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Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jan. - Feb. - Mar. 2011

Tamilnadu Pharmaceutical
Sciences Welfare Trust

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EDITORIAL

Dear Readers,

This is the 9th issue of our quarterly Newsletter since inception. In the last issue, we completed the publishing of all the technical matters pertaining to IPA Convention - 2010 held in Chennai. In this issue we have covered the article pertaining to TRIPS and TRIMS under Doha Declaration . This article narrates about compulsory licensing under TRIPS pertaining to public health issues in developing nations. This is one of the important articles for the drug manufacturers as well as government drug regulators. This article also describes provisions in compulsory licensing and access to drugs to the developing nations. The objective of this article is to develop proper national drug policy for the availability of patented drugs to developing nations.

In this issue, the notification by Government of India on ISM drugs and also registration of clinical Research Organisation is published. In this notification the definition of ISM drugs including P & P medicines are incorporated, the safety and effectiveness of ISM drugs and also specifying standard books are included in this notification. The CRO notification is a draft one. The readers may give their comments for this draft.

The report on scholarship awards to M. Pharm students for their projects is published in this issue. These awards are pertaining to the period of 2010-2011. These scholarships are instituted by our Trust.

Various technical news pertaining to drugs and pharmaceuticals and also events from various pharmacy colleges like celebration of Nation Pharmacy Week and seminars are published in this issue.

The questions and answer pertaining the drug and pharmaceutical in Lok Sabha and Rajya Sabha in the winter session of 2010 are also published in this Newsletter for the usefulness of our readers.

We congratulate Dr. Bangarurajan & Mr. P. B. N. Prasad for their appointment as Deputy Drug Controllers, India through Union Public Selection Commission.

With best regards

Mr. R. Narayanaswamy

ARTICLE

Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations

Raadhika Gupta
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While the TRIPS Agreement provides for the patenting of drugs, it also provides for compulsory licensing as a mechanism to check the abuse of patent rights that might flow from such a rigid patent regime. However, it was only after the subsequent Doha Declaration that the developing nations could use this provision of compulsory licensing to access drugs from the developed world. This article examines international law on compulsory licensing in patents, the extent to which it restricts the scope of developing countries in taking advantage of technology in the developed world, the space it leaves open for them to further promotion of public health and the manner in which it has been used in some developing countries. It argues that although there are a number of obstacles placed through the new patent law regime mandated by TRIPS, there is still immense scope left for the developing countries to exploit. Careful planning and policy making can enable an effective balancing of the conflicting interests of protecting patent rights and making essential drugs accessible to all.

Keywords: Patent, compulsory licensing, TRIPS, Doha Declaration, access to drugs

Patents vest monopoly rights in the creator to manufacture, use and sell a product. Monopoly is often coupled with possibilities of abuse of patent rights. With the implementation of the TRIPS Agreement and inclusion of pharmaceutical products within the ambit of patentable subject matter, fears about the abuse of patent rights on drugs on drugs has grown, including whether drugs would be available and affordable, especially in the developing countries.

One the ways TRIPS answers this concern is by incorporating a provision on compulsory licensing, that is, the state can issue licences to manufacturers other than the patentee to produce, use or sell the product, without the consent of the patentee. Doha Declaration further enables developing countries to take benefits of the technology in developed nations through the mechanism of compulsory licensing. with the developed and developing countries taking opposite stands on the issue of patentability of life saving drugs, these international instruments are seen as an attempt to create a balance.

This article examines the international law on compulsory licensing in patents, the extent to which it restricts the scope of developing countries in taking advantage of technology in the developed world, the space it leaves open for them to use to further the interest of promotion of public health, and the manner in which it has been used in some developing countries of the world. It argues that although there are a number of obstacles placed through the new patent law regime given by TRIPS, there is still immense scope left open for the developing countries to exploit to their own advantage. Careful planning and policy making can enable an effective balancing of the conflicting interests of protecting patent rights and making essential drugs accessible to all.

The Access to Drugs Debate and Compulsory Licensing

A patent is an exclusive right granted to a person who has invented a new and useful product or process or has improved an existing product. It is a monopoly right preventing others from exploiting the invention, the rationale being that rewarding the

inventor for the effort, skill and resources expended will encourage innovation.

Conferring monopoly rights over life-saving drugs is highly contentious. Many argue that pharmaceuticals should be excluded from the purview of patent law, due to the possibility of abusing monopoly right and taking unfair advantage of the absence of competition that results from the grant of patent. This gets especially problematic in case of medicines since it is possible that the inventor raises price of the patented drug making it inaccessible to the poor. On the other hand, proponents of patent law justify patents on drugs by arguing that removing or limiting patent rights will drastically affect research and development in the pharmaceutical sector.

Compulsory licence is a method to check the abuse of patent rights, while not defeating the law itself. Compulsory licences are 'involuntary contracts between a willing buyer and an unwilling seller imposed or enforced by the state.' The State, under some conditions, may grant licence to an applicant to produce or use the patented product and sell it in the market even without the consent of the patentee. Both Indian Patents Act, 1970 and the TRIPS have provided for the conditional grant of compulsory licences.

The TRIPS Agreement aims to promote global competition in trade and thus, tries to establish a strong global patent regime. However, this puts at a disadvantage countries with a poor capacity to manufacture essential drugs. Before the TRIPS regime, product patents (including drugs) were not granted in India. The generic industry in India, therefore, flourished through reverse engineering, inspite of the strict patent regime in developed countries. Now, since drugs can be patented in India too, generic versions cannot be produced. Such a patent regime allows the patentee to exercise a larger control over both availability and accessibility (in terms of price, quantity, etc.) of the life-saving drug. On the contrary, limiting patent rights can help in bringing down prices by facilitating the entry of generic products. For example, adoption of price controls and a process-only patents regime in India transformed Indian drug prices from among the highest in the world to among the lowest.

Compulsory Licensing under TRIPS and Subsequent Developments

Article 27 of TRIPS provides that patents shall be available for any inventions, whether products or processes, in all fields of technology. However, Article 27(2) allows members to exclude inventions from patentability to protect public order or morality, including to protect health. TRIPS attempts to strike a balance between the short-term objective of providing access to life-saving medicines and the long-term objective of providing incentives to the pharmaceutical industry for the development of new medicines. Hence, it also imposes certain restriction on the rights of the patent holder, including compulsory licensing.

Article 8 of TRIPS allows member countries to adopt measures, consistent with the TRIPS Agreement, necessary to protect public health and nutrition. It also allows states to take measures to prevent the abuse of intellectual property rights or resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 30 is a broad provision which allows the member countries to provide limited exceptions to patent rights. when TRIPS was originally negotiated , Article 30 was seen as a mechanism similar to 'fair-use' of copyrighted materials. It allows limited exceptions provided that they do not unreasonably conflict with normal exploitation of the patent nor prejudice the legitimate interest of the patent owner; taking account of the legitimate interests of third parties.

Article 31 of the TRIPS Agreement deals with compulsory licensing in case of patents, although TRIPS phrases it as 'other use without authorization of the right holder'. It allows such

Authorization under certain conditions, like prior efforts to obtain authorization from the patentee (however, this requirement may be waived in case of national emergency, extreme urgency or public non-commercial use); non-exclusive and non-assignable use; payment of adequate remuneration to the patentee, etc.

The most significant clause here is subparagraph (f) of Article 31 which says that 'such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'. This provision effectively limits the benefits of compulsory licensing to member countries having a good manufacturing capacity only. By requiring licensees to supply a predominant part of their production to their domestic market, it limits the licensee's ability to export medicines to countries with public health needs, thus barring nations with insufficient or no manufacturing capabilities, the exceptions in TRIPS failed to satisfy the needs of those countries that the exceptions were designed to benefit. The Doha Declaration, however, made some amends as discussed below.

TRIPS in the process has become a platform for heated debate. Developing countries want a relaxation of the law as they argue that patent protection prevents millions of people from accessing life-saving drugs, forcing these countries to devote their limited resources to development of such drugs. They also argue that increased patent protection will lead to higher pharmaceutical prices. On the other hand, developed countries are arguing for a stronger protection in order to promote development of the pharmaceutical industry.

Doha Declaration

The Doha Declaration in 2001 sought to resolve the issue of use of compulsory licensing to export drugs to developing countries. The Declaration lays down certain general principles and confers certain rights. It recognizes the need to address public health problems afflicting many developing countries. The TRIPS Agreement should be interpreted and implemented in a manner supportive of countries' right to protect public health and to promote access to medicines for all. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. Each member has the right to determine what constitutes national emergency or extreme urgency and public health crises.

Paragraph 6 of the Declaration recognizes that nation with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement, and instructs the Council for TRIPS to find an expeditious solution. In 2003, the WTO announced its decision to implement Paragraph 6, allowing for a waiver of the Article 31(f)'s 'domestic market' restriction on compliance with certain conditions. It allowed any Member country to issue compulsory licence to produce generic drugs for export to least developed countries and other countries which establish that they have insufficient or no manufacturing capacities in the pharmaceutical sector.

Obstacles Created by the Present Compulsory Licensing Law

Even after the clarification issued during Doha Declaration and the subsequent decision, law on compulsory licensing suffers from many drawbacks, preventing the effective use of this law for access to drugs.

Disincentives Against using Compulsory Licensing by Developing Nations

At times, it has been observed that developing notions themselves may not want to avail benefits arising from compulsory licensing provisions due to political reasons. Amir Attaran argues that for attracting future investment and technology, many developing nations choose not to issue compulsory licences since it could be perceived as indifference towards intellectual property rights and Consequently weaken trade relations or scare off investors. Past history, shows that some low

-Income nations like Thailand, Colombia and Souch Africa have even been pressurized by developed nations like the US to adopt more rigorous intellectual property laws.

Practical Difficulties

Developing countries have to pass through maze of rules and procedure to procure drugs from developed countries. This is against the very purpose of Doha Declaration to provide easy access to medicines to all, Many developing countries may simply lack coordinated mechanism within the government to undertake such steps.

Heavy Reliance on the Will of the Exporting Country

A major problem is the heavy reliance on countries with manufacturing capacity to first issue compulsory licences. Developed countries following a strict patent regime may not be amenable to granting compulsory licences. Nation with good manufacturing capacity have no incentive to issue compulsory licences for export. Besides, in a scenario where even the developing countries are reluctant to issue compulsory licences due to the above-mentioned disincentives, it is even less likely that the developed nations will use this measure for the benefit of other nations. There have been very few cases of grant of compulsory licences for exportation.

Further, since TRIPS leaves a vast scope for nations to legislate according to their own needs, a lot depends on the country where the product is patented. For example, Canada has a better-developed and more liberal law on compulsory licensing than US which follows a strict patent regime.

