



KARNATAKA REGISTERED PHARMACISTS ASSOCIATION[®]

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IT'S
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TIME

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Autism Spectrum Disorder (ASD) or commonly known as Autism is a group of neurodevelopment disorder which are usually characterized by problems in communication and social interactions. The Centers for Disease Control and Prevention (CDC) have stated that autism occurs more often in males than females with a ratio of 4 male: 1 female, which mainly can be due to the structural difference of brain between the sexes, genetic variations, etc. The CDC estimates that 1 in 59 children have been identified with ASD in 2014.

Currently, in 2013 Diagnostic and Statistical Manual of Mental Disorders (DSM) has recognized 5 different subtypes of ASD which are:

1. With or without accompanying intellectual impairment
2. With or without accompanying language impairment
3. Associated with known medical/ genetic condition or environmental factor
4. Associated with another neurodevelopment, mental or behavioural disorder
5. With catatonia (symptoms usually involving lack of movement and communication, may also involve agitation, confusion and restlessness)



Usually, in ASD, symptoms typically begin during early childhood. Early symptoms are usually delayed in language or social development. They usually exhibit problems with communication and social interactions such as difficulties sharing emotions, sharing interests, trouble maintaining eye contact, or reading body language and restricted or repetitive patterns of behaviour or activities such as repetitive movements, motions, or speech patterns or rigid adherence to specific routines.

The exact cause for ASD is unknown. However, some of the suspected risk factors are genetic mutations, hereditary, low birth weight, metabolic imbalance, viral infections, exposure to heavy metals, or drugs like Thalidomide or environmental toxins. DNA testing for genetic disease, behavioural evaluation, visual and audio tests to rule out any visual or auditory impairment and Autism Diagnostic Observation Schedule (ADOS) questionnaires are some of the screening tests done to confirm autism.

There is no complete cure for ASD. Treatment for ASD usually is to improve the quality of life without worsening the symptoms. Some of the treatment options are behavioural therapy, occupational therapy, physical therapy, speech therapy. Some of the pharmacological therapies are high-dose vitamins, chelation therapy, hyperbaric oxygen therapy, etc. Diet also plays a role in minimising behavioural changes and improving the quality of life. They should be counselled to avoid food having artificial additives, preservatives, sweeteners, etc. Prompt them to consume foods containing fresh fruits and vegetables, lean poultry, fish, unsaturated fats and a good amount of water daily.

April is considered World Autism Month. April 2nd is the World Autism Awareness Day, which mainly aims for the need to increase awareness about autism and to bring in an understanding about ASD to the teachers, health care professionals and parents. Understanding autism begins through awareness. Autism-friendly events and educational awareness activities should take place aiming to increase understanding and to accept people with autism and to provide worldwide support. On this awareness day let us stand together to support each other and show unity with people having autism.

Dr. RAVINA RAVI

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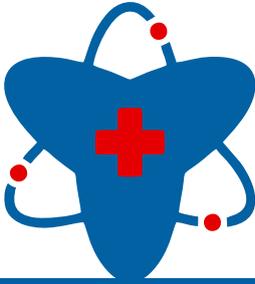
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USP OF A PHARMACY



Introduction:

The world of pharmacy is truly an exciting one – pharmacists in India are uniquely trained. Pharmacists from India get exposure to the industry, regulatory field, R & D, manufacturing, quality, pharmacy practice and exports. Furthermore, many a pharmacist has made a name as media pharmacists too! The allure of being a pharmacist is that this is a knowledge based profession with the potential to make a difference between life and death. The pharmacist can improve the quality of life and increase the life span of patients too! Pharmacy is a life-changing profession, where the pharmacist is professionally qualified to prepare and dispense drugs.

Today's challenges in community pharmacy

There was a time when medicines did not have the MRP printed on the pack. The pharmacy could decide the MRP of a particular product from his counter. In many countries, even to this day, there is no printed MRP concept on the product packaging. MRP is the highest price labelled on the product that can be charged by a seller. It was in 1990 that the “Standards of Measures and Weights Act” was amended and it became mandatory to print MRP on the product label. However, in this era of deep discounts, chain pharmacies, online pharmacies and challenge pricing from pharmacies; this is leading to financial stress particularly on small neighborhood pharmacies.

