution across states and districts is highly uneven. For instance Sikkim has over 60 such stores while Bihar has just four, even though it's over 150 times more populous than Sikkim. Also ET found out by talking to chemists that not every such store with schedule X has ready stocks of this flu drug, another loophole the government said it is trying to plug.

There is no shortage of the drugs. We are doing our best to maintain availability of the drug at licenced stores through our frequent meetings and communications with Pharma companies, state drug regulators, trade bodies representing chemists and other stakeholders," said a government official.

The government fears that if it relaxes the rules around the drug, it may lead to abuse and resistance, a much bigger challenge to grapple with."if we relax the stringent rules, the market will be flooded with the drug and rampant and unchecked misuse of the drug may result in resistance, whichwill be much more damaging" the official said.

People today are not aware of the stores with valid licences, so they end up searching for the drug in four-five unlicenced outlets and get frustrated", said Gupta

Several leading domestic Pharma companies including Cipla,Hetero and Strides Arcolabs make this drug in sufficient quantities. A senior executive at one of these firms said on the condition of anonymity that at full capacity his firm can churn out over six lakh tablets and over six tons of bulk drugs in a single day.

Source: *The Economic Times, 20th February 2015*

India May Miss Pharma Export Target as Biz Climate Changes

India's pharmaceutical exports may fall short of target this fiscal year because of delayed regulatory approvals and consolidation of pharmacy players in North America and steep depreciation of currencies in emerging markets like Russia, Ukraine and Venezuela, say commerce ministry officials.

The Pharmaceutical Exports Promotion Council of India (Pharmexcil), which comes under the commerce ministry, now estimates the pace of growth to halve to around 5 per cent in the year through March from the original projection at least 10 per cent.

Several Indian drug exporters, including large listed companies, which suffered subdued sales growth over past few quarters, are projecting no significant change in sales and profit over the next few quarters.

The US accounts for nearly 40 per cent of the global pharma sales of $980 billion. India's drug makers export more than $4 billion (Rs 24,970 crore) of products to the US out of their annual exports of around $15 billion.

While large firms like Ranbaxy Laboratories, Sun Pharmaceutical Industries, Dr Reddy's Laboratories and Lupin account for around $3 billion of exports to the US, the rest comes from dozens of mid- and small-sized drug makers.

"Delays in regulatory approvals and consolidation of pharmacy players are among the challenges in the US market," said Lupin's chief financial officer Ramesh Swaminathan. This is hurting growth in exports, he said. "Consolidation of pharmacy players in the US market is also affecting the profit margins of the drug exporters."

Glenmark chairman and managing director Glenn Saldanha said growth will continue to be a challenge in the US unless the approval process picks up, adding to the pressure on margins owing to ever increasing competition.

"Russia and other CIS markets like Ukraine are witnessing a slowdown in demand and the pharma market here has de-grown as compared to last year," he said.

"Product approval delays and the devaluation of currencies due to political factors have added to the woes of companies operating in the region."

To highlight the increasing pressure on Indian generic drug makers, analysts cite the global alliance among three large pharmacy distributors - Walgreen, Alliance Boots and Amerisource-Bergen - in early 2013.

They also refer to the joint venture between the second-largest US wholesale distributor, Cardinal Health, and CVS Caremark in December 2013 and the US pharmacy McKesson's announced acquisition of US distributor Celesio in January 2014

"Such consolidations in the US pharmacy market have created a few dominant players with better bargaining power which has accentuated pricing pressures for generic companies in an already competitive market," Kotak Securities' analyst MeetaShetty wrote in a recent report.

The prices of highly genericised drugs decreased 20-30 per cent over the past 19 months, the report said.

Pharmexcil Director-General PV Appaji said the commerce ministry had earlier estimated growth of at least 10 per cent in Indian pharmaceuticals exports.

"Going by the global cues, the estimates seem difficult to achieve. We may hardly cross $16 billion of exports this fiscal (year)," he told ET. India's pharma exports had totaled about $15 billion in fiscal 2014.

During the first nine months of the current fiscal

year, India reported $11.52 billion of drug exports, translating into growth of around 4.34 per cent over the same period last fiscal year.

A pharma analyst with a foreign brokerage said the possibility of Indian pharma exports crossing $16 billion also appeared difficult given the muted growth suffered by some of the large Indian pharma companies, including Ranbaxy, Dr Reddy's and Lupin in the US market and emerging markets like Russia.

"Widespread regulatory actions by overseas regulators could affect exports, "ndia Ratings said in a report on Monday.

Source: *The Economic Times, 14th February 2015*

India May Miss Pharma Export Target as Biz Climate Changes

India's pharmaceutical exports may fall short of target this fiscal year because of delayed regulatory approvals and consolidation of pharmacy players in North America and steep depreciation of currencies in emerging markets like Russia, Ukraine and Venezuela, say commerce ministry officials.

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Stronger IPR is about Big Pharma Profits, Not Health: Joseph Stiglitz

Nobel laureate for economics Joseph Stiglitz has strongly argued against US pressure on India's intellectual property regime. Stiglitz, along with his colleagues Dean Baker and ArjunJayadev, spoke on the controversial issue of patents and public interest in India.

You say patents stifle innovation. How do they do that?

If patent rights are too strong and maintained for too long, they prevent access to knowledge, the most important input in the innovation process. In the US, there is growing recognition that the balance has been too far tilted towards patent protection in general (not just in medicine). The growing problem of patent trolls is an example. Firms have to maintain a buffer to protect themselves against lawsuits by patent owners who may never have intended to produce a product at all.

Given India's limited health budget, would US-style IP protection support its public health goals and needs?

India has already increased patent protection on medicines relative to a few decades ago by acceding to TRIPS (Trade-Related Aspects of Intellectual Property Rights Agreement). Greater IP protection for medicines would, we fear, limit access to life-saving drugs and seriously undermine the very capable indigenous generics industry that has been critical for people's well-being in not only India but other developing countries as well. The government would face impossible choices: spending more money to provide drugs that people need for survival at the exorbitant prices charged by the drug company, and thus taking away money that could be used for education or other developmental objectives, or letting people die.

Are Americans also affected by the US patent system?

Yes. A prominent example is of Myriad Genetics that isolated and patented two human genes that can contain mutations that predispose women who

carry them to breast cancer. Information about whether you carry the gene is critical for early detection and prevention. The patent allowed it the right to prevent others from testing for these genes. Although the test can be done very cheaply, women were unable to do so at an affordable price because of the patent. Some would surely die because of this or others be severely financially penalized for simply finding out whether something they actually 'own' (their own genes) is present in their body because it is the property of a corporation.

How would India be hit by adopting data exclusivity, as sought by the US?

Data exclusivity is in many ways a stronger form of monopoly protection than patents. It prohibits drug regulators, while approving generic medicines, from relying on prior clinical test results showing that a drug is safe and effective. A generic producer wanting to get its drug approved during the period of exclusivity (which could be from 5-12 years if the US government gets its way) would have to perform its own clinical trials which is both expensive and unethical.

The effect of data exclusivity will be higher prices, extended monopoly protection for patented drugs and possibly monopolies for off-patent drugs. High prices also give drug companies more incentive to misrepresent the safety and effectiveness of their drugs. While pharmaceutical companies may claim that it would give them a greater incentive to research new drugs, such R&D is unlikely to be directed at public health needs of developing countries and any hypothetical gains will likely be dwarfed by the additional costs of delayed generic competition.

Whose interest does the US trade representative serve when it pressurizes India to adopt stronger IP rights?

Clearly, the direct beneficiaries are the US pharmaceutical industry. It can be argued that by increasing industry profits there will be more incentive to innovate, but this chain of causation is weak at best. This is about profits of Big Pharma — not jobs, innovation or health.