It is also possible that developed nations use the threat of compulsory licensing to make companies voluntarily take measures to make their drugs accessible, without actually issuing the licence. Some nations have lowered prices while others have offered voluntary, royalty-free licences. In 2001, US used such threat to arthorize imports of generic ciprofloxacin, for stockpiles against a possible anthrax attack. Although such measures might be beneficial for the patenting country, it serves no purpose to nations which need to import such drugs.

The Way Ahead for the Developing Nations

Inspite of the above-mentioned obstacles, there still is adequate scope in the present regime of patent laws and compulsory licensing which developing nations can exploit. There is a need of a balance between protecting patent rights to encourage innovation and providing access to medicines to all. A careful analysis and application of the provisions show that such a balance is possible.

The Need for Innovation

At the outset, it is important to understand that effective use of compulsory licensing provisions or otherwise limiting patent rights will not completely curb innovation. Like developed nations, it is the goal of developing nations not to prevent but to promote the development of a flourishing pharmaceutical industry.

Facilitating entry of generic products has in fact a positive impact on the development of domestic pharmaceutical industry in developing nations. Since technological demands of producing an already patented product are substantially less than undertaking research to create the patented product, less technologically sophisticated enterprises are able to produce generics. This provides an opportunity for fledgling companies in the developing world with sufficiently large domestic markets. For example, India, Argentina and Turkey have developed flourishing domestic pharmaceutical industries in the last three decades, due to policies of granting no pharmaceutical product patents (Argentina and Turkey) or imposing significant limits (India). Even in Brazil, lower patent protection facilitated industrial development. Compulsory licensing allows Generic manufacturers to lower their marginal costs by expanding their demand pool, that is by selling in other countries. Compulsory licensing schemes can be utilized in many third world

Countries for a common market approach. For example, East African nations could develop an integrated compulsory licensing and generic drug manufacturing and marketing approach. Third world countries not adopting strict patent policies have proven more innovative than others who have. It was through imitation that virtually every industrialized country built up its technological capacity. For promotion of research and development, third world countries require a science and technology infrastructure a national system of advanced education and research which a patent system cannot provide. Many industrialized countries developed pharmaceutical industries in the absence of patent protection.

Besides, development of a sound domestic industry is much more beneficial than relying on multinationals. Domestic companies are more likely to adapt and modify technologies for local use. They promote local technological infrastructure development and favour generics. Profits accumulated by domestic companies stay within the country.

A Liberal Construction of Compulsory Licensing Provisions

Due to the non-specific language employed in international instruments, national legislations decide the degree of flexibility in the conditions for compulsory licensing. Many terms have been left undefined, for example, 'public non-commercial use', 'national emergency', 'extreme urgency', 'adequate remuneration', etc. Which can have varied interpretations. TRIPS provides no clear guidance on how nations are to implement these provisions. For example, while TRIPS specifies that remuneration shall be determined taking into account the economic value of the authorization, it nowhere defines 'economic value' nor prescribes a method to calculate it. TRIPS does not specify at what level a compulsory licence can or should be authorized. According to Bryan Mercurio, four main areas which are not satisfactorily resolved are: (i) the scope of diseases and products covered under the exception; (ii) countries that would be eligible to use the system; (iii) ensuring adequate remuneration; and (iv) safeguarding the system against diversion of drugs into other markets.

The ambiguity in the provisions can serve as a tool to promoting access to drugs and can enable experimentation with different patent schemes to serve this cause.

Under TRIPS, it is possible for developing countries to define the content of the standards imposed, the singular requirement of international law being that this is done in good faith. Developing countries should utilize this opportunity to tailor domestic legislation in a way that promotes local inventiveness by, for example, permitting lower standards of inventiveness, preventing broad claims, protecting improvements as separate inventions, employing a liberal test for non-obviousness, etc. Undefined words and phrases may be interpreted according to local requirements and may be flexibly applied. For example, Thailand authorized compulsory licence for the drug Plavix under the provision for 'public non-commercial use', under Article 31 of TRIPS, rather than the provision on 'national emergency or other situation of extreme urgency. Developing countries should craft domestic legislation in a way that benefits their immediate societies.

The fact that these loopholes can be exploited to the advantage of the developing countries is also evident from the pre-TRIPS situation. The heavy dependence on protection afforded by national legislation pre-TRIPS resulted in a number of disparities, but they actually benefitted the developing nations. They not only allowed for the possibility and right to tailor the patent system as per respective needs of the state, but also facilitated access to technology. Hence, a balancing act is possible through a careful policy making on administering price controls, setting royalties in Compulsory licensing system, or determining length of domestic patent protection.

Other Alternatives

Articles 8 and 30 of TRIPS Agreement provide other viable alternatives apart from Article 31 route

of compulsory licensing. Article 8(1) allows the nations to adopt measures necessary to protect public health, subject to the provisions of TRIPS. Read along with Article 27, this provision can be used and domestic patent policy can be tailored accordingly. Recently, the Indian subsidiary of Swiss drug-maker, Novartis's cancer drug, Glivec, was denied a patent by Intellectual Property Appellate Board (IPAB). It cited Section 3(d) of the Indian Patents Act, 1970, which makes therapeutic efficacy a prerequisite for grant of patent under specific conditions. This is an example where available flexiblity in the TRIPS regime was used to lay down the principles to be followed for subject matter analysis.

Similarly, the broad language of Article 30 can be exploited to promote public health interest. Articles 30 and 31 determine the outer limits of the scope of initiative that developing countries may legitimately rely upon. The need to provide pharmaceuticals or combat shortages arising from outbreaks of disease or other national emergencies would clearly fall under these provisions. In addition, availability of pharmaceutical goods at affordable rates should constitute a valid ground for invoking the exceptions under the TRIPS Agreement. Article 30 does not limit the purposes for which a country may make exceptions to the Agreement. The three limitations under Article 30 are not self-defining and these limitations may reasonably be interpreted to preserve a broad range of exceptions under Article 30, and hence a broad range of pharmaceutical patent policy alternatives for developing nations.

The Need to Create a Favourable Paradigm

The developing nations must themselves take the initiative to protect their interests. They need to create an environment favourable for restricting the scope of patent rights in the larger interests of public health and for issuing compulsory licences and adopt measures to replace the paradigm of strict patent regimes. This involves providing for effective domestic legislations incorporating the required compulsory licensing provisions and creating smooth administrative procedures to avoid red tapism.

Those developing countries which have developed a strong pharmaceutical industry today as a result of their past policies must ply an important role. For example, India has developed a strong industry and is one of the main suppliers of drugs to under-privileged countries. By allowing easier policies towards nations which need drugs from India, such a favourable atmosphere can be created. Apositive outcome results, if countries with the ability to manufacture drugs recognize and respond to the needs of other countries. Canada has set and example by introducing legislation to amend its Patent Act in 2003 to facilitate access to pharmaceuticals and address public health problems in developing countries.

After the Doha Declaration and subsequent development Section 92A was added to the Indian Patents Act, 1970 in 2005 providing for export of pharmaceutical products to countries with no or insufficient manufacturing capacity in pharmaceutical sector. In this context, the case Natco v Pfizer, pending before the Delhi High Court is significant. In this case, a Hyderabad-based generics manufacturer, Natco Pharma Ltd, filed an application for a compulsory licence to export to Nepal, Erlotinib, patented by Swiss firm, Roche in India. Natco contends that the generic versions can be manufactured at one-fifth the cost of production by the innovators. Since Nepal is a least developed country, TRIPS permits the export of drugs to the country under the compulsory awaited as it would be significant in determining what line India takes.

Since the use of compulsory licensing is Dependant on the exporting country, creating such a paradigm world wide may help pressurize the developed nations to themselves adopt liberal measures.

Compulsory Licensing of Pharmaceuticals in Asia: Some Examples

The use of compulsory licensing provisions in certain countries like, Malaysia, Indonesia and

Thailand demonstrate how TRIPS flexibilities can be utilized to benefit public health. In these three countries , compulsory licensing was effectively used to significantly bring down the prices of essential HIV antiretroviral (ARV) drugs.

Malaysia

In 2003, Malaysia became the first Asian country to implement a compulsory licence after the Doha Declaration and Council Decision. Section 84 of the Malaysian Patents Act, 1983 provides for issue of such licence in case of national emergency or in public interest. Based on this provision, Malaysia issued a compulsory licence to import generic versions of patented HIV antiretrovirals (ARV) from India. This measure helped bring down the cost of treatment substantially.

Indonesia

The Indonesian government also used compulsory licensing to overcome the high cost of ARVs. Unlike Malaysia which imported generic versions of the drugs, Indonesia used the compulsory licensing to appoint a local manufacturer to produce the drug. After the use of compulsory licensing, the price of drug dropped considerably.

Thailand

In 2006, Thailand issued a compulsory licence for the domestic manufacture of the patented HIV drug Efavirenx in accordance with Section 51 of Thailand's Patent Act of 1979, which, inter alia, provides for the issue of such licence in order to carry out any service for public consumption or to prevent or relive a severe shortage of food, drugs or other consumption items for any other public service. The government issued a compulsory licence for use in public health services. The law in Thailand further facilitates the use of the TRIPS flexibility of compulsory licensing by minimizing red-tapism. The law allows any ministry, bureau or department of the government, by itself, to exercise compulsory licensing. Thus, Thailand implemented the licence domestically much faster than countries like Malaysia and Indonesia.

Conclusion

Although the TRIPS regime attempts to create a strict patent regime, it also contains provisions like those regarding compulsory licensing, which gives some consideration to developing nations' concern about access to drugs to address their public health needs, However, these concessions offered by TRIPS regime limit the extent to which compulsory licensing can be utilized to access drugs from the developed nations. But a careful analysis shows that there is still enough leeway for the developing nations. The primary concern of a rational drug policy for the developing nations should be to disseminate useful drugs widely and cheaply, and encourage research and development of products to address local illnesses. Within the realm of patent policy, the best means of providing drugs widely and cheaply is to promote generic production. This can be effectively done if the TRIPS Agreement is intelligently applied and compulsory licensing provisions are enforced in a manner beneficial to the public heath interests. The fact that TRIPS flexibilities can be used to benefit public health has already been demonstrated by some South-East Asian countries, including India. By careful planning and policy making, the third world can work towards protecting the interest of the public, while still complying with the TRIPS patent regime.

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M. PHARM SCHOLARSHIPS 2010 - 2011

Every year the Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai awards scholarships to selected M. Pharm final year students from various colleges in Tamilnadu for their on-going project work.