Which way forward - to compete and survive?

The reality of life is competition. All products are vying with each other to make their appeal to prospects and ensure customers are created. Businesses always work competitively and focus on creating and maintaining customers. Thus, the challenge is to make every pharmacy competitive and competent. One interesting approach is to have a Unique Selling Proposition (USP) of a pharmacy, which should render the pharmacy appealing to target audiences and should help draw prospects (unconverted customers), create customers and maintain a loyal base of repurchasing customers. This creates viability to any business operation amidst competitive forces.

USP stands for Unique Selling Proposition. It is a compelling value offering that differentiates the business firm or product from another, thus making the uniqueness alluring to the customer. For instance, the convenient location of a pharmacy may be a draw attention or the variety of brands stocked makes the pharmacy attractive to the public, or there may be extended timings that provide an attraction for the pharmacy, or the stock of veterinary products makes the pharmacy attractive ... thus it is time to build in some USP to differentiate the pharmacy and make it an attractive option for target consumers to repeatedly visit.

Importance of displays

Today, it is a buyer's market for most products and services. Thus, buyers are always looking to get the best deal or value while making a purchase. In pharmacy, the launch of Jan-Aushadi has made many people conscious about generics and branded medicines. Thus, again this has led to people asking doctors or pharmacists for a good brand of medication. The pharmacist is the most accessible and trusted healthcare professional. His or her advice is readily accepted by patients or buyers and this makes the pharmacist a very amenable healthcare advisor.

That is where attractive display counters come in handy to the pharmacist. When the community pharmacy is well stocked, and the stocks are kept systematically and in an orderly manner, the next add-on is attractive displays - where the brand packs are adding to the colour, appeal and mesmerism of the pharmacy. Such a picture will draw potential customers to the pharmacy.

Have a cachet!

It is wise for pharmacists to make their pharmacy have a distinguishing feature. For example, the pharmacist can advertise that veterinary products are available along, with routine products, and another pharmacy can stock and showcase all oral care products in a corner (the pharmacy will have other products too), thus making the pharmacy a one-stop destination for oral care products. Today, there is strong trend of nutraceuticals. So how about naming the pharmacy: Nutraceuticals? The name itself will speak to potential customers that along with medicines the stock of nutraceuticals is good and the pharmacist can use his knowledge to counsel buyers of the right choice. Another approach is focusing on first-aid kits and other first-aid materials in a corner and positioning the pharmacy as the ideal destination for buying first-aid related products. So factories and homes alike can look up the first – aid products there, get the right advice from the pharmacist and buy the needful.

Closing remarks: When the going gets tough, the tough get going! This is a popular saying, and what the words mean is that when there are challenges, it is time for people to pull up the socks and respond to the challenge with creativity and alacrity. Online pharmacies, chain pharmacy and deep discount pharmacies are no doubt putting financial pressure on regular pharmacies. A repositioning exercise based on creating a unique look and feel of the pharmacy will help the pharmacist gear up and win over the challenges. One very important aspect is learning continuously, having all the education material at hand while communicating with patients, and developing the ability to counsel patients on various healthcare issues and medicines. For instance, what is the best response of the pharmacist when a patient asks if the Covid-19 vaccine is safe? Does it cause blood clots that can precipitate heart attack? The ideal advice in this scenario, of the pharmacist, is to advise the patient to discuss with a doctor or go directly to the lab and get the blood CRP (c reactive protein) level checked. If CRP blood level is less than 1, the vaccine administration confidence is better. Also, it is wise for the pharmacists to be armed with the information of post Covid-19 vaccination side-effects, these needs to be counselled to patients. Thus, the USP (unique selling proposition) of a pharmacy is twofold:

- (a) Uniquely positioning the pharmacy and
- (b) Having a high level of professional counselling by the pharmacist will make survival and growth of the pharmacy a sure shot thing.