What is the danger in India signing bilateral trade pacts with developed nations or joining mega-FTAs like the Trans-Pacific Partnership Agreement?

The biggest problem is the lack of transparency. After being negotiated largely behind closed doors, these agreements will be brought out for national parliaments to approve on an all-or-nothing basis. The worst provisions are those related to IP and "investment protection", which pose a risk for regulations intended to protect health", the environment, workers, and consumers.

Source: *The Times of India, 1st March 2015*

Natco Pharma Ties up with Gilead on Hepatitis C Drug

Natco Pharma Ltd., the Indian drugmaker that had challenged Gilead Sciences Inc.'s patent claims on a blockbuster hepatitis C treatment in the Asian country, said it signed a licensing agreement with the US company for the drug.

The agreement allows Natco to manufacture and sell generic versions of Sovaldi and combination therapies using the active ingredient in the medicine in 91 developing countries, the Indian company said in a statement on Monday.

The agreement expands on a pact Gilead made with eight other Indian drug makers to make the

drugs for mainly low-income countries including India, Indonesia, Cambodia and many nations in Africa. The agreement with Natco could help ensure the Hyderabad-based company won't challenge its patent on the $10 billion drug.

"Natco will now back off its aggressive stance on the patent," said Hitesh Mahida, an analyst at Antique Stock Broking in Mumbai. "Gilead wouldn't have agreed to license the product to them earlier -- Natco is a small company, it doesn't have the international clout of companies like Cipla. They got noticed by doing this patent challenge."

Natco shares rose as much as 5% to Rs 1,442.6 in Mumbai on Monday. M. Adinarayana, a company spokesman, didn't immediately respond to an e-mail and a call to his mobile phone seeking comment. "The launch of generic Solvadi will be competitive, but the market is huge in the countries covered by these licenses -- India, Egypt," Mahida said. "This is a huge opportunity."

The Indian patent office rejected a key patent claim on Sovaldi in January. Natco was challenging another patent claim on the grounds that the therapy "lacks novelty" and lacks an "inventive step," according to a filing with the patent office. The Initiative for Medicines, Access & Knowledge, a group of scientists and lawyers, has opposed the patent on similar grounds.

Source: *The Times of India, 3rd March 2015*

ChikungunyaVaccine Using Measles Virus Promising

A vaccine against chikungunya that is based on a measles vaccine virus has shown encouraging results in its first human trial.

There is currently no approved vaccine against chikungunya. The candidate vaccine reported this week in *The Lancet Infectious Diseases* is only the third to go into clinical trials.

The vaccine, developed by Themis Bioscience, an Austrian biotechnology company, utilises a live but weakened measles vaccine virus, the Schwarz strain. The genetic material of this virus has been modified to incorporate five structural genes taken from a chikungunya virus.

When injected, this modified virus infects cells, which then churn out chikungunya proteins that assemble into virus-like particles and are secreted. The virus-like particles are able to activate the immune system, giving it the capability to recognise and respond to a chikungunya infection.

Use of the Schwarz strain was “a good technique,” observed Penny Rudd and Suresh Mahalingam of Giffith University, Australia, in a commentary published in the same journal. “The measles virus vaccine is one of the safest on the market and has been mass-produced at low cost in many countries since the early 1960s,” they noted.

After the vaccine's efficacy was demonstrated in laboratory mice, Phase 1 clinical trials were carried out at the Medical University of Vienna in Austria. The tests were carried out on 42 healthy men and women. The vaccine was administered at three different doses (low, medium and high), with a second booster immunisation given either 28 or 90 days after the first injection.

All doses of the candidate vaccine were effective. However only 44 per cent of participants in the low-dose group developed antibodies against chikungunya after the first injection, compared to 92 per cent and 90 per cent in the medium- and high-dose groups. But after the subsequent booster

injection, all participants produced such antibodies, according to the paper by KatrinRamsauer and colleagues.

The trial also showed that pre-existing measles immunity did not block the vaccine and prevent recipients from generating antibodies against chikungunya.

"We are currently working on the preparation of Phase 2 trials" scheduled to start later this year, said Erich Tauber, Chief Executive Officer of Themis Bioscience, in an email.

The first chikungunya vaccine to go into human trials was developed at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and utilised a live, weakened form of the chikungunya virus itself. A report on its Phase 2 trials was published in 2000.

Despite this, unfortunately "the first vaccine fell victim to a lack of funding and marketable interest," noted Dr. Rudd and Dr. Mahalingam.

Last year, scientists at the National Institute of Allergy and Infectious Diseases in the U.S published results from the Phase 1 trial of their vaccine. The vaccine used virus-like particles generated from three surface proteins of the chikungunya virus (see 'Chikungunya vaccine shows promise,' *The Hindu*, August 21, 2014).

Consequently, along with the vaccine from Themis Bioscience, there are at present two candidate vaccines against chikungunya that can go into Phase 2 trials.

Source: *The Hindu, 5th March 2015*

Targeting drugs to diseased heart shows promise

In an exciting finding that holds potential for on-target drug delivery to an afflicted cardiac tissue and prevent heart attacks, Indian scientists have successfully delivered therapeutics to a diseased myocardium through a nanoparticle-tagged peptide, which resulted in improved functioning of the heart.

The scientists have filed a patent for the finding, which was published in the*Journal of Controlled Release*.

"I am excited. There is huge potential from bench-to-bedside translation", said Dr. SagartirthaSarkar, lead scientist and Associate Professor, Genetics and Molecular Cardiology Laboratory, Department of Zoology, University of Calcutta. Observing that there was currently no drug which could treat heart ailment by directly targeting the heart tissues, he said most of the drugs were directed to related problems like diabetes and hypertension. And in most cases, the drugs that treat cardiac conditions have toxic effect to other organs.

While surgical intervention was the only option available so far, the other alternative of gene therapy too was ineffective due to associated problems like tumourigenesis. He said that research has already shown that knocking down P-53, (a tumour suppressing gene) would improve cardiac functioning considerably. But it would at the same time lead to tumours all over the body.

Dr.Sarkar said his lab has been looking at the role of different genes in propagating various regulators that ultimately lead to a heart attack.

In a bid to overcome therapeutic challenge in treating cardiovascular dysfunction, the researchers in this study delivered through a nanoparticle a small peptide that not only penetrated the tissue but was specific to heart cells, cardiomyocytes. .About 80 per cent of the heart cells consist of cardiomyocytes which give

contractility.

He said two animal models with compromised heart function due to cardiac hypertrophy were used in the study. Through the nanoparticle-tagged peptide, the drug was delivered through the tail vein. "To our surprise, we found that it not only improved cardiac function significantly but the p-53 gene was suppressed only in heart without causing tumourigenesis in other parts of the body".

He said they now plan to reduce the size of peptide so that it could become commercially viable. "We are the first ones to report that you can successfully target the heart tissue in a living animal", he added.

Dr.UtpalBhadra of the Centre for Cellular and Molecular Biology said for the first time it was shown that cardiovascular disease could be treated with siRNA molecule.

Centre for Chemical Biology, Indian Institute of Chemical Technology, CCMB, Department of Chemistry, IIT, Kharagpur and Division of Virology, National Institute of Cholera and Enteric Diseases, Kolkata are the institutions that collaborated in the study.

Source: *The Hindu, 5th March 2015*

Sun Pharma to Buy Opiates Business of GSK in Australia

Sun Pharmaceutical Industries and global pharmaceutical major GSK, on Tuesday, announced an agreement, whereby Sun will acquire GSK's opiates business in Australia.

A joint statement by the two companies said that their respective wholly-owned subsidiaries had reached an agreement related to GSK's opiates business in Australia.