This is the 13th year of these awards. This year, we received 268 applications from seven different branches of Pharmacy from 19 Colleges. 262 synopses were sent to **Dr. Madhusudan Rao,** Principal, University College of Pharmaceutical Sciences, Kakatiya University, Warangal and his team for evaluation. Based on their best marks, **21** students have been selected for award for scholarship as per the following details:

First Rank --- Rs. 8,000/- each for 7 candidates.
Second Rank --- Rs. 7,000/- each for 7 candidates
Third Rank --- Rs. 6,000/- each for 7 candidates

SUBJECT-WISE BREAK-UP

Subject		Applications	First	Second	Third
Pharmaceutics	:	61	1	1	1
Pharmaceutical Chemistry	:	53	1	1	1
Pharmaceutical Analysis	:	30	1	1	1
Pharmacology	:	49	1	1	1
Pharmacognosy	:	30	1	1	1
Pharmacy Practice	:	29	1	1	1
Biotechnology	:	10	1	1	1
TOTAL	**:**	**262**	**7**	**7**	**7**

COLLEGE-WISE BREAK-UP

Name of the college	:	Awards
1. J. S. S. College of Pharmacy, Ooty	:	6
2. College of Pharmacy, SRIPMS, Coimbatore	:	3
3. S. R. M. College of Pharmacy, Kattankolathur	:	1
4. Ultra College of Pharmacy, Madurai	:	*
5. Periyar College of Pharmacy, Trichy	:	*
6. K. M. C. H. College of Pharmacy, Coimbatore	:	1
7. Vinayaka Mission's College of Pharmacy, Salem	:	*
8. C. L. Baid Metha College of Pharmacy, Chennai	:	*
9. Padmavathi College of Pharmacy, Dharmapuri	:	*
10. P. S. G. College of Pharmacy, Coimbatore	:	3
11. Vel's College of Pharmacy, Chennai	:	*
12. Adiparashakthi College of Pharmacy, Melmaruvathur	:	2
13. J. K. K. Munirajah College of Pharmacy, Komarapalayam	:	*

14. Madras Medical College, Chennai	:	*
15. Madurai Medical College, Madurai	:	1
16. K. M. College of Pharmacy, Madurai	:	1
17. J. K. K. Natarajah College of Pharmacy, Komarapalayam	:	*
18. Sankaralingam Bhuvaneswari College of Pharmacy	:	*
19. R. V. S. College of Pharmacy, Coimbatore	:	2
20. Arulmighu Kalasalingam College of Pharmacy, Srivilliputhur	:	1
TOTAL	:	21

RESULT

PHARMACEUTICS

Rank	Name	Institute	Amount
First	Mr. Vimal K. R.	PSG College of Pharmacy, Coimbatore	Rs. 8,000/-
Second	Mr. Syam Potnuru	Adhiparasakthi College of Pharmacy, Melmaruvathur	Rs. 7,000/-
Third	Ms. Anindita De	JSS College of Pharmacy, Ooty	Rs. 6,000/-

PHARMACEUTICAL CHEMISTRY

Rank	Name	Institute	Amount
First	Mr. Jeevanantham S.	RVS College of Pharmacy, Coimbatore	Rs. 8,000/-
Second	Ms. Hemalatha V.	SRM College of Pharmacy, Kattankolathur	Rs. 7,000/-
Third	Ms. Sona Joseph	KMCH College of Pharmacy, Coimbatore	Rs. 6,000/-

PHARMACEUTICAL ANALYSIS

Rank	Name	Institute	Amount
First	Mr. Kumanan E.	Adhiparasakthi College of Pharmacy, Melmaruvathur	Rs. 8,000/-
Second	Ms. Harsha Manjusha	JSS College of Pharmacy, Ooty	Rs. 7,000/-
Third	Mr. Manu M.	RVS College of Pharmacy, Coimbatore	Rs. 6,000/-

PHARMACOLOGY

Rank	Name	Institute	Amount
First	Ms. Kalpana Eluri	PSG College of Pharmacy, Coimbatore	Rs. 8,000/-
Second	Mr. Ranjith Kumar R.	PSG College of Pharmacy, Coimbatore	Rs. 7,000/-
Third	Mr. Anand R.	KM College of Pharmacy, Madurai	Rs. 6,000/-

PHARMACOGNOSY

Rank	Name	Institute	Amount
First	Mrs. Mubeen M.	Madurai Medical College, Madurai	Rs. 8,000/-
Second	Ms. Jothi Rani V.	Arulmigu Kalasalingam College, Srivilliputhur	Rs. 7,000/-
Third	Ms. Aparna Sarepaka	JSS College of Pharmacy, Ooty	Rs. 6,000/-

PHARMACY PRACTICE

Rank	Name	Institute	Amount.
First	Mr. Raj Kucherlapati VSP	JSS College of Pharmacy, Ooty	Rs. 8,000/-
Second	Ms. Merin Levy Philips	SRIPMS, Coimbatore	Rs. 7,000/-
Third	Mr. Karthic Kumar C.	JSS College of Pharmacy, Ooty	Rs. 6,000/-

BIOTECHNOLOGY

Rank	Name	Institute	Amount
First	Mr. Karthikeyan N.	SRIPMS, Coimbatore	Rs. 8,000/-
Second	Mr. Karthikeyan S.	SRIPMS, Coimbatore	Rs. 7,000/-
Third	Mr. Mahesh Thondawada	JSS College of Pharmacy, Ooty	Rs. 6,000/-

M. Pharm Scholarship 2010-2011
Profile of 1st Rank Projects

PHARMACEUTICS

Name: Mr. Vimal K.R
Title: Enhancement of Follicular Delivery of Finastride in Niosomal Gel Form for Treating Androgenetic Alopecia
College: PSG College of Pharmacy, Coimbatore
Guide: Dr. V. Sankar

PHARMACEUTICAL CHEMISTRY

Name: **Mr. Jeevanantham S.**
Title: Synthesis, Docking Studies and Antibacterial Activity of Benzimidazole containing Pyrazolidine-3, 5-Dione on Peptide Deformylase and Heptosyltransferase Waac
College: RVS College of Pharmacy, Coimbatore
Guide: Mr. R. Shivakumar

PHARMACEUTICAL ANALYSIS

Name: Mr. Kumanan E.
Title: Simultaneous estimation of Doxophylline and Terbutaline sulphate in bulk and in tablet dosage form by UV Spectrophotometry and RP-HPLC method.
College: Adhiparasakthi College of Pharmacy, Melmaruvathur
Guide: Mrs. D. Nagavalli

PHARMACOLOGY

Name: Ms. Kalpana Eluri
Title: Evaluation of the Effect of Tetrahydrocurcumin on HMG Co-A Reductase and Lipoprotein Lipase Enzymes in High Fat Diet Induced Hypercholesterolemia in Rabbits.
College: PSG College of Pharmacy Coimbatore
Guide: Mr. K. G. Prasanth

PHARMACOGNOSY

Name: Ms. Mubeen M.
Title: Dual Control of Obesity with Cardiac Protection Using the Negelected Green Gold Betel Leaf (Piper belel L. Variety Sirukamani) Family Piperaceae
College: Madurai Medical College, Madurai
Guide: Mr. K. Perianayagam

PHARMACY PRACTICE

Name: Mr. Raj Kucheralapati VSP
Title: Effect of CYP 2C19 Genetic Polymorphism on the Metabolism of Amitriptyline in South Indian Population
College: JSS College of Pharmacy Ooty
Guide: Mr. K. P. Arun

PHARMACEUTICAL BIOTECHNOLOGY

Name: Mr. Karthikeyan N.
Title: Detection of Plasmid-Mediated Ampc β-Lactamase Genes in Clinical Isolates Of *Escherichia coli* & *Klebsiella Pneumonia f*rom UTI Patients.
College: College of Pharmacy, SRIPMS Coimbatore
Guides: Dr. S. Gopalakrishnan and Dr. Sumitha Singh

For the kind attention of Pharmaceutical manufacturers / Pharma educational institution

TRAINING / PLACEMENT VACANCIES FOR PHARMACY GRADUATES

TNPSWT is creating a database for placement of graduates / post-graduates in Pharmacy who require job opportunities like academics / industries (Production, QA & QC) / marketing / Research and Regulatory Affairs, etc.

You are requested to forward the details of positions available in your organisation to enable us to communicate to the appropriate candidates. The details may be emailed to us at pictrust@hotmail.com

NOTIFICATIONS

Drugs and Cosmetics (6th Amendment) Rules, 2010

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

NOTIFICATION

New Delhi, the 10th August, 2010

***G.S.R.663(E).—**Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, vide notification of the Government of India in the Ministry of Health and Family Welfare, number G.S.R.377(E), dated 3rd May, 2010, in the Gazette of India, Extraordinary, inviting objections and suggestions from persons likely to be affected thereby before the expiry a period of Forty Five days from the date on which copies of the Official Gazette containing the said notification were made available to the public; And whereas, the said Gazette was made available to the public on the 4th May, 2010; And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government; Now, therefore, in exercise of the powers conferred by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940) the Central Government, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely :-

RULES

1. These rules may be called the **Drugs and Cosmetics (6th Amendment) Rules, 2010.** They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945 (herein after referred to as the said rules), after rule 158-A, the following rules shall be inserted, namely:-

158(B) Guidelines for issue of license with respect to Ayurveda, Siddha or Unani drugs.

I.(A). Ayurveda, Siddha Unani Medicines under section 3(a):-

Ayurveda, Siddha or Unani drugs includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb system of medicine, as specified in the First Schedule;

(B). Patent or Proprietary medicine under section 3(h); (i) In relation to Ayurvedic, Siddha and Unani Tibb system of medicine of all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb system of medicines specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a); (ii) **Balya/Poshak/Muqawi/Unavuporutkal/positive health Promoter** formulations having ingredients mentioned in books of First Schedule of the Drugs and Cosmetics Act and recommended for promotional and preventive health. (iii) **Saundarya Prasadak (Husane afza)/Azhagh-sadhan** formulation having ingredients mentioned in Books of First Schedule of the Drugs and Cosmetics Act and recommended for oral, skin, hair and body care. (Iv) **Aushadh Ghana (Medicinal plant extracts – dry/wet)** extract obtained from plant mentioned in books of First Schedule of the Act including Aqueous or hydro-alcohol.