Mr. Sunil S Chiplunkar

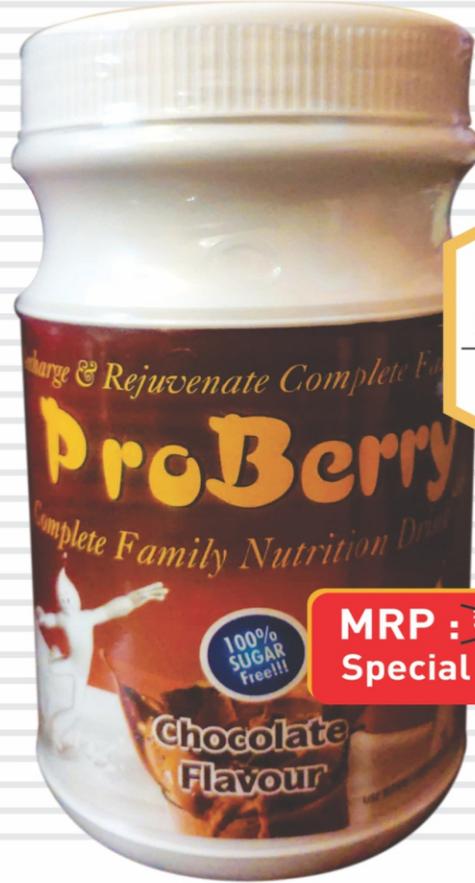
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MANIPAL ACADEMY OF HIGHER EDUCATION

establishes a Centre for current Good Manufacturing Practices (cGMP)

cGMP

that building a strong Quality Culture and Data Integrity systems are the need of the hour, especially for the Indian pharmaceutical sector. Both Quality Culture and Data Integrity go hand in hand, and we believe that these good practices should be inculcated into young minds right from academic set up so that fresh candidates entering regulated pharma companies are well versed with the GMP practices and know the importance of Data Integrity and various challenges associated well in advance. Centre for cGMP shall be working towards mitigating these lapses right from academic set up and this will definitely bring a positive change in the thinking of freshers joining a regulated company and help to work with commitment from day one until the last day of their entire professional career. This is an untouched and unexplored area, and for information, no other pharma institute in India has a "Center on cGMPs".

Mr. Harish K Jain carries experience of about 29 years and is a successful pharma entrepreneur apart from holding key positions for various pharmaceutical bodies. Mr. G Sundar is Director at PharmQA Compliance Services, Chennai with 27 plus years of rich experience in the fields of Quality Assurance, Quality Control, Bioequivalence and Pharmaceutical Regulations. Mr. Sundar is a successful GMP trainer and has conducted about 500 training sessions for the technical staff in the pharma sector. Mr. Sundar has also assisted his clients to successfully face audits of various regulatory agencies like USFDA, UKMHRA, WHO, etc and helped many pharma companies for audit compliance.

Dr. Pai said that the centre has plans to come out with volume II of Pharmaceutical Consumer Complaints and a book on Pharma Quality. The centre shall be rolling out well-defined achievable objectives that will benefit the pharma students and technical staff at pharma companies.

Manipal Academy of Higher Education, (MAHE: an Institute of Eminence) has established a Centre for current Good Manufacturing Practices (cGMP). The centre is established at Manipal College of Pharmaceutical Sciences, a constituent unit of MAHE, Manipal.

cGMP is the part of Quality Assurance that ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as per design specification. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors. This, in turn, protects the consumer from purchasing a product that is not effective or even dangerous. Failure of firms to comply with GMP regulations can result in very serious consequences including recall, seizure and fines. This is a unique centre and at present, there is a huge industry-academia gap concerning GMP concepts in academic curriculum and actual industry practice, therefore academia has a major role to inculcate a strong GMP foundation in young brains, said the Coordinator of the centre Dr. Girish Pai Kulyadi.

The cGMP centre shall be assisted by a 5-member in-house team from academia and 2 highly experienced industry experts. The in-house team includes Dr. Girish Thunga, Dr. Muddukrishna BS, Dr. Arvind Pai, Dr. Vasudev R Pai, Mr. Ravindra U Shenoy and mentors from the pharma industry include Mr. Harish K Jain and Mr. G Sundar.