According to the agreement, the current GSK opiates business, including related manufacturing sites in Latrobe (in the State of Tasmania) and Port Fairy (in the State of Victoria) and its portfolio of opiates products along with inventory, will transfer to a subsidiary of Sun Pharma. GSK's product portfolio consists of poppy-derived opiate raw materials, used primarily in the making of analgesics to treat moderate to severe pain.

The statement said all employees from both sites would be offered employment by Sun.

The transaction is expected to allow GSK to simplify its operations in Australia and allow it to focus on delivering its innovative product portfolio that will be central to the company's growth strategy there.

Details of the transaction were not disclosed, but it is expected to close by August, subject to customary closing conditions and requisite regulatory and other approvals.

Sun Pharma has an established footprint in Australia.

"The global opiates market holds good potential and the addition of GSK's opiates business will strengthen our positioning further," Sun Pharma Executive Vice President (API business) Iftach Seri said in a statement.

"The acquisition is a part of our strategy towards building our portfolio of opiates and accessing strong capabilities in this segment," the statement added.

Source: *The Hindu, 4th March 2015*

Approval for 2 Ranbaxy Drugs Cancelled in US

Approvals granted to Ranbaxy by the US Food and Drug Administration (USFDA) for marketing generic versions of two blockbuster medicines and the 180-day marketing exclusivity stand cancelled. The DC Federal Court in the US has upheld the USFDA's decision to revoke tentative approvals given to the company for the generic versions of AstraZeneca's digestive disorder drug Nexium and Roche's antiviral Valcyte.

SarabjitKourNangra, VP research (Pharma), Angel Broking said, "The decision is a lost opportunity for the company as it stands to lose potential sales of over $1 billion for that exclusively period six months for both the drugs together".
In November last year, Ranbaxy had sued USFDA over evoking an approval to sell the generic drugs.

Source: *The Times of India, 4th March 2015*

Bar Code on Drug Packaging to Track and Trace Authenticity

To ensure medicines sold in the country are genuine products, the health ministry has developed a 'Track and Trace' mechanism which will enable consumers to check safety and authenticity of a drug through the internet.

Under the system, the primary, secondary and tertiary packs of medicines will carry a unique bar code, which will be allotted to each manufacturer. Consumers, buying medicines from retail pharmacy store, can use the bar code on the pack on internet to check information about the source of manufacturing of the product, whether it is an approved drug, it's date of expiry as well as price fixed by the government etc.

The move is significant because of the highly fragmented Indian pharmaceutical market, pegged at around Rs 89,000 crore annually. The huge size of the market makes it difficult for regulators and monitoring agencies to track medicines, mainly in rural areas and distant villages. This leads to a potential risk of spurious, inefficacious and low quality medicines being sold in the market.
The government is yet to finalise a date for launching the 'Track and Trace' system in the local market, Union health minister J P Nadda said companies will be given a reasonable time for transition to the new packaging system. "Rules for implementing the Track and Trace mechanism will be framed and will be operationalized after allowing a reasonable period for transition," Nadda said. He added, compliance will be mandatory for all drug manufacturers.

Following allegations from some international markets that spurious medicines are making their way from India, the commerce ministry in 2012 had made it mandatory for pharmaceuticals exporters to have bar- coding for secondary and tertiary packaging on their export consignments. India is one of the largest exporters of low cost generic medicines to many countries including developed markets like the US and Europe. During 2013-14, Indian pharmaceutical exports were at $14.8 billion. Now, the government is also working to create an integrated database with all details of a product, which will enable tracking and monitoring of these products.

Source: *The Times of India, 14th March 2015*

Shasun Pharma to Exit Alivira

Shasun Pharmaceuticals plans to sell its stake in veterinary products venture Alivira Animal Health for about Rs.75 crore to the other shareholders of the venture following Shasun's merger with Strides Arcolab. In Alivira, Sequent Scientific held 73 per cent and Shasun the balance. This venture is focussing on veterinary products, including active pharmaceutical ingredients and formulations.

Private equity firm Ascent Capital picked up a undisclosed minority stake in the venture.

Shasun had invested Rs.63 crore in the venture.

"Considering the proposed merger of the company (Shasun) with Strides Arcolab, and since the animal health business is not the main focus of the merged entity, it is proposed to sell the investment to the other shareholders of Alivira Animal Health for a consideration of not less than Rs.75 crore," Shasun said in a postal ballot note to shareholders.

The sale proceeds will be utilised for repayment of term loans, it added.

Source: *The Hindu, 18th February 2015*

Fairness Creams, Unfair Results

For K Radha, her dream of becoming fair and beautiful' was ensconced in the squished tube that her neighbour had given her. The domestic help slathered herself with it twice a day. In a few days, her complexion became lighter, but only a week later the real effect showed: dark pigments surfaced on her skin, which soon became itchy eruptions.

What the 32-year-old didn't know was the 'wonder-cream' contained topical steroids ?used to treat extreme skinconditions under the supervision of a dermatologist ? and its sale over the counter is banned across the world, including India. "My neighbour had bought it from a pharmacist who told her she would become fair," she said.

It is not just over the counter (OTC) sales of drugs that is worrying doctors. The free availability of ointment containing topical corticosteroids without a prescription has resulted in many of these brands becoming household names as 'fairness' cream and no longer seen for their therapeutic value. "These creams, when used indiscriminately, reverses the effect and causes more damage to the skin," said Dr KN Sarveswari, a consultant dermatologist and member of the Indian Association of Dermatologists, Venereologists and Leprologists.

Doctors say pharmacies are not the only culprits. Beauty parlours, too, are turning into dispensaries. "In the beginning it may seem like your face looks brighter and fairer. But after a few applications, the acne returns, and this time it leaves a rash or a scar that could remain," said Dr.Sarveswari.

The most common side-effects include thinning of skin, extreme sun sensitivity, patchy skin, excessive facial hair growth and eruptions. In most cases, they don't identify the tube in their hand as the villain. "They use it for a long time to see that initial glow. And by the time they come to us, the scars are already deep," said DrSarveswari. Doctors say sometimes correct prescriptions are misused by repeatedly using it to get the same ointment from the chemist.

Worse, the user becomes increasingly dependent on the cream and suffers from withdrawal symptoms. "They refuse to give up. Their drive for fair skin is that deep-rooted," said Dr S M Augustine, who retired from the dermatology department at the Government General Hospital. He recently saw a 10-year-old girl with her blood vessels showing on her skin. "She was brought for a rash on her leg. When I spoke to her mother, she told me she also applied the prescribed cream on the child's face, hoping she would become fair. I was shocked. Her vessels showed because her skin had become thin," he said.

Source: *The Times of India, 7th March 2015*

Duty on Imported Med Devices May Be Raised

Medical devices such as stents, pacemakers and catheters may soon become expensive. The government is likely to increase basic custom duty by 5% on imported medical devices in the upcoming Budget, official sources said.

At present, the customs duty on imported medical devices varies from 5% to 10%, depending on the usage. These devices are broadly classified into three categories. While the duty is lower at 5% for high-end medical equipment such as MRI machines and CT scanners mostly used in hospitals and radiology laboratories, imported disposables such as syringes, catheters, etc have 10% customs duty. Implants such as stents and pacemakers also have a 5% basic customs duty.

According to sources, the government's proposal to increase the duty is aimed at encouraging companies to manufacture in India in line with Prime Minister NarendraModi's 'Make in India' mission.

However, the industry feels creating tariff barriers will not help indigenous manufacturing. Instead, it would lead to a hike in prices of medical devices, which as it is contributes significantly to healthcare costs for patients.

"Most of these devices that are imported are not being manufactured in India currently. Therefore, an increase in customs duty would not help manufacturing here, instead it may work against the government's FDI policy," Poly Medicure MD HimanshuBaid said.