II.(A) For issue of license to the medicine with respect to Ayurvedic, Siddha and Unani, the conditions relating to safety study and the experience or evidence of effectiveness shall be such as specified in columns (5) and (6) of the Table given below:-

Serial number	Category	Ingredient(S)	Indications(s)	Safety study	Experience/Evidence of Effectiveness	
(1)	(2)	(3)	(4)	(5)	(6)	
					Published Literature	Proof of Effectiveness
1	(A) Ayurveda, Siddha and Unani drugs given in 158-B as referred in 3(a)	As per text	As per text	Not Required	Required	Not Required
2	(B) Any change in dosage form of Ayurveda Siddha and Unani drugs as described in section 3(a) of the Drugs and Cosmetics Act, 1940	As per text	As per text	Not Required	Required	Not Required
3	(C) Ayurveda, Siddha and Unani drugs referred in 3(a) to be used for new indication	As per text	As per text	Not Required	IFRequired	Required

(B) For issue of license with respect to Patent or Proprietary medicine. The condition relating to Safety studies and experience or evidence of effectiveness shall be specified As follows:-

Serial number	Category	Ingredient(S)	Indications(s)	Safety study	Experience/Evidence of Effectiveness	
(1)	(2)	(3)	(4)	(5)	(6)	
					Published Literature	Proof of Effectiveness
1	Patent or Proprietary medicine	As per text	Textual rationale	Not Required	Of Ingredients	*Pilot study as per relevant protocol for Ayurveda, Siddha and Unani drugs.
2	Ayurveda Siddha, Unani drug with any of the ingredients of Schedule E(1) of The Drugs and Cosmetics Act, 1940.	As per text	Existing	Required	Required	Required

(III) For issue of license with respect to Balya and Poshak medicines the person who applied for license is required to submit the following:

(i) Photo-copy of the textual reference of ingredients used in the formulation as mentioned in thebook of 1st schedule;

(ii) Conduct safety studies in case the product contains of any of the ingredients as specified in the Schedule E(1), as per the guidelines for evaluation of Ayurveda Siddha and Unani Drugs formulations;

(iii) For textual indications the safety and effectiveness study is not required.

(IV) For issue of license with respect to Saundarya Prasadak (Husane afza/Azhagu Sodhan) the person who applied for license is required to:-

(i) Submit photo-copy of the textual reference of ingredients used in the formulation as mentioned in the book of 1st schedule;

(ii) Conduct safety studies, in case the formulation contains of any of the ingredients as specified in the Schedule E(1), as per the guidelines for evaluation of Ayurveda, Siddha and Unani formulation;

(iii) For textual indications the safety and effectiveness study is not required.

(V) For issue of license with respect to medicine Aushadh Ghana [extract of medicinal plant (dry or wet).

Serial number	Category	Ingredient(S)	Indications(s)	Safety study	Experience/Evidence of Effectiveness	
(1)	(2)	(3)	(4)	(5)	(6)	
					Published Literature	Proof of Effectiveness
1	(A) Aqueous	As per text	As per text	Not Required	Not Required	Not Required
2	(A1). Aqueous	As per text	New indication	Not Required	Not Required	Not Required
3	(B) Hydro-Alcohol	As per text	As per text	Not Required	If Required	Not Required
4	(B1) Hydro-Alcohol	As specified	New Indication**	Not Required	If Required	Not Required
5	Other than Hydro/Hydro-Alcohol	As specified	As specified	Required Acute, Chronic, Mutagenicity and Teratogenicity	If Required	Required

* The standard protocol will also include concept of Anupan, Prakriti & Tridosh etc. published by Central Research Councils Ayurveda, Siddha, Unani and other Government/Research Bodies. ** New indication means which is other than mentioned in 1st schedule books of Drugs & Cosmetics Act 1940.

[No.K.11020/02/2010-DCC (AYUSH)]
S. JALAJA, Secy. (AYUSH)

Foot Note: The Principal rules were published in Official Gazette vide notification No. F.28-10/45-H(I) dated the 21st December, 1945 and the last amended vide No. GSR 602(E), dated 19-7-2010.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 19th January, 2011

***G.S.R.40(E).—**The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public;

Any person interested in making any objections or suggestions on the proposed draft rules may do so in writing for consideration of the Central Government within the period so specified through post to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi-110011.

DRAFT RULES

1. (1) These rules may be called the drugs and Cosmetics (First Amendment) Rules, 2011.
2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules) after rule 122 DAA, the following rule shall be inserted, namely:-

"Rule 122 DAB. - Registration of clinical research organisation for conducting clinical trials:- (1) The clinical trials:-

(1) The clinical research organisations shall be required to be registered by the Licensing Authority defined in clause (b) of rule 21 for the purpose of conducting clinical trials in the country.

(2) An application for registration of clinical research organisation for the purpose of conducting clinical trials shall be made to the Licensing Authority defined in Clause (b) of Rule 21 accompanied by the information as required under Schedule Y-1.

(3) If the Licensing authority after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the rules have been complied with and the conditions of registration will be observed, he may grant registration subject to the conditions stated therein.

(4) A registration, unless it is sooner suspended or cancelled, shall be valid for a period of five years from the date issue.

(5) If the licensing authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and conditions which must be satisfied before the registration can be granted.

(6) If the clinical research organisation fails to comply with any of the conditions of registration, the licensing authority may after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel the registration for such period as deemed fit.

(7) The clinical research organisation, whose registration has been suspended or cancelled by the licensing authority, may within ninety days of the receipt of the copy of the order by him prefer an appeal to the Central Government and the Central Government may after giving an opportunity of being heard, confirm, reverse or modify such order Explanation- For the purpose of this rule a clinical research organization is an individual or an organisation (commercial, academic or other) to which the sponsor may transfer of delegate some or all of the tasks, duties and / or obligations regarding a Clinical trial, provided that all such contractual transfers or obligations are defined are defined in writing."

(2) They shall come into force on the date of their final publication in the Official Gazette.

3. In the said rules after Schedule Y, the following Schedule shall be inserted, namely:-

"Schedule Y - 1
(See Rules 122 DA, 122 DAA, 122 DAB)
Requirements and Guidelines for registration of clinical research organisations

1. Scope

The guidelines cover all organisations, individuals, institutions and companies that take the responsibility of conducting clinical trials including those who seek permission for clinical trial from Licensing Authority defined in clause (b) of rule 21. It does not include clinical trial sites.

These guidelines are not stand alone guidelines and are not in derogation of any other rule or guidelines applicable to the clinical trials e.g. Schedule Y of the rules, Indian Good Clinical Practice (GCP) guidelines and Ethical Guidelines for Bio-Medical Research on human participants by the indian Council of Medical Research.

2. Criteria for Registration

(i) The Clinical Research Organisation shall be under the charge of a person who is responsible for the overall activities of the organisation. The organisation should have competent persons who are thoroughly familiar with the investigational product(s), the protocol, written informed consent forms or other information provided to the subjects, the standard operative procedures by the sponsors, GCP guidelines and other rules applicable to the conduct of clinical trials.

(ii) The organisation shall have adequate resources, qualified and trained staff for oversight of clinical trials. The staff members are required to be trained regularly to update their skills.

(iii) The trial related duties and functions transferred to and assumed by the Clinical Research Organisation shall be specified in writing and property quantified.

(iv) The organisation shall ensure that the trials are adequately monitored and the trial related responsibilities to it, partially or fully, by the sponsor are discharged effectively and efficiently.

(v) The organisation shall implement quality assurance and quality control as per standard operative procedures designed for the purpose. Such Standard Operative Procedures shall be well documented.

(vi) The organisation shall maintain complete data, documentations and other related records accurately. The organization shall also check and ensure that the investigator(s) have maintained properly the essential documents required for the conduct of the trial.

(Vii) The organisation shall ensure that the investigator(s) received all documents and trial related supplies needed to conduct the trial properly.

(viii) The organisation shall have education programmes to help its investigator to carry out the research studies as per guidelines and regulations applicable to such trials. Training will include protocol adherence GCP guidelines, informed consent process, and investigator's responsibilities for GCP compliance.

3. Record Keeping

All records (written documents, electronic, magnetic or optical records, scans, etc.) such as protocols, approvals from the Central Drugs Standard Control Organization (CDSCO) and ethics committee, investigator(s) particulars, blank consent forms, monitor reports, audit certificates, relevant correspondence, reference ranges, completed and the final reports, shall be maintained. All documentation and communication are to be dated, filled and preserved safely for a period of 5 years after the completion of study or submission of the data to CDSCO. Strict confidentiality is to be maintained during access and retrieval procedures.

4. Information required for registration

(i) Name and address of the organisation to be registered along with its telephone number, fax number, e-mail address.

(ii) Name and address of the proprietors/partners/directors.

(iii) Status of the organisation as legal entity.

(iv) A brief profile of the specific activities/services undertaken by the organisation including facilities, resources and infrastructure.

(v) An organogram of the organisation including brief CVs of key personal.

(vi) List of Standard Operative Procedures with salient highlight about specific areas to be scrutinised.

(vii) An undertaking to declare that-,

(a) we shall comply with the conditions imposed on the registration certificate along with the adhererice to other guidelines like GCP guidelines and provisions of the Drugs and Cosmetics rules, 1945.

(b) we shall comply with such further requirements, if any, as may be specified by the Government of India, under the Act and the rules, made thereunder.

(c) we shall allow the licensing authority and/or any person authorised by him in that behalf to enter and inspect the premises and to examine the process/procedure and documents in respect of any clinical trial conducted by us."

[F.No. X-11014/2/2010-DFQC]
ARUN PANDA, Jt. Secy.

Food note : The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H(1) dated 21st December, 1945 and last amended vide notification number G.S.R. 683(E), dated the 19-08-2010.

Salient points of the notification

Govt. Of India, Ministry of Health & FW issued a draft notification on 19th January 2011 to register (to licence) Clinical research Organisation (CRO) for conducting Clinical Trials in our country. The salient points of the Draft Rules are as under:

1. DCGI will be the registering authority for CROs.
2. These rules are inserted under rule no. 122 DAB of Drugs and Cosmetics Rules.
3. The requirements and guidelines for registration of CROs are as per Schedule Y1.
4. The guideline includes a competent person responsible for the overall activities of the CRO, adequate qualified and trained staff for conducting clinical trials, to maintain all necessary documents for conducting trials and also adherence of proper protocol and GCP guidelines.
5. There is no fees for registration of CROs.
6. This is a Draft Rule. All the persons concerned may give their comments, if any, to Mr. Arun Panda, Joint seceretary, Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi - 110011.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 10th February 2011

***G.S.R.40(E).—**Whereas the Central Government is satisfied that use of the following drugs is likely to involve certain risks to human beings and whereas safar alternatives to the said drugs are available;

And whereas the Central Government is satisfied that it is necessary and expedient to prohibit the manufacture, sale and distribution of the said drugs in public interest;

Now, therefore, in exercise of the powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture, sale and distribution of the following drugs with immediate effect, namely:-

1. Nimesulide formulations for human use in children below 12 years of age.
2. Cisapride and its formulation for human use.
3. Phenylpropanolamine and its formulations for human use,
4. Human Placental Extract and its formulations for human use,
5. Sibutramine and its formulations for human use, and
6. R-Sibutramine and its formulations for human use.

[F.No.X. 11014/1/2011-DFQC]
DR.ARUNKUMAR PANDA, Jt. Secy.

Source: *www.cdsco.nic.in*

EVENTS

49th National Pharmacy Week Celebrations by Indian Pharmaceutical Association, TN Branch

The Valedictory function of the 49th National Pharmacy Week Celebrations was jointly organized by Indian Pharmaceutical Association, TN Branch and Tamilnadu Pharmaceutical Sciences Welfare Trust on 27th November 2010 at Hotel Days Inn, Deccan Plaza, Chennai. Dr. K. Allauddin, Principal Secretary to Government of Tamilnadu was the Chief Guest and Mr. M. Bhaskaran, Director of Drugs Control, Tamilnadu and Dr. B. Suresh, President, Pharmacy Council of India were the Guest of Honour.

Mr. M. M. Yousuf, Vice - President, IPA, TN Branch welcomed the gathering Dr. G. Parthasarathi, HoD, Department of Clinical Pharmacy, J. S. S. College of Pharmacy, Mysore delivered the lecture on this year's theme : **"Safety First with Medicines: Ask Your Pharmacist"**.

In recognition of his services rendered to the profession of Pharmacy, IPA, Tamilnadu Branch conferred **Pharmacist of the year** award on Dr. V. Ravichandhiran, Director, School of Pharmacy, Vels University, Chennai. It was followed by award of scholarships by Tamilnadu Pharmaceutical Sciences Welfare Trust to M. Pharm students based on their best projects.

School of Pharmaceutical Sciences, Vels University, Chennai

School of Pharmaceutical Sciences, Vels University, Chennai celebrated National Pharmacy Week in the name of PHARMAFEST from 4th to 7th January 2011. Various events and poster presentation were conducted on the ***topic "Safety First with Medicines: Ask Your Pharmacist"***. Health awareness program was conducted More than 50 schools participated.

International speakers like Dr. Shrikanth Ananth, Dr. Animesh Dhar, from University of Kansas and Dr. Balakrishnan Lokeshwar, from School of Medicine, University of Miami delivered lectures on cancer prevention and its research.

A guest lecture was delivered by Dr. Ramu Govindasamy, Associated Professor & marketing specialist, School of Environment & Biological Sciences, USA on topic ***"Global Natural Products: Industry Perspectives and Trends".***

Dr, V. Ravichandiran, Director, School of Pharmaceutical Sciences talked about the future trends of pharmacy. The chief guest, Mr. M. Bhaskaran, Director, Drugs Control, Tamilnadu spoke about the current status of pharmacy.

College of Pharmacy, SRIPMS, Coimbatore

The 49th National Pharmacy Week celebrations of College of Pharmacy, SRIPMS, Coimbatore were held during 3rd and 4th week of November 2010.

As part of celebrations, staff members visited various schools for propagating the theme of this year ***"Safety First with Medicines: Ask your Pharmacist"*** and created awareness.

As part of the celebrations the college conducted a one day seminar on ***"Emerging Roles of Pharmacist towards Patient Care Services"*** in co-ordination with The Tamilnadu Dr. MGR University, Chennai and Education Division of IPA.

Dr. G. P. Mohanta, Professor of Annamalai University and Dr. Anand Vijayakumar, Professor of J. S. S. College of Pharmacy, Ooty spoke on the topic ***"Safety Monitoring of Pharmaceutical Products: Challenges and Opportunities in India"***. and on ***"Drug Information An Art to Learn"*** respectively. Dr. A. M. Ismail from Periyar College of Pharmaceutical Sciences, Trichy talked on the topic ***"Counseling Concepts Need of the Hour".*** Mr. V. Sivakumar, of Novartis and Dr. T. K. Ravi and Dr. S. Sriram, of SRIPMS delivered lectures on various topics like clinical research and Pharmacy education.

200 students of various colleges were benefited by the seminar.

The semifinal round of IPA's National Elocution Competition 2010 was held on 4th December 2010. Also Power-Point presentation, essay writing and pencil sketching competitions were conducted for the students of the college.

PSG College of Pharmacy, Coimbatore

PSG College of Pharmacy, Peelamedu, Coimbatore organised a quiz competition ***"Pharma Quest 2010"*** for Pharmacy students at national level.

The College also organised a National level Technical Symposium on ***"Emerging Opportunities and Challenges for Clinical Pharmacist in National Health Care"*** in October 2010. The symposium was sponsored by Department of Science and Technology, Council for Scientific and Industrial Research, Indian Pharmacy Graduates Association and Dr. M. G. R. Medical University, Chennai. Dr. T. K. Ravi, Principal, College of Pharmacy, SRIPMS, Coimbatore inaugurated the symposium. Dr. M. Ramanathan, Principal, P. S. G. College of Pharmacy presided over the function.

A two day Seminar cum Workshop programme on "Computer aided drug design" was conducted on January 4th and 5th 2011 in the Department of Pharmaceutical Chemistry, College of Pharmacy, Madras Medical College, Chennai.Various computational tools like 3D-QSAR, Pharmacophore Modelling, In-silico Modelling, Molecular Docking and Induced Fit Docking were discussed and subsequently hands-on training on the relevant software was imparted. The workshop was conducted by Dr. Arun, M/s Schrodinger and Dr. Raghu, M/s Schrodinger. Totally 31 participants including PG students and staff of MMC and staff from five different universities like SRMC, Osmania, Sastra, Mother Teresa and Calicut participated in the seminar.

College of Pharmacy, Madras Medical College, Chennai

The theme of this year's Pharmacy Week Celebration was ***"Safety first with Medicines: Ask Your Pharmacist".*** Dr. V .Kanagasabai, Director of Medical Education & Dr. N. Narayanan, Joint Director of Medical Education (Pharmacy) were the Guests of Honour.

The National Pharmacy Week celebrations of the college started from the last week of October when a Pan South India Quiz Competition was organized for the D. Pharm, B. Pharm, M. Pharm, and Pharm. D students of various pharmacy colleges in South India.

A two day Seminar cum Workshop programme on ***"Computer aided drug design"*** was conducted on January 4th and 5th 2011 in the Department of Pharmaceutical Chemistry, Madras Medical College, Chennai.

Adhiparasakthi College of Pharmacy, Melmaruvathur

The 49th National Pharmacy Week was celebrated by Adhiparasakthi College of Pharmacy under the inauguration of Dr. T. Illango, Registrar, Tamilnadu Pharmacy Council. The Chief Guest, Mr. A. Balaji Kumar, Zonal Manager, British Biologicals, Bangalore gave a lecture on ***"Opportunities in Pharma Marketing".***

Retired Drugs Control Officers Association

The First Annual General Body meeting of Retd. Drugs Control Officers Association was held on 30/1/11 in Chennai under the Presidentship of Mr. C. V. Ramaiah., Former Director of Drugs Control, Tamilnadu. Mr. K. Rajamanickam, former ASDC was honoured and felicitated for his services rendered to the department. The office bearers of the association spoke on various activities of the Association.

NEWS

Domestic Drug Retail Market Sales up by 18%

Sales in the domestic retail drug market rose by 18.36% in 2010, making India an attractive destination for foreign players who have been looking to buy local companies to increase exposure in one of the fastest growing healthcare markets globally.

The size of the Indian drug retail market crossed Rs. 46,500 crore for the twelve months ended November 2010, according to research firm IMS Health Information and Consulting Services.

The stock market also captured the double-digit growth in the Pharma market with BSE Healthcare, a share index of drug makers generating 31% returns for shareholders, better than the market benchmark Sensex.

Ranjit Kapadia, VP Institutional Sales at brokerage HDFC Securities, who tracks Pharma companies said: "Many companies forayed in rural market through new marketing teams and channels expanding the overall market".

American drug maker Abott Laboratories, which acquired Mumbai based Piramal Healthcare's domestic branded medicine business for $3.7 billion in May this year, held on to its top position with a 6.9% market share despite a sluggish growth of its new business.

The acquired business grew a meager 12.7% for the 12-month period ended November 2010 over the year ago period. For November alone, it was the worst performer among the top 20 drug makers with a mere 1.1% growth.

Sales of its best-selling brand Phensedyl (cough syrup) fell as much as 72% to Rs. 5.4 crore in November, due to shortage of raw materials.

This has pushed Phensedyl down to the fourth position among the top selling medicine brands in the country.

Until recently, it used to compete closely with Pfizer's cough syrup Corex, the best-selling drug in India.

Source: *The Economic Times, 1st January 2011*

300 lakh doses of DPT vaccine down the drain

About 300 lakh doses of the diphtheria, pertussis and tetanus (DPT) vaccine meant for children have been rendered unusable after a substandard component tetanus toxoid was added to the triple vaccine at the Pasteur Institute of India, Coonoor, an internal inspection has found. The loss because of the spoilt vaccines and their vial monitor labels, now rendered useless, is pegged at Rs 8.5 crore. This may force the government to buy the vaccine from private labs at a higher cost.

Insiders told TOI that intense pressure from the ministry of health and family welfare and over-enthusiasm on the part of the institute resulted in hurried preparation of the vaccine, giving a go-by to quality control norms.

Incidentally, the Tamil Nadu Directorate of Drugs Control on Tuesday rejected the institute's application for the World Health Organisation's (WHO) good manufacturing practices (GMP) certificate.

The Drug Controller General of India had cancelled the manufacturing licenses of Pasteur Institute; BCG Lab, Chennai; and the Central Research Institute, Kasauli, on January 15, 2008, citing non-adherence of good manufacturing practices. The suspension was revoked on February 22, 2010, to allow the labs to carry on with production using materials in the pipeline and upgrade themselves to WHO GMP standards before resuming full-fledged production.

Following an enquiry from the ministry of health in March 2010, Pasteur Institute said it could supply 320 lakh doses of DPT vaccine and went into manufacturing mode before getting the GMP certificate.

However, early this month, samples from 50 lakh doses of the prepared vaccine were tested before being filled into vials and were found unusable. Another 250 lakh doses will also now be of no use as the tetanus toxoid for them is from the same batch.

Source: *The Times of India, 30th December 2010*

NPPA Hikes Prices of Six Drugs

The National Pharmaceutical Pricing Authority (NPPA) on Friday said it has increased prices of six drugs, including anti-asthmatic and pain killers.

At the same time the authority has cut prices of 29 other drugs following a meeting of the NPPA held last week, which reviewed prices of 59 formulations for treating ailments like diabetes, allergy and asthma along with pain killers.