India imports 80% of medical devices used here. Recently, the government allowed 100% foreign direct investment in medical devices through automatic route, as part of a strategy to not just reduce imports but also promote local manufacturing for the global market, which will be worth over $400 billion next year. Besides the customs duty hike, the medical devices sector may also witness certain incentives such as separate testing laboratories and a manufacturing hub with tax incentives in Gujarat, “Government must create the right infrastructure to promote indigenous manufacturing. 'Make in India' has to be a comprehensive plan, “siad Terumo MD Probir Das.

Source: *The Times of India, 25th February 2015*

Antibiotic Use for Sore Throat Makes TB Cure Tougher

For tuberculosis patients, the second course of treatment is often the last line of defence. Rampant abuse of an antibiotic that is prescribed for respiratory ailments is helping the bacteria breach that boundary.

Public health experts are on tenterhooks on how to handle the emergence of multi-drug resistant tuberculosis (MDR-TB, where the strain is unaffected by isoniazid and rifampicin, two powerful first-line drugs). A study has now found high prevalence of resistance to ofloxacin that forms the backbone of the second line of treatment. This, they believe, is because some doctors prescribe the drug for ailments as minor as sore throat.

Ofloxacin, an antibiotic belonging to the fluoroquinolone class, is commonly prescribed for bronchitis, urinary tract infections, skin infections and pneumonia. The study, done by the National Institute for Research in Tuberculosis, covered 2,425 patients enrolled and treated under the Revised National Tuberculosis Control Programme (RNTCP) across Tamil Nadu. It studied the extent of antimicrobial resistance to four key anti-TB drugs - isoniazid, rifampicin, ofloxacin and kanamycin.

Source: *The Times of India, 6th March 2015*

PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

Approval of the Bachelor of Pharmacy (B.Pharm course) under the Pharmacy Act, 1948

The Bachelor of Pharmacy (B.Pharm) Course Regulations, 2014 have come into force with effect from the 10th December 2014. It is hereby informed that-

For New Institutions

- No person, institution, society, trust or university shall start and conduct the B.Pharm programme for the purpose of registration as a pharmacist under the Pharmacy Act, 1948 without the prior approval of the Pharmacy Council of India (PCI).

- Any authority desirous of obtaining the permission of the PCI for starting of the B.Pharm course from 2016-2017 academic session under sub-section 1 of section 12 of the Pharmacy Act, 1948 shall apply, to the PCI in the prescribed proforma (SIF-B) available on Council's website www.pci.nic.in with complete documents during the period from 1st August to 31st August 2015. Applications received after 31st August, 2015 will be summarily rejected.

For already exisitng institutions running B.Pharm course without obtaining prior approval of the PCI

- Any authority which is already running the B.Pharm course without the prior approval of the PCI is hereby required to apply in prescribed proforma (SIF-B) available on the Council's website www.pci.nic.in with complete documents so as to reach the PCI by 31.5.2105 positively.

- Please note that no further opportunity will be provided by the PCI in this regard in the light of stautory provisions of The Bachelor of Pharmacy (B.Pharm) Course Regulations, 2014 under Regulation 9(1).

- In the event of failure, the institution will run the B.Pharm course at its own risk and responsibility and the students will not be eligible form registration to practice the profession of pharmacy under the Pharmacy Act, 1948.

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Source: *The Hindu, 14th March 2015*

PALIAMENT QUESTION - ANSWERS
LOK SABHA
MINISTRY OF HEALTH AND FAMILY WELFARE

Question No. 4547
Answered on 19.12.2014

QUALITY AND SAFETY OF GENERIC DRUGS

4547 **Gavit Dr. Heena Vijaykumar**

Mahadik Shri Dhananjay Bhimrao, Satav Shri Rajeev Shankarrao, Patil Shri Vijaysinh Mohite, Sule Smt. Supriya Sadanand, Mahto Dr. Banshilal

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether certain pharmaceutical companies are reported to be manufacturing and marketing untested generic drugs in the country, and if so, the details thereof;
(b) whether the Indian Council of Medical Research have taken up the matter with the Drug Controller General of India (DCGI) for action against such erring companies, and if so, the details thereof;
(c) the action taken/proposed to be taken by DCGI against such pharmaceutical companies; and
(d) the measures being taken by the Government to ensure the safety, quality and efficacy of generic drugs in the country?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a): The Government is aware of the reports appearing in the media regarding manufacturing of generic versions of some drugs without proper testing.
(b): Yes.
(c): Action as permissible under the Drugs & Cosmetics Act, 1940 and the rules made thereunder, will be taken by Drugs Controller General (India) after verification of facts.
(d): The manufacture for sale of drugs is regulated through a system of inspection and licensing under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. The manufacturer is required to comply with the conditions of license and follow the Good Manufacturing Practices (GMP) to ensure that the drugs manufactured by them are of standard quality. One of the conditions of the license is that the licensee shall either in his own laboratory, or in any other laboratory approved by the Licensing Authority, test each batch of the raw material used by him for manufacturing products as also each batch of the final product and shall maintain records showing the particulars of such tests.

MINISTRY OF CHEMICALS AND FERTILIZERS

Question No. 446
Answered on 25.11.2014

REGARDING RISE IN PRICES OF DRUGS

446 **Nete Shri Ashok Mahadeorao, Mani Shri Jose K. Lokhande Shri Sadashiv Kisan**

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether inordinate increase has been made in the prices of certain drugs/lifesaving drugs such as cancer, diabetes and medicines for HIV patients in the country;

(b) if so, the details thereof and the reasons therefor along with the steps taken to curb /control/reduce the prices of drugs during each of the last three years and the current year, State/UT-wise;

(c) the percentage of increase made in the prices of each drug;

(d) whether the Government has set up/proposes to set up any high powered Committee for reviewing the price control mechanism of drugs;

(e) if so, the details thereof; and

ANSWER

MINISTER OF CHEMICALS & FERTILIZERS (SHRI ANANTH KUMAR)

(a) to (c):

The Government has notified Drugs (Prices Control) Order, 2013 (DPCO, 2013) on 15.05.2013. The list of medicines specified in the 'National List of Essential Medicines, 2011 (NLEM)' included in the First Schedule of DPCO, 2013

(b) also covers drugs used in the treatment of cancer, diabetes and medicines for HIV patients. Ceiling price for 489 medicines have been fixed under provision of DPCO, 2013. No person is authorized to sell any such formulation to any consumer at a price exceeding the ceiling price fixed by the NPPA. Also, the existing manufactures of these scheduled formulations selling at a price lower than the ceiling price so fixed by the NPPA are required to maintain their existing maximum retail price with the annual increase in maximum retail price as per the increase in the wholesale price index with respect to previous year. In respect of other medicines not covered under scheduled category of DPCO, 2013, the manufacturers are allowed to increase in maximum retail price upto 10 percent annually. As such, there is no specific information available regarding inordinate increase in the price of Life Saving drugs.

(d) &(e):

No, Sir.

Question No. 406
Answered on 25.11.2014

MEDICAL DEVICES

406 Raghavan Shri M. K.

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) Whether the National Pharmaceutical Pricing Authority (NPPA) has been authorized to monitor the cost and sale of medical devices in the country;

(b) If so, the details thereof and the manner in which the cost of medical devices has been fixed; and

(c) If not, the reasons therefor and remedial steps taken by the Government in this regard?

ANSWER

MINISTER OF CHEMICALS & FERTILIZERS (SHRI ANANTH KUMAR)

(a) National Pharmaceutical Pricing Authority (NPPA) is authorized to monitor the cost and sale of only those medical devices which are considered as drugs as per the provisions of the Drugs & Cosmetics Act.