"Out of the 59 formulations which were considered, there is increase in prices of only six, while there has been a decrease in the prices of 29 formulations," NPPA Chairman S. M. Jharwal told PTI.

The companies which would be affected by the price revision of drugs include Eli Lilly, Pfizer, Novartis, Sanofi Aventis, GSK, Aventis Pharma and Cipla, the NPPA said.

Aventis Pharma's pain killer Novalgin will now cost Rs.27.52 for 30 ml vial as against Rs.22.28 earlier. However, 500 mg tablets of the same will come cheaper at Rs.7.01 as against Rs.7.28 earlier.

The price of Novartis India's Vitalux plus TR tablets which is indicated for maximising vision and health of the eye, was reduced from Rs.256.91 to Rs.247.39 for a pack of 30 tablets.

Similarly Cipla's anti-asthmatic Asthalin syrup, which costs Rs.11.80 per 100 ml, will now be priced at Rs.12.98.

Mr. Jharwal said prices of 24 formulations had been left unchanged, while adding that the effect of the price increase would be minimal.

The increase in prices follows the NPPA's decision to hike the rates of three bulk drugs. "The prices have been revised based on cost price study," Mr. Jharwal said.

According to a notification on December 21, NPPA has revised the price of human insulin to Rs.39.5 lakh as compared to the previous price of Rs.33.96 lakh a kg. NPPA has also revised the price of Cefotaxime Sodium to Rs. 7,025 from Rs.6,805 a kg. It has also revised the price of aspirin to Rs.173 from Rs.148 a kg.

The increase in prices follows hike in three bulk drugs rates

Source: *The Hindu 24th December 2010*

Vaccines spiked with harmful adjuvants administered to children

Adjuvants with severe physiological side effect have been administered to hundreds of children during vaccine trials conducted at a government hospital in Indore over the last few years, and that too without the approved Standard Operating Procedure (SOP).

The trials conducted on at least 836 children at the Chacha Nehru Bal Chikitsalaya, the paediatric division of the Maharaja Yashwantrao Hospital, were spiked with adjuvants that contain high levels of mercury, aluminium, detergents, pesticides and human carcinogens.

Banned by FDA

An adjuvant is used to spike a vaccine to boost its impact and amplify the body's immune response to the vaccine.

Two of the adjuvants used, Thimerosal and Squalene, are banned by the Food and Drug Administration (FDA) department of the United States. In India, there is still no protocol regarding the use of adjuvants.

Thimerosal, which contains 49.6 per cent mercury, can be so dangerous that vaccines in several Western countries are branded as Thimerosal-free. Its side effects include neuro-developmental disorder, autism, attention-deficit hyperactivity disorder and speech delay, while Squalene can cause the Gulf War Syndrome and dementia.

RTI information

"In special cases, the maximum recommended dose of Thimerosal is 1 mcg [microgram], while these children at CNBC were administered doses of 25 mcg," said whistleblower Anand Rai, who accessed the information under the Right To Information Act.

Other adjuvants used include Tween-80 (detergent), 2-Phenoxyethanol (pesticide), Formaldehyde (carcinogen), and Amorphous Aluminium Hydroxyphosphate Sulphate (aluminium).

The adjuvants were administered along with vaccines such as HPV 503 cervical cancer vaccine, H1N1 flu vaccine, hepatitis vaccine, easy five vaccine and Imovax polio vaccine.

The trials were conducted without the required SOP by hospital paediatrician Hemant Jain.

Schedule Y of the Drugs and Cosmetics Act, and the 2006 guidelines of the Indian Council of Medical Research, require the SOP to be cleared by an Ethics Committee before the commencement of any clinical trial.

In reply to an RTI query, Dr. Jain stated: "To the best of my knowledge, none of the adjuvants used to boost the immunity of vaccines has any clinically significant side effect."

Expresses ignorance

However, when contacted by The Hindu about the fact that the administered adjuvants had harmful ingredients such as mercury, pesticides and carcinogens, Dr. Jain expressed ignorance.

"I don't know anything about the contents of the adjuvants, but they have always been used with vaccines. You should ask the companies about adjuvants," he said.

Even the adjuvants used on children in Indore that are not banned by the FDA have side effects termed insignificant by Dr. Jain ranging from skin irritation, hypertension and irritable bowel syndrome to brain damage, Alzheimer's, infertility, genetic mutation, hypertension, acute renal failure, convulsions and damage to the central nervous system.

Source: *The Hindu, 24th December 2010*

Abbott's HIV Drug Patent Move Rejected

The Mumbai patent office has rejected American drug maker Abbott Laboratories' patent application for an HIV combination drug, allowing low-cost local drug makers to make and sell their generic versions in India and other countries where the medicine is not patented.

The decision to reject the patent application for Lopinavir & Ritonavir is a major victory for millions of HIV patients globally, who have failed to stay healthy with the first round of medicines, said Medicines, Access & Knowledge (I-MAK), the not-for-profit organisation which is behind the legal action.

Tahir Amin, Director of the I-MAK, said the Mumbai authority refused to grant the patent to Abbott Laboratories in its decision last weekend, because the drug was 'not an invention,' a key reguisite to get a patent in the country.

Source: *The Economic Times, 4th January 2011*

Bristol-Myers Patent Plea for HIV Drug Rejected

India has rejected American drug maker Bristol-Myers Squibb's (BMS) patent application for one of its HIV drugs, allowing local drug makers to make and sell the medicine in the country.

Last month, the Delhi Patent Office shot down the patent application for Atazanavir bisulphate due to 'lacked inventive ingenuity', Médecins Sans Frontières (MSF), a global nongovernment organization, said on Monday.

BMS' Atazanavir bisulphate is recommended by World Health Organisation (WHO) for HIV patients on whom the first line of medication do not work. BMS has filed other patent applications related to its drug which are still pending, MSF said.

This is the second such setback for foreign drug makers seeking to carve a market for HIV drugs in India, home to about 2.3 million suffering from the disease. Last month, patent application of another American drug maker Abbott Laboratories' for its HIV combination drug, Lopinavir & Ritonavir, was rejected following opposition by Cipla and US-based Mylan-owned Matrix Laboratories .

"These decisions show how India's patent law, which prevents routine improvements from being patented, works in favour of public health by only granting patents for drugs that are truly innovative," said Leena Menghaney MSF's Campaign for Access to Essential Medicines . The decision will benefit Indian drugmakers such as Cipla, Ranbaxy, and Natco who can now make their low-cost version of the HIV drug to sell in India as well as other countries where the medicine is not patented.

Source: *The Economic Times, 11th January 2011*

Revolutionary test for TB

A new test developed for diagnosing active tuberculosis is set to revolutionise treatment of a disease that kills 1.8 million people round the world every year. It recently won approval from the World Health Organisation for a worldwide rollout over the next few years. The approval comes within three months of publication in the New England Journal of Medicine ("Rapid molecular detection of tuberculosis and Rifampicin resistance," by Catharina C. Boehme et al.,) of the results of a trial conducted on 1,700 patients in five countries, including India. The new test has several advantages over the currently used smear microscopy and conventional nucleic acid-amplification method. While the sensitivity of smear microscopy is about 50 per cent, this (Xpert MTB/RIF) has 72 per cent sensitivity with one test, and 90 per cent with three tests in the case of smear-negative patients. The sensitivity goes up to 98 per cent in the case of smear-positive and culture-positive patients. Xpert has 99 per cent specificity. Further, the test's ability to provide reliable results within two hours, compared with 4-6 weeks in the case of culture, will help begin treatment earlier and reduce the chances of an individual infecting others. The greatest beneficiaries will be those co-infected with HIV and TB. The long wait for the results before starting TB treatment is one of the main reasons for the death of many co-infected individuals.

Unlike smear microscopy, Xpert can identify Rifampicin drug resistance. It correctly identified 98 per cent of bacteria that were resistant to Rifampicin. In India and many other countries where multidrug resistant TB (MDR-TB) is not high, much of the testing that goes on now is mainly for diagnosing active TB and not for drug resistance. But Xpert is all set to change this: Rifampicin resistance is an excellent marker of MDR-TB. Most patients who are resistant to rifampicin are also resistant to Isoniazide drug. Patients who are resistant to Rifampicin will need culture to find out which drugs work for them. Following this protocol before starting the treatment will go a long way in preventing MDR-TB from becoming widespread. There is one major problem, however: the diagnostic test is prohibitively expensive. India being one of the high-burden countries, the public sector and certain NGOs will be eligible for a special pricing agreement. Uninterrupted power supply and temperature control, which are essential, will turn out to be major challenges in rural areas. India must find ways to embrace this technology swiftly after necessary field testing considering that TB kills two Indians every three minutes.

Corrections and Clarifications

The Editorial, "Revolutionary test for TB" (December 28, 2010), referred to a published paper, "Rapid molecular detection of tuberculosis and Rifampicin resistance," by Catharina C. Boehme et al., in the New England Journal of Medicine. The correct name of the paper is: "Rapid molecular detection of tuberculosis and Rifampin resistance."

The Editorial also referred to "the results of a trial conducted on 1,700 patients in five countries." It was wrong. The study was conducted at five trial sites in four countries.

PARLIAMENT QUESTION - ANSWERS

RAJYA SABHA

GOVERNMENT OF INDIA MINISTRY OF HEALTH AND FAMILY WELFARE

STARRED QUESTION NO 299
ANSWERED ON 30.11.2010

WHO LIST OF MEDICINES FOR TREATMENT OF HIV AIDS

299SHRI NAND KUMAR SAI

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

(a) whether the World Health Organisation (WHO) has released a list of medicines for treatment of HIV/AIDS;

(b) if so, whether generic medicines developed by Indian companies have also been included in this list;

(c) whether some multinational companies have termed the medicines developed and manufactured by Indian companies as inferior;

(d) if so, the details thereof and the reasons therefor;

(e) whether these medicines were included in the list of AIDS Control Programme; and

(f) if so, the details thereof?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a)to(f): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 299 FOR 30TH NOVEMBER, 2010

(a)&(b): Yes Sir, the World Health Organisation (WHO) has released the guidelines for Antiretroviral Therapy (ART) for HIV infection in adults and adolescents (2010 revision). The guidelines describe the newer strategies with regard to the starting of treatment and the drug regimen recommended for the same.

The generic medicines manufactured by Indian companies are also indicated in the list of drugs in these guidelines.

(c)to(f): No, Sir. The generic medicines developed by Indian pharmaceutical companies are not considered inferior internationally.

The medicines used in the National AIDS control programme are included in the WHO list of medicines (Antiretroviral drugs).