(b) & (c)

Two medical devices notified as drugs namely condom and IUD containing copper are included in the First Schedule of the DPCO, 2013 and their prices have been fixed by NPPA as per the provisions in the said order.

Question No. 366
Answered on 25.11.2014

PRICES OF IMPORTED MEDICINES

366 Sreeramulu Shri B. Bhuria Shri Dileep Singh

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) Whether the prices of imported and patented medicines fixed by the National Pharmaceuticals/Pricing Authority is higher vis-à-vis the same medicine produced indigenously:

(b) If so, the details of thereof and foreign exchange earned on account of import of finished medicines, during each of the last three years; and

(c) The steps taken in cooperation with the Drug Controller General of India to stop draining of foreign exchange?

ANSWER

MINISTER OF CHEMICALS & FERTILIZERS ((SHRI ANANTH KUMAR)

(a) The ceiling prices fixed / notified by the NPPA in respect of scheduled formulations under Drug Prices Control Order, 2013 are applicable to both imported and indigenously produced medicines.

(b) & (c)

Information is being collected and will be laid on the table of the House.

Question No. 299
Answered on 25.11.2014

MANUFACTURING OF API

299 Jaiswal Dr. Sanjay

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the Government has taken any steps to encourage manufacturing of Active Pharmaceutical Ingredient (API) required for production of the essential medicines in the country;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

ANSWER

MINISTER OF CHEMICALS AND FERTILIZERS(SHRI ANANTH KUMAR)

(a) Yes, Sir.

(b) to (c)

In a meeting held in Prime Minister's Office on 08.10.2013, it was decided to set up a Committee of Secretaries under the Chairmanship of Secretary, Department of

Health Research to study and identify the Active Pharmaceutical Ingredients (APIs) of critical importance and to workout a package of interventions/concessions required to build domestic production capabilities, and examine the cost implication. In addition to the Chairman, the Committee comprises of Member Secretary, National Manufacturing Competitiveness Council (NMCC), Secretary, Department of Pharmaceuticals, Secretary, Department of Health, Secretary, Department of Commerce and Secretary, Department of Industrial Policy & Promotion. The report of the said Committee is awaited.

Question No. 259
Answered on 25.11.2014

IMPLEMENTATION OF DPCO

259 Innocent Shri Biju Shri Parayamparanbil Kuttappan, Sampath Shri Anirudhan

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) Whether the Government proposes to decrease the price of 350 essential medicines under the Drugs (Prices Control) Order, 2013;
(b) If so, the details thereof;
(c) The time by which said proposal is likely to be implemented;
(d) Whether the Government has any proper mechanism to ensure the proper working of DPCO, 2013; and
(e) If so, the details thereof and the total number of pharma companies forced to close their establishments, company-wise?

ANSWER

MINISTER CHEMICALS & FERTILIZERS (SHRI ANANTH KUMAR)

(a)to (c)

All the medicines specified in the National List of Essential Medicines 2011 (NLEM) have been included in the First Schedule of DPCO, 2013 and brought under price control.

Significant reduction in prices have been effected on the medicines notified under DPCO, 2013 as compared to the highest price prevailed prior to the announcement of DPCO, 2013. The details of price reduction are as follows:

% reduction with respect to Highest prevailing Price to the Retailer	No. of drugs
0<= 5%	46
5<=10%	44
10<=15%	53
15<=20%	43
20<=25%	62
25<=30%	55
30<=35%	30
35<=40%	34
Above 40%	112
Total	489

(d) & (e)

Yes, Sir. The prices under DPCO, 2013 are fixed and monitored by National Pharmaceutical Pricing Authority (NPPA),as per the powers delegated to them. Further Para 31 of DPCO, 2013 provides that any person aggrieved by any notification issued or order made under paragraph 4,5,and 6 of this Order, may apply to the Government for a review of the notification or order within a period of thirty days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper.

This Department has not received any information from any company which has been forced to close their establishment due to implementation of DPCO, 2013.

Question No. 245
Answered on 25.11.2014

DEPENDENCY OF DRUGS ON CHINA

245 Galla Shri Jayadev

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether India is depending on China for its drug ingredients as highlighted by the Report of Boston Consulting Group and CII;
(b) if so, the reason therefor;
(c) whether it is true that fifteen essential drugs manufactured in the country are dependent on the ingredients from China and if so, the details thereof;
(d) whether the Government has set up/proposed to be set up an expert committee for the purpose; and
(e) if so, the details of recommendations made by the committee and the follow up action taken by the Government on the recommendation made by the committee?

ANSWER

MINISTER OF CHEMICALS AND FERTILIZERS (SHRI ANANTH KUMAR)

(a) to (c):

As per the records available with the Department of Pharmaceuticals in case of 12 essential drugs as defined in National List of Essential Medicines 2011, there is significant dependence on imports for the drug ingredients and 80-90% of these imports are from China. These essential drugs include -

i. Paracetamol
ii. Metformin
iii. Ranitidine
iv. Amoxicillin
v. Ciprofloxacin
vi. Cefixime
vii. Acetyl salicylic acid
viii. Ascorbic acid
ix. Ofloxacin
x. Ibuprofen
xi. Metronidazole
xii. Ampicillin

The decision to import and the country of origin for such imports are based on economic considerations.

(d) to (e):

In a meeting held in Prime Minister's Office on 08.10.2013, it was decided to set up a Committee of Secretaries under the Chairmanship of Secretary, Department of Health Research to study and identify the Active Pharmaceutical Ingredients (APIs) of critical importance and to workout a package of interventions/concessions required to build domestic production capabilities, and examine the cost implication. In addition to the Chairman, the Committee comprises of Member Secretary, National Manufacturing Competitiveness Council (NMCC), Secretary, Department of Pharmaceuticals, Secretary, Department of Health, Secretary, Department of Commerce and Secretary, Department of Industrial Policy & Promotion. The report of the said Committee is awaited.

Question No. 128
Answered on 02.12.2014

ESSENTIAL MEDICINES AND FORMULATIONS

128 Basheer Shri E. T. Mohammed Patil Shri A.T. (Nana)

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the Government proposes to broaden the mandate of the National Pharmaceutical Pricing Authority (NPPA) and include all the 348 essential medicines and 680 formulations listed by the Department of Pharmaceuticals under its ambit;
(b) if so, the details thereof and if not, the reasons therefor along with the details of action being taken by the Government thereon;

(c) whether a number of life saving and other patent/branded drugs including those for treatment of cancer, AIDS, diabetes etc. are outside the ambit of the above authority and if so, the details thereof and the reasons therefor; and
(d) whether the Government proposes to include such drugs under its fold and if so, the details thereof?

ANSWER

MINISTER OF CHEMICALS & FERTILIZERS (SHRI ANANTH KUMAR)

(a) to (d):
A statement is laid on the Table of the House. Statement referred to in reply to Lok Sabha Starred Question No.128 for answer on 02/12/2014 regarding Essential Medicines and Formulations
(a) and (b):
Government of India notified Drugs (Price Control) Order 2013 (DPCO 2013) on 15.5.2013. As per DPCO 2013, 680 medicines based on 348 bulk drugs / active pharmaceutical ingredients with specified dosage and strength are contained in Schedule I and the prices of these formulations
are fixed by National Pharmaceutical Pricing Authority (NPPA) as per the provisions contained in DPCO 2013.
(c) and (d):
NPPA is authorized to fix the prices of drugs contained in the National List of Essential Medicines and included in the first schedule of DPCO 2013. The prices fixed by NPPA are applicable to both branded as well as generic versions of the drug. Patented drugs enjoy market exclusivity till their patent is valid. The NPPA has already fixed prices of 47 medicines of Cancer, 19 of AIDS and 3 of Diabetes which are part of Schedule-I of DPCO 2013.