UNSTARRED QUESTION NO 2235
ANSWERED ON 30.11.2010

ILL EFFECTS OF VEGETABLES INJECTED WITH OXYTOCIN ON HEALTH .

2235SHRI JAI PRAKASH

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :-
(A) whether Government is taking any step to detect ill-effects on health by vegetables injected with oxytocin;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

ANSWER

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE(SHRI DINESH TRIVEDI)

(a) to (c) : As per available information, oxytocin is functional only when it is directly injected into the blood circulation.

Following reports in media/press regarding the use of oxytocin in vegetables, a 'Core Committee' has been constituted under the co-chairmanship of the Secretary, Department of Health Research (DHR) & Director General, Indian Council of Medical Research (ICMR) and the Secretary, Department of Agricultural Research and Education (DARE) & Director General, Indian Council of Agricultural Research, to review the extent of use of oxytocin in fruits and vegetables, its effects on health and identify researchable issues pertaining to it.

UNSTARRED QUESTION NO 2252
ANSWERED ON 30.11.2010

POLICY FOR SUPPLY OF CHEAP AND GENERIC MEDICINES

2252 SHRI PRABHAT JHA

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

(a) whether Government is aware of the fact that the World Health Organization (WHO) had given a list of almost one hundred and fifty mandatory medicines to developing countries;

(b) if so, the details thereof;

(c) whether Government is having any plan to frame a policy for providing cheap and generic medicines sufficiently in the country; and

(d) if so, the details thereof?

ANSWER

THE MINSITER OF STATE FOR HEALTH & FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a)&(b): World Health Organization (WHO) has published a model list (March 2010) of essential medicine needed for basic health care system. These medicines are claimed to be safe, efficacious and cost effective with relevance for public health.

(c) & (d): In a bid to provide low cost generic medicines, Department of Pharmaceuticals has launched Jan Aushadhi Campaign under which Jan Aushadhi Stores would be opened at /near Government Hospital premises with the support of State Governments concerned. Under this Programme, 80 such Stores, spread over in nine States including Delhi and Chandigarh have been set up so far. Low cost but good quality Generic Medicines produced by Central Public Sector Undertakings are made available in these stores.

STARRED QUESTION NO 394
ANSWERED ON 07.12.2010

ILL EFFECTS OF HONEY MIXED WITH ANTIBIOTICS

394 SHRI BHARATKUMAR RAUT

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

(a) whether it is a fact that according to a study carried out by the Centre for Science and Environment most of the honey brands available in the market contain varying amount of antibiotics;

(b) whether it is also a fact that the over consumption of such branded honey could induce resistance to antibiotics, leading to blood-related disorder and injury to the liver; and

(c) the steps Government intends to take to stop mixing antibiotics in honey by the well known Ayurvedic medicine producing companies like Dabur, Himalaya, Patanjali, Baidyanath, Khadi, Gold, Himflora Mehsons, Umang, etc?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a)to(c): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 394 FOR 7TH DECEMBER, 2010

(a) The Centre for Science and Environment (CSE), New Delhi, an NGO, in a laboratory study on antibiotics in honey in September, 2010, has reported that out of 12 samples of honey analysed by them 11 samples contained antibiotics, out of which 2 samples were of imported honey.

(b) The Department of Health Research has constituted an Expert Group at the Indian Council of Medical Research (ICMR) to address issues relating to antibiotics in honey.

(c) The standards of honey have been prescribed under the Prevention of Food Adulteration (PFA) Rules, 1955, wherein antibiotics are not permitted to be added in honey. The implementation of PFA Act and Rules is carried out by the State/U.T. Governments who draw samples of various food articles including honey and take action in case of any violation of Prevention of Food Adulteration Rules, 1955. An advisory has been issued to all State Governments/U.T. Governments to keep a strict vigil on the quality of honey sold in the market and to take necessary action under the provisions of PFA, 1954 in case samples do not conform to the standards prescribed in PFA Rules, 1955. The Port Health Officers, Authorised Officers at the Ports and Customs Collectors, have also been advised to analyse all consignments imported into the country as per quality parameters prescribed under PFA Rules, 1955, as well as for the presence of antibiotics before the same is released for human consumption.

STARRED QUESTION NO 3002
ANSWERED ON 07.12.2010

SELLING OF DRUG LACED CANDY .

3002 SHRI SHANTARAM LAXMAN NAIK

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :-
(a) whether it is a fact that a candy by name `Strawberry Quick` containing a harmful drug is sold to school children in Mumbai;

(b) whether the culprits candidly distributing drugs in the form of candys have been apprehended;

(c) whether it is also a fact that school management and parents are worried over the fact that some children have already become addicted to such candys;

(d) whether some students eat such candys to improve their concentration during exams; and

(e) if so, the details thereof?

ANSWER

THE MINISTER OF STATE FOR HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI)
(a) to (c) Government has not received any report in this regard.

(d) & (e) The Food Safety & Standards Authority of India has informed that the Prevention of Food Adulteration Rules, 1955 do not permit harmful drugs in food articles.

UNSTARRED QUESTION NO 3007
ANSWERED ON 07.12.2010

DRUG TRIALS ON PREGNANT AND LACTATING WOMEN

3007 SMT. JAYANTHI NATARAJAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :-
(a) whether it is a fact that incidences of drug trials on unsuspecting patients particularly on pregnant and lactating women in hospitals and medical colleges have come to the notice of Government;

(b) if so, the details thereof; and

(c) the action taken by Government in this regard?

ANSWER

THE MINISTER OF STATE FOR HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI)

b(a) to (c): No such report has come to the notice of the Government. Clinical trials of drugs/vaccines in the country are permitted to be conducted in accordance with the requirements and guidelines specified in the Drugs and Cosmetics Rules 1945.

UNSTARRED QUESTION NO 3014
ANSWERED ON 07.12.2010

SURVEY ON EXTENT OF SPURIOUS DRUGS IN THE COUNTRY

3014 DR. GYAN PRAKASH PILANIA

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state :-
(a) whether to assess the extent of spurious drugs in the country, a country wide survey has been undertaken by the Ministry through CDSCO, if so, its outcome;

(b) whether Indian Pharma Industry estimate is that 20-25 per cent is share of spurious drugs in annual turnover of 85,000 crore;

(c) if so, what is Government`s reaction thereto;

(d) how many FIRs have been registered, since 5 December, 2008, whence offences under the Drugs and Cosmetics (Amendment) Act, 2008, have become cognizable and non bailable;

(e) how many have been punished; and

(f) how effective has the whistle-blower policy proved to be?

ANSWER

THE MINISTER OF STATE FOR HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) Yes. Ministry of Health & Family Welfare through Central Drugs Standard Control Organization (CDSCO) conducted the countrywide survey to assess the extent of spurious drugs in the country. In this study 24,136 samples of 62 popular brands from 30 manufacturers were collected for analysis. The survey has revealed that 0.046% samples were only found spurious.

(b) & (c): The Government of India is not aware of any survey conducted by the pharma industry by way of drawing samples for analysis indicating that 20-25% is the share of spurious drugs in the annual turnover.

(d) & (e): As per the data made available by the State Drugs Control Organisations, 633 FIRs have been registered since 5th December, 2008 while 2 people have been convicted by the court of law.

(f): The information in respect of spurious drugs from the public spirited persons are being received by the designated authorities in CDSCO under Whistle Blower Scheme.

UNSTARRED QUESTION NO 3032
ANSWERED ON 07.12.2010

PRODUCTION OF BIO PHARMACEUTICAL DRUGS

SHRI VIJAY JAWAHARLAL DARDA

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

(a) whether Government is aware that Bio-pharmaceutical drugs are made using living systems such as micro-organisms, plants or animal cells;

(b) if so, whether adequate safety precautions/measures exist as even if unintentionally or unwittingly administered, these can cause diseases like cancer, coronary heart disorder or infertility;

(c) the effectiveness of the existing Drugs and Cosmetic rules in such situation; and

(D) whether Government had received complaints of this nature during 2008 and 2009?

ANSWER

THE MINISTER OF STATE FOR HEALTH AND FAMILY WELFARE (SHRI DINESH TRIVEDI)

(a) Yes.

(b) & (c) The bio-pharmaceutical drugs are produced by recombinant DNA technology using micro-organisms. The product development of such drugs is examined by the Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology, Ministry of Science and Technology for its safety and efficacy in preclinical studies. The bio-pharmaceuticals containing living modified organisms are evaluated by Genetic Engineering Approval Committee (GEAC) under the Environment Protection Act. Such products also have to prove safety and efficacy in human subjects before approval under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 made there under.

(d). No.

***Source** : www.rajyasabha.nic.in*

LOK SABHA

UNSTARRED QUESTION NO 1825
ANSWERED ON 19.11.2010

PROCUREMENT OF DRUGS

1825 Shri SYED SHAHNAWAZ HUSSAIN

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

(a) whether the Union Government purchases medicines through open tender from the lowest bidder (L-I) for its hospitals and the CGHS dispensaries;

(b) if so, whether the Government proposes to make changes in the acquisition system of medicines so that best quality medicines can be provided to the people;

(c) if so, the details thereof;

(d) the quantity of the medicines procured by CGHS and other hospitals of the Central Government during the last three years and the current year, so far;

(e) the details of the sources from where such medicines have been procured; and

(f) the details of the companies which have been blacklisted during the said period for supplying inferior quality/spurious medicines?

ANSWER

THE MINISTER OF HEALTH & FAMILY WELFARE(SHRI GHULAM NABI AZAD)

(a) to (c): In so far as the Central Government Hospitals located in Delhi, namely, Dr. RML Hospital, Safdarjung Hospital and LHMC & Associated Hospitals are concerned, the essential medicines/drugs are procured through Government Medical Stores Depot (MSD) according to formulary and through tendering process by the hospitals for the drugs which are not supplied by MSD. The CGHS purchases generic and proprietary drugs on Medical Store Organisation (MSO) approved rates. The MSO approves L-1 rates for generic drugs after inviting open tender.

(d) During 2007-08, 2008-09, 2009-10 and 2010-11 (as on middle of November), quantity of medicines worth 1157.45 crore has been procured by the hospitals mentioned above and CGHS.

(e): In CGHS, the drugs in bulk are procured from manufactures through their authorised distributors and local purchase of drugs is made from authorised chemists.

(f): No company has been blacklisted by CGHS or Hospitals mentioned above, for supplying inferior quality/spurious medicines.

UNSTARRED QUESTION NO861
ANSWERED ON 12.11.2010

PURCHASE OF DRUGS AND MEDICAL EQUIPMENT

861. Shri NAVEEN JINDAL

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

(a) the existing mechanism to procure drugs and medical equipment for the government hospitals and health centres;

(b) whether the Government proposes to set up a separate body for the procurement of such drugs and equipment;

(c) if so, the details thereof; and

(d) the time by which such body is likely to be set up?

ANSWER

THE MINISTER OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a): In so far as the Central Government Hospitals located in Delhi, namely, Dr. RML Hospital, Safdarjung Hospital and LHMC & Associated Hospitals are concerned, the essential medicines/drugs are procured through Government Medical Stores Depot (MSD) according to formulary and through tendering process by the hospitals for the drugs which are not supplied by MSD.

These hospitals procure Hospital Equipments following the procedure laid down in DGS&D Manual, GFR Rules, CVC Guidelines and instructions issued by Ministry of Health & Family Welfare/ Directorate General of Health Services.

(b) to (d): Planning Commission has accorded in principle approval to set up a professional Central Procurement Agency (CPA) with one time grant of Rs.50.00 Crores for the purpose of procuring, storing and distributing health sector goods for various national programmes of the Ministry.

UNSTARRED QUESTION NO 1622
ANSWERED ON 19.11.2010

UMBILICAL CORD BLOOD BANK

1622 Shri SONAWANE PRATAP NARAYANRAO

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

(a) whether the Government proposes to set up Centralised Cryo service- Umbilical Cord Blood Bank for preservation of umbilical cord coming out at the time of child birth;

(b) if so the details thereof;

(c) whether the Government is carrying out any campaign for preserving umbilical cord or sensitizing the family of pregnant women in all the States of the country so as to make them understand its importance; and

(d) the place where the first umbilical cord bank of the country is proposed to be set up by the Government?

ANSWER

THE MINISTER OF HEALTH & FAMILY WELFARE(SHRI GHULAM NABI AZAD)

(a)to(d): This Ministry has no proposal for establishing umbilical cord blood bank.

UNSTARRED QUESTION NO 1627
ANSWERED ON 19.11.2010

TREATMENT BY STEM CELLS

1627. Dr. SOLANKI KIRITBHAI PREMAJIBHAI

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

(a) the names of the hospitals where stem cell therapy is being provided, State/ UT-wise;

(b) whether the Government pensioners and their dependents are entitled to get free treatment by stem cells in private hospitals which are on C.G.H.S. panel; and

(c) if so, the details thereof ?

ANSWER

THE MINISTER OF HEALTH & FAMILY WELFARE(SHRI GHULAM NABI AZAD)

(a) to (c) Stem Cell Therapy is not an approved mode of treatment. Only Bone Marrow Transplantation for haematological disorders and cancers, is an approved form of Stem Cell Therapy and which is in practice for past more than 20 yrs and is provided in most of the hospitals including AIIMS, PGI, CMC, etc. Stem Cell Therapy for other conditions/diseases is still to be proven safe and efficacious, hence, question does not arise of therapy being provided.

Government pensioners and their dependents are entitled to get cashless facility treatment in private hospitals which are on C.G.H.S panel, on the basis of advice by a Government specialist.

UNSTARRED QUESTION NO 1682
ANSWERED ON 19.11.2010

USAGE OF CHEMICALS IN CHOCOLATES

1682 Shri SANJAY SINGH CHAUHAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-
(a) whether usage of health hazardous chemicals like methamphetamine in chocolates, ice-cream and other such items have been reported across the country;

(b) if so, the details thereof; and

(c) the steps taken/proposed by the Government to check the usage of such chemicals and punish those found guilty?

ANSWER

THE MINISTER OF HEALTH & FAMILY WELFARE(SHRI GHULAM NABI AZAD)

(a) & (b) : No such instance of usage of health hazardous chemicals like methamphetamine in chocolates, ice-cream and other such items, has come to the notice of this Ministry.

(c) The quality standards of food articles including chocolates and ice-cream are prescribed under Prevention of Food Adulteration Rules (PFA), 1955.The implementation of PFA Act, 1954 and Rules, 1955, is with State/U.T. Government. Violation of the provisions of PFA Act/Rules attracts penal action.

UNSTARRED QUESTION NO 1737
ANSWERED ON 19.11.2010

PROPER TESTING OF VACCINES

1737. Smt. MEENA SINGH JOSE K. MANI

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-
(a) whether vaccines for measles, polio drops and other diseases are being supplied to hospitals after

UNSTARRED QUESTION NO 1737
ANSWERED ON 19.11.2010

PROPER TESTING OF VACCINES

1737. Smt. MEENA SINGH JOSE K. MANI

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

(a) whether vaccines for measles, polio drops and other diseases are being supplied to hospitals after proper testing by the Government;

(b) if so, the details thereof;

(c) whether the Government has conducted epidemiological and costbenefits tests before allowing for the introduction of new and combination vaccines in the country like those for polio, influenza, tetanus, etc.;

(d) if so, the details thereof;

(e) whether the details of these tests are publicly available; and

(f) if so, the details thereof and if not, the reasons therefor?

ANSWER

THE MINISTER OF HEALTH & FAMILY WELFARE(SHRI GHULAM NABI AZAD)

(a) & (b) Vaccines for measles, polio drops and other diseases such as TT, DPT, BCG and Hep-B procured under Routine Immuniztion Programme are supplied to Government Medical Store Depots (GMSDs) and States after undergoing mandatory quality test by Central Drugs Laboratory, Kasauli. Only those vaccines are supplied which pass this mandatory test.

(c) to (f) The polio vaccine and tetanus vaccine have been introduced in 1978 under the Expanded Programme of Immunization (EPI). There is no record available suggesting that these two vaccines were introduced after conducting epidemiological and cost benefit testing. Influenza vaccine is not under the National Immunization Programme. At present, as per recommendation of National Technical Advisory Group on Immunization (NTAGI), newer or combination vaccines are to be enrolled in National Immunization Programme based on epidemiological data.

UNSTARRED QUESTION NO 1747
ANSWERED ON 19.11.2010

IMMUNIZATION OF BCG

1747 Shri JOSE K. MANI

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

(a) whether the immunization coverage at the national level of BCG against TB coverage has gone down across the country;

(b) if so, whether the Government is taking any steps to arrest this trend;

(c) if so, the details thereof; and

(d) if not, the details thereof?

ANSWER

THE MINISTER OF HEALTH & FAMILY WELFARE(SHRI GHULAM NABI AZAD)

(a) No, the immunization coverage of BCG against TB coverage has not gone down at the national level. As per District Level Household and Facility Survey (DLHS) the BCG national coverage has increased over the years. As per DLHS-2 (2002-03), national wide BCG coverage was 75% and has increased to 86.7% in DLHS-3 (2007-08).

(B) to (d) In view of the above, question does not arise.

UNSTARRED QUESTION NO 1822
ANSWERED ON 19.11.2010

COST OF MEDICINES USED FOR RURAL HEALTH CARE

1822 Shri P.R. NATARAJAN

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

(a) whether the Government has any estimation for the cost of medicines used for Rural Health care;

(b) if so, the details of percentage of cost of medicines attributed to rural health care; and

(C) the action taken/being taken by the Government for ensuring availability of quality medicines at affordable prices for all?

ANSWER

THE MINISTER OF HEALTH & FAMILY WELFARE(SHRI GHULAM NABI AZAD)

(a) & (b) Under National Rural Health Mission, the expenditure on the procurement of drugs, vaccines, contraceptives, equipments etc. for supply to all States and UTs for the year 2009-10 is given below:
Name of programme

Expenditure	(in Rs. Crores)
(i) Routine Immunization	363.02
(ii) Pulse Polio Immunization	624.07
(iii) Reproductive & Child Health	260.99
(iv) Vector Borne Diseases	205.93
(v) Tuberculosis Control	54.81
(vi) Family Welfare	208.14

(c) Government procures drugs, devices and vaccines etc. with generic names and the procurement is carried out as per approved technical specification, including packaging, quality assurance requirement and qualification criteria of products and suppliers. In order to ensure wider participation, procurement process involves International Competitive Bidding/National Competitive Bidding so as to ensure quality measures at affordable prices.

UNSTARRED QUESTION NO 750
ANSWERED ON 12.11.2010

HARMFUL ELEMENTS IN SOFT TOYS

750 Shri ADHIR RANJAN CHOWDHURY

DILIP KUMAR MANSUKHLAL GANDHI
SANJAY BRIJKISHORILAL NIRUPAM

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

(a) whether many local and imported soft toys being sold in the country are contaminated with harmful elements which have adverse effect on health;

(b) if so, the details thereof;

(c) whether the Government has assessed/conducted any study in this regard;

(d) if so, the details and the findings thereof; and

(e) the follow-up action taken thereon?

ANSWER

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE (SHRI S. GANDHISELVAN)

(a) to (e): The Ministry of Health and Family Welfare has constituted an Expert Committee to look into the presence of harmful elements in toys

(under the Chairmanship of Dr. Y.K. Gupta. Prof. of Pharmacology, AIIMS, New Delhi. Under which, a study has been initiated which is examining the presence of some heavy metals and phthalates in the plastic toys in the market.

UNSTARRED QUESTION NO 798
ANSWERED ON 12.11.2010

BANNED DRUGS

798 Shri ARJUN RAM MEGHWAL

MILIND MURLI DEORA
ASADUDDIN OWAISI
RUDRAMADHAB RAY

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

(a) whether the Government has decided to ban diabetes pill rosiglitazone marketed as Avandia in the country;

(b) if so, the details thereof;

(c) whether despite the ban, a number of medicines including oxytocin are still being sold in the country;

(d) if so, the details thereof; and

(E) the corrective measures taken/proposed by the Government in this regard?

ANSWER

THE MINISTER OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b): The Central Drugs Standard Control Organisation (CDSCO) has requested all State Drugs Controller on 7.10.10 to suspend all the licences granted by them to manufacture for sale and distribution of the drug Rosiglitazone and its fixed dose combinations with other drugs with immediate effect.

(C) to (e): No. Any drug prohibited under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 for manufacturing and sale in the country is not permitted to be sold in the markets in the country. Manufacture, sale and distribution of any banned drug is punishable under the provisions of the Drugs and Cosmetics Act, 1940. The Act contains stringent penal provisions for manufacture, sale and distribution of the drugs not conforming to the standards prescribed in the Act. Further, the drug Oxytocin is not banned in the country as it is considered as an essential drug in medical practice both in human and veterinary

Source : *www.loksabha.nic.in*

CONGRATULATIONS

We congratulate Dr. Bangarurajan and Mr. P. B. N. Prasad for their selection as Deputy Drugs Controller, India in CDSCO through Union Public Service Commission. Dr. Bangarurajan joined as DDCI in CDSCO, HQ, New Delhi and Mr. P. B. N. Prasad joined as DDCI in CDSCO, South Zone, Chennai

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