Question No. 1603
Answered on 02.12.2014

MECHANISM TO CONTROL PRICES OF DRUGS

1603 Kodikunnil Shri Suresh Singh Shri Dushyant

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-
(a) the mechanism put in place to fix prices of medicines in the country;
(b) whether the Government proposes to set up drug price monitoring cells across the country and if so, the details thereof and time by which it is likely to be set up and made functional;
(c) whether the Government is aware that India is one of the countries with the highest price of drugs in the world;
(d) if so, the details thereof and reaction of the Government thereto;
(e) whether the Government has signed any agreement with United States of America on price control of drugs; and
(f) if so, the details thereof?ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI HANS RAJ GANGARAM AHIR)

(a) Prices of drugs contained in National List of Essential Medicines and included in the First Schedule of the Drug (Price Control) Order (DPCO), 2013 are fixed as per the provisions contained in the DPCO, 2013.

(b) A scheme of National Pharmaceutical Pricing Authority (NPPA) for setting up price monitoring cells in States which wiil render technical assistance to State Drug Controllers and NPPA in monitoring the notified price of medicines, price movement of scheduled/non-scheduled formulations, collection/monitoring availability of drugs etc., as required under provisions of DPCO, 2013, is under initial scrutiny of the Department.

(c) & (d)

Price fixed under the provisions of DPCO, 2013

are reasonable and based on market price data of the drugs sold in the country. There is no available comparison of prices with other countries.

(e) & (f)

No, Sir. Does not arise.

Question No. 1602
Answered on 02.12.2014

PROFIT MARGIN ON DRUGS

1602 Maurya Shri Keshav Prasad Rao (Avnthi) Shri Muthamsetti Srinivasa

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether some States including Andhra Pradesh has requested for promotion of pharmaceutical industry in the States;

(b) if so, the details thereof and the action taken on the said request, State/UT-wise;

(c) the quantity of drugs manufactured in proportion to their requirement;

(d) whether the Government proposes to fix the maximum percentage of profit to be earned by the manufacturers on the drugs manufactured by them in the country; and

(e) if so, the details thereof and if not, the reasons therefor and the steps being taken by the Government in this regard?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) No, Madam. The Department of Pharmaceutical has not received any such request.

(b) Does not arise.

(c) The Department of Pharmaceutical does not have information about the requirement of drugs. However, as per CMIE Industry Outlook data the total sales of Pharmaceutical Industry was Rs. 1,25,374.28 crores in 2013-14.

(d) & (e)

Under the Drug Policy, 1994 the control over prices was on the basis of the cost of product with allowance being given for post production expenses. However, in the National Pharmaceutical Pricing Policy, 2012 the basis of regulating the prices of formulations is through market based pricing. The methodology of fixing of ceiling prices under National Pharmaceutical Pricing Policy (NPPP), 2012 is the single average price of all brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of the medicine. Hence, there is no concept of fixing the maximum percentage of profit in the NPPP-2012.

Question No. 1537
Answered on 02.12.2014

PRICES OF MEDICINES UNDER NPPP

1537 Birla Shri Om Kumar Shri Kunwar Sarvesh

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether prices of medicines have been fixed/ charged arbitrarily by various drug companies including foreign and multinational companies in the country;

(b) if so, the details thereof and the number of complaints received/cases reported alongwith the action taken against such companies involved in the said activities during each of the last three years and the current year, company-wise;

(c) whether the Government proposes to implement uniform system regarding price control of drugs and if so, the details thereof;

(d) whether generic medicines are cheaper in comparison to branded medicines;

(e) if so, the details thereof and the details of steps / action taken to promote use of generic medicines and to provide medicines to common man at affordable/ cheaper prices; and

(f) whether the Government has approved the new National Pharmaceutical Pricing Policy 2012 in recent past and if so, the details and the safient features including objective thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI HANS RAJ GANGARAM AHIR)

(a) to (c)

Prices of drugs contained in National List of Essential Medicines and included in the Frist Schedule of the Drug (Price Control) Order (DPCO), 2013 are fixed as per the provisions contained in the DPCO, 2013. These prices are uniformly applicable to all brands and generic versions of medicines. All manufacturers of a scheduled drug / formulation have to comply with the price fixed by the Government/NPPA from the date of its notification. If any company is found selling a scheduled drug/formulation at a price higher than the notified price, notice for recovery of the overcharged amount is issued to it. So far, demand notices for recovery of overcharged amount have been issued to 11 (eleven) companies under DPCO, 2013 and an amount of Rs. 54.58 crorers has L_.T recovered as on 28.11.2014.

(d) & (e)

The ceiling price notified under DPCO, 2013 are uniformly applicable to both the generic name and brand name. Inter- brand price difference exists in respect of generic and branded medicines of the same molecule / drugs available in the domestic market. However, as provided under DPCO, 2013 all the existing manufacturers of scheduled formulations , selling the branded or generic or both the versions of scheduled formulations at a price lower than the ceiling price so fixed and notified by the NPPA are required to maintain their existing maximum retail price. No person

is authorized to sell the medicines at the price higher than the price notified by the NPPA.

In order to provide a relief to the common man in the Area of Health care a countrywide campaign for ensuring availa- bility of generic medicines at affordable prices to all, in the name of `Jan Aushadhi Campaign` was launched by Department of Pharmaceuticals, in November, 2008. A Bureau of Pharma PSUs of India (BPPI) was established in December, 2008 under the Department of Pharmaceuticals, Government of India, comprising of all the CPSUs for monitoring the scheme. Government of India propose to open atleast one Jan Aushadhi Store in each of the 630 districts of India but so far 170 Jan Aushadhi Stores have been opened in 15 States out of which 99 are functional. The cost of the medicine sold at Jan Aushadhi Store is much less than the branded medicine sold in the market.

(f) The salient feature of the new National Pharmaceutical Pricing Policy (NPPP) 2012 notified by the Government on 07.12.2012 are as under:

(1) Essentiality of Drugs
(2) Control of Formulations prices only
(3) Market Based Pricing

The objective of the new NPPP-2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines- `essential medicines`- at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all.

Question No. 1510
Answered on 02.12.2014

PRICES OF GENERIC AND BRANDED MEDICINES

1510 Chandumajra Shri Prem Singh Patel Shri Dilip

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether there is a big gap in the prices of generic and patent branded medicines;
(b) if so, the details thereof and the reasons therefor;
(c) whether same basic salt is used in both generic and branded medicines and their effect on the diseases is also the same;
(d) if so, the reaction of the Government thereto and the annual average production generic and branded medicines in the country at present;
(e) the share of generic and non-generic medicines in the total medicine sale in the country during each of the last three years and the current year; and
(f) whether the Government is taking any steps to control the prices of drugs and to promote the use of low-cost generic drugs in the country and if so, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS f SHRI HANSRAJ GANGARAM AHIR)

(a) to (c)

Prices of drugs contained in National List of Essential Medicines and included in the Frist Schedule of the Drug (Price Control) Order (DPCO), 2013 are fixed as per the provisions contained in the DPCO, 2013. These prices are uniformly applicable to all brands and generic versions of medicines of the same molecule/APIs. All manufacturers of a scheduled drug/formulation have to comply with the price fixed by the Government/NPPA from the date of its notification. If any company is found selling a scheduled drug/formulation at a price higher than the notified price, notice for recovery of the overcharged amount is issued tc So far, demand notices for recovery of overcharged amount have been issued to ll(eieven) companies under DPCO, 2013 and an amount of Rs. 54.58 crores has been recovered as on 28,11.2014.

(d) & (e)

Government does not maintain the data relating to production and market share of generic and non-generic medicines.

(f) Ceiling price of drugs under Scheduled category are fixed by NPPA on the market based data taking into account the market price of medicines in generic name and brand name. In order to promote use of low-cost generic drug in the country, a count- rywide campaign in the name of `Jan Aushadhi Campaign` was launched by Department of Pharmaceuticals, in November, 2008. A Bureau of Pharma PSUs of India (BPPI) was established in December, 2008 under the Department of Pharmaceuticals, Government of India, comprising of all the CPSUs for monitoring the scheme. Government of India propose to open atieast one Jan Aushadhi Store in each of the 630 districts of India but so far 170 Jan Aushadhi Stores have been opened in 15 States out of which 99 are functional. The cost of the medicine sold at Jan Aushadhi Store is much less than the branded medicine sold in the market.

Question No. 1504
Answered on 02.12.2014

REGULATE PRICES OF PATENTED DRUGS

1504 Singh Deo Shri Kalikesh Narayan Reddy Shri Ch. Malla

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the Government proposes to regulate the prices of patented drugs in the country;

(b) if so, the details thereof and the reaction of the drug industry thereto along with its likely impact on prices of generic and locally produced drugs;

(C) whether drug manufacturers from some countries including US have expressed displeasure over the issue of being denied grant patent of certain drugs for which Indian companies are producing generic drugs; and

(d) if so, the details thereof and the reaction of the Government thereto?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS fSHRI HANSRAJ GANGARAM AHIR)

(A) and (b):

To address the issues of Price Negotiation mechanisms for patented drugs, an Inter-ministerial Committee of Joint Secretaries has been set up to look into the issues and to suggest ways and means to fix the prices of patented drugs in the country.

(c) No, Madam.

(d) Does not arise.

Question No. 1451
Answered on 02.12.2014

OVERCHARGING OF MEDICAL DEVICES

1451 Chavan Shri Ashok Shankarrao Kirtikar Shri Gajanan Chandrakant

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the Government is aware that huge difference exist between import cost and MRP of medical devices like drug eluting stents, orthopaedic implants;

(b) if so, whether these medical devices are not included under the Drug (Price Control) Order, 2013 and if so, the details thereof and the reasons therefor;

(c) whether Food and Drug Administration of Maharashtra had carried out a detailed investigation into over- charging of various medical devices and submitted the report to the National Pharmaceutical Pricing Authority (NPPA);

(d) if so, whether any action has been taken by the NPPA in this regard; and

(e) if so, the details thereof and if not, the reasons therefor and the corrective steps taken/being taken by the Government in this regard?

ANSWER

\MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI HANSRA3 GANGARAM AHIR)

(a) Information is being collected and will be laid on the table of the House.

(b) National Pharmaceutical Pricing Authority (NPPA) is authorised to monitor the cost and sale of only those medical devices which are considered as drugs as per the provisions of the Drug & Cosmetics Act. Two medical devices notified as drugs namely condom and IUD containing copper are included in the First Schedule of the said Orderbased on the National List of Essential Medicines, 2011 and their prices have been fixed by NPPA as per the provisions of DPCO, 2013.

(c) to (e)

NPPA vide its letter dated 08.10.2014 has informed the Food and Drug Administration of Maharashtra that a high level Core Committee has been constituted under the Chairmanship of Dr. V.M. Katoch, Secretary, Department of

Health Research, Government of India and Director General, ICMR for revision of NLEM-2011, by the Ministry of Health & Family Welfare. Further, NPPA has undertaken a detailed study of the drugs already included in NLEM-2011 and to Identify drugs that require inclusion so as to ensure that all lifesaving and essential drugs of mass consumption are included for safeguarding the public interest. In this regard, FDA, Maharashtra has been requested to provide necessary input for revision of the recommendation made by them for inclusion of 14 medical devices under drug price control for examination in the context of the ongoing exercise for revision of NLEM, which is being carried out by the Ministry of Health & Family Welfare.

Question No. 1404
Answered on 02.12.2014

OVERCHARGING OF MEDICAL DEVICES

1404 Hansdak Shri Vijay Kumar

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the Government has taken note of exorbitant prices of patented and imported medicines used for the treatment of diseases like cancer etc. in the country;
(b) if so, the details thereof and the reasons therefor;
(c) the mechanism put in place to monitor/control/ regulate the prices of patented/imported drugs in the country;
(d) whether control over the prices of such medicines are outside the purview of the National Pharmaceutical Pricing Authority; and
(e) if so, the reaction of the Government thereto and the corrective steps taken by the Government to control the prices of imported and patented medicines?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) to (e)

Patented drugs are not part of the National List of Essential Medicines(NLEM), 2011 and, are not included in the First Schedule of Drug Price Control Order (DPCO), 2013 as per the National Pharmaceutical Pricing Policy, 2012. However, all imported drugs which are included in the First Schedule of DPCO, 2013 are subject to the provisions of Drug Price Control Order, 2013 and are under price control. The ceiling prices fixed by National Pharmaceutical Pricing Authority (NPPA) for 489 NLEM medicines under DPCO includes 47 anti-cancer medicines. No person is authorized to sell any scheduled formulations including imported medicines used for cancer disease to any consumer at a price exceeding the ceiling price fixed by the NPPA.

Question No. 2759
Answered on 09.12.2014

PROMOTION OF CRITICAL CARE DRUGS

2759 Pal Shri Jagdambika

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the Government proposes to promote manufacturing the critical care drugs in the country;
(b) if so, the details thereof;
(c) whether there is any proposal to provide any incentives/exemptions to encourage their production and if so, the details thereof;
(d) whether the Government is taking steps to ensure that such drugs are made available at affordable prices to the common man; and
(e) if so, the details thereof and if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) to (c):

Yes, Sir. In a meeting held in Prime Minister`s Office on 08.10.2013, it was decided to set up a Committee of Secretaries under the Chairmanship of Secretary, Department of Health Research to study and identify the Active Pharmaceutical Ingredients (APIs) of critical importance and to workout a package of interventions/concessions required to build domestic production capabilities, and examine the cost implication. In addition to the Chairman, the Committee comprises of Member Secretary, National Manufacturing Competitiveness Council (NMCC), Secretary, Department of Pharmaceuticals, Secretary, Department of Health, Secretary, Department of Commerce and Secretary, Department of Industrial Policy & Promotion. The report of the said Committee is awaited.

(d) and (e):

Pursuant to the announcement of NPPP, 2012, the Government has notified Drug (Price Control) Order, 2013 (DPCO, 2013) on 15.05.2013 in supersession of DPCO, 1995. All the medicines specified in the National List of Essential Medicines (NLEM), 2011 have been included in the first schedule of DPCO, 2013 and brought under price control. Monitoring of shortage and availability of drugs is carried out by the National Pharmaceutical Pricing Authority (NPPA) as an on-going process for ensuring smooth supply of the drugs in the country.

Question No. 2734
Answered on 09.12.2014

PRODUCTION/ IMPORT OF BULK DRUGS

2734 Kamaraaj Dr. K.

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) the estimated production of bulk drugs by indigenous drug manufacturing companies in the country during each of the last three years and the current year, company-wise;
(b) the quantum of bulk drugs imported and the name of countries from which these drugs were imported during the said period;
(c) the steps taken by the Government to increase the production of bulk drugs in the country;
(d) whether the Government proposes to revive penicillin G and its derivative six aminopenicillin manufacturers in the country; and
(e) if so, the details of action/steps taken so far and if not, the reasons therefor?

ANSWER

MINISTER OF STATE FOR CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) and (b)

Department of Pharmaceuticals does not maintain data regarding production of bulk drugs by indigenous drug manufacturing companies in the country and bulk drugs imported. However, as per the Boston Consulting Group report of 2013, the estimated production of bulk drugs by indigenous drug manufacturing companies in 2013 was US $ 10.4 billion and import for the period was US $ 3.5 billion which came primarily from China.

(c) to (e)

In a meeting held in Prime Minister`s Office on 08.10.2013, it was decided to set up a Committee of Secretaries under the Chairmanship of Secretary, Department of Health Research to study and identify the Active Pharma- ceutical Ingredients (APIs) of critical importance and to workout a package of interventions/concessions required to build domestic production capabilities, and examine the cost implication. In addition to the Chairman, the Committee comprises of Member Secretary, National Manufacturing Competitiveness Council (NMCC), Secretary, Department of Pharmaceuticals, Secretary, Department of Health, Secretary, Department of Commerce and Secretary, Department of

and its derivative six aminopenicillin are used for manufacturing of widely used anti-biotics like Amoxiciilin, ampicillin etc which are also part of National List of Essential Medicines-2011. The report of the said Committee is awaited.

Question No. 2564
Answered on 09.12.2014

PRICES OF PATENTED DRUGS

2564 Hansdak Shri Vijay Kumar, Dubey Shri Satish Chandra

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether an Inter-Ministerial Group assigned with the task of regulating the prices of patented drugs has suggested the use of a per capita income associated Reference Pricing System;

(b) if so, the details thereof and the benefits likely to be accrued by introduction of this scheme;
(C) whether such move has not been beneficial for the pharmaceutical industry;
(d) if so, the details thereof and the reaction of the Government thereto; and
(e) the difference between the Reference Pricing System and the Negotiating Pricing Model?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a): The Department constituted a Committee for examination of issues and suggestions of ways and means for fixing prices of patented drugs in the country. The Committee submitted its final report in June, 2012 on which comments were invited from various stakeholders. In view of the divergent comments received from various stake holders, an Inter-ministerial Committee of Joint Secretaries has been set up on 07.11.2013 to look into the issues and to suggest ways and means to fix the prices of patented drugs in the country.

(b) to (e):
In view of above, do not arise.

Question No. 3736
Answered on 16.12.2014

B / M PHARMA COURSES

3736 Galla Shri Jayadev

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-
(a) whether it is a fact that the course content for B. Pharma and M. Pharma does not contain chapters on disposal of pharmaceutical waste and the students are not given training in pharmaceutical waste management;
(b) if so, the reasons therefore;
© whether the Government proposes to take steps/ action in this regard;
(d) if so, the details thereof, and
(e) if not, the reasons therefor?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a): No Sir. Pharma students arc taught on the subject of disposal of waste and related topics. At Masters level in National Institutes of Pharmaceutical Education and Research (NIPER) some of the courses have chapters on waste management.

(b) to (e):
Do not arise.

Question No. 5006
Answered on 23.12.2014

RESEARCH ACTIVITIES BY DRUG MANUFACTURING COMPANIES

5006 Giluwa Shri Laxman

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

a) whether the foreign/Indian drug manufacturing companies have their own Research & Development facilities in the country;

(b) if so, the details thereof and the statutory provision in this regard;

© the names of the foreign pharmaceutical companies engaged in manufacturing of drugs; and

(d) the value of drugs manufactured by these companies along with the value of research work undertaken therein during each of the last three years and the current year, company-wise?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a): Yes, Madam.

(b): The major Indian and foreign Pharmaceutical companies like Ranbaxy Laboratories Ltd., Piramal Enterprises Ltd., Dr. Reddy`s Laboratories Ltd., Cipla Ltd., Sun Pharmaceuticals Inds. Ltd., Lupin Ltd., Cadila Healthcare Torrent Pharmaceuticals Ltd., Glenmark Pharmaceuticals Ltd., Biocon Ltd., Alembic Pharmaceuticals Ltd,, Glaxo-SmithKline Pharmaceutical Ltd., Pfizer Ltd., Sanofi India Ltd., Novartis India Ltd., Abbott India Ltd., Fresenius Kabi Oncology Ltd., Merck Ltd. etc. are having their own Research & Development (R&D) facilities in the Country. All the R&.D facilities which are recognised by Department of Scientific & Industrial Research (DSIR) get certain income tax exemption under the Income Tax Act.

(c): DSIR has informed that the following companies having foreign equity above 50% are engaged in the manufacturing of drugs: Fresenius Kabi Oncology Ltd., Sanofi-Synthelabo (India) Ltd., Novartis Healthcare Pvt. Ltd., MJ. Biopharm Pvt. Ltd., Abbott Healthcare Private Limited, Watson Pharma Private Limited, Getz Pharma Research Pvt. Ltd., Amol Pharmaceuticals Pvt Ltd., EPR Pharmaceuticals Pvt. Ltd., Mylan Laboratories Ltd., Ahlcon Parenterals (India) Ltd., Johnson & Johnson Ltd., TherDose Pharma Private Limited, Pfizer Limited, Merck Ltd., GlaxoSmithKline Pharmaceuticals Ltd., Abbott India Ltd.

(d): This data is not maintained by the Department.

Question No. 4863
Answered on 23.12.2014

IRREGULARITIES IN NIPER

4863 Bhuria Shri Dileep Singh

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the Government has received any complaints regarding`corruption/irregularities in National Institute of Pharmaceutical Education & Research (NIPER), Mohali; and

(b) if so, the details thereof and the action taken thereon during the last three years?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) & (b)

The complaints received about NIPER, Mohali in the Department are forwarded to NIPER, Mohali. As per NIPER Act 1998, being an autonomous institute, the Board of Governors (BOG) is responsible for the general superintendence, dire- ction and control of the affairs of the institute.

Question No. 4855
Answered on 23.12.2014

RECOMMENDATION OF TASK FORCE

4855 Ramachandran Shri Krishnan Narayanasamy Gutha Shri Sukender Reddy

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the Government has set up a Task Force with regard to availability of drugs at reasonable prices;

(b) if so, the details of recommendations made by the Task Force along with the follow up action / steps taken by the Government on the said recomme- ndations;

(C) whether the Government proposes to set up Genome Valley between East and West Godavari district in Andhra Pradesh to develop the pharmacy sector; and

(d) if so, the details and the present status thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI HANS RAJ GANGARAM AHIR)

(a) & (b):

High Powered Inter-Ministerial Co-ordination Committee (HPIMCC) set up on 5 March, 2010 to implement Government commitment to provide quality medicines at affordable

Prices had decided to constitute two Working Groups of which one pertained to pricing of medicines. This group was expected to suggest ways to make the drugs affordable. The Working Group recommended:

(I) Broad criteria to bring drugs under price control

(ii) Monitoring of prices

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(iii) A single state agency be authorised to decide the price through Tenders for public health programmes

(iv) Reduce Inter-Brand Price differences

(v) Need to rationalize prices of imported medicines

(vi) keep a check on Launch Price

\(vii) MNREGA Labour to be covered by Health Insurance

(viii) Need to include more drugs in NLEM

(ix) JAS(Jan Aushadhi Scheme) & RSBY (Rashtriya Swasthya Bima Yojna) to be made sustainable

(x) A Road Map needed to meet the manpower requirement

(xi) Wide publicity be geven to the policies & prices fixed

(xii) Cover hilly, tribal and inaccessible areas on priority basis:

(xiii) Prices of medical devises to be rationalized

(xiv) Mechanism to improve availability of medicines at reasonable prices- Compulsory Licensing

(xv) Use Corporate Social Responsibility (CSR) in a coordinated manners

(xvi) Enforcement of Competition Act.

The recommendation of the Working Group were placed before the HPIMCC and the concerned Departments were requested to take further action.

©: No Sir, such a proposal is presently not under consideration of the Government,

(d): Does not arise.