Mr. Harish K Jain, Director, Embiotic Laboratories (P) Ltd Bengaluru and Secretary, Karnataka Drugs and Pharmaceutical Manufacturers Association (KDPMA) Bengaluru, expressed that the recent audit outcomes of various global regulators reflect

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MANIPAL



HEMOVIGILANCE

Transfusion safe



Hemovigilance is defined as the set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components. It aims to promote the safe and effective use of blood components and transfusions. It involves monitoring, reporting, investigating, and analyzing the adverse events occurring during the donation, processing and transfusion process. Also involves preventive measures to reduce the adverse event occurrence or recurrence.

The term “Hemovigilance” is derived from the Greek word “haema” (blood) and the Latin word “vigilans” (watchful). Hemovigilance was first implemented by France in the early 1990s, after the event where many hemophilic patients in the United Kingdom (UK), France, Canada, Japan, and United States (US) contracted hepatitis C virus (HCV) and human immunodeficiency virus (HIV) from blood transfusion and factor concentrates.

In 1994, the French Hemovigilance system was established, UK followed by the launch of the Serious Hazards of Transfusion (SHOT). The European Blood Directive was introduced initially voluntarily and subsequently on a mandatory basis. Many countries have established a system for monitoring and reporting adverse events following transfusion.

Globally, the International Hemovigilance Network (IHN) was developed from the European Hemovigilance Network (EHN), involving around 34 countries as members which aim at developing and maintaining a joint structure related to the safety of blood and blood components. The IHN coordinates with the International Society of Blood Transfusion (ISBT) to standardize the hemovigilance system worldwide. The International Surveillance of Transfusion Associated Reactions and Events is an international database of hemovigilance data.

Hemovigilance systems governance differs according to countries which are managed either by regulatory authorities (France, Germany, Switzerland), blood manufacturers (Japan, Singapore, South Africa), medical societies (Netherlands, UK), or public health authorities (Canada).

The hemovigilance data is necessary for:

- making changes in transfusion policies
- amending transfusion practices in hospitals and blood banks
- enhancing transfusion standards
- aiding in formulating transfusion guidelines
- improving quality and safety of the transfusion process as a whole



Definitions:

The European Blood Directive defines a serious adverse event as “any untoward occurrence associated with the collection, testing, processing, storage, and distribution of blood and blood components that might lead to death or life-threatening, disabling or which results in, or prolongs hospitalization or morbidity.”

- Grading for severity: 0 = no sign; 1 = immediate signs without vital risk and full resolution; 2 = immediate signs with vital risk; 3 = long term morbidity; 4 = death of the patient.
- Grading for imputability: 0 = no relationship; 1 = possible; 2 = likely; 3 = sure.
- Clinical and biological signs:
 - Immediate reaction: hemolysis; non-hemolytic febrile transfusion reaction (NHFT); allergic reactions-rash, erythema, urticaria, anaphylaxis; transfusion related acute lung injury (TRALI)
 - Delayed reaction after transfusion
 - Microbiological/viral transmission
 - Allo-immunization
 - Incorrect blood component transfusion
 - Others

Hemovigilance Programme of India:

The hemovigilance programme of India was launched in December 2012, as a component of the Pharmacovigilance Programme of India (PvPI). It is collaboration between the National Institute of Biologicals (NIB) and the Indian Pharmacopoeia Commission (IPC). There are over 154 centers across the country enrolled under this programme.

Conclusion:

Hemovigilance is a continuous process, which is an essential component of the healthcare system to ensure and maintain quality and safe transfusions of blood and its components. It is necessary to monitor and prevent the occurrence of transfusion adverse events, thereby promoting better patient safety and safe use of blood and its components.





WHITENING CREAMS & ITS EFFECTS

"**Skin whitening products**", "depigmenting agents", "skin bleaching products" are referred to uses of skin fairness products which ranges from 27 to 77% in various countries such as Europe, Asia, Africa and North America. The global beauty industry is the fastest-growing segment, and it is estimated to reach 31.2 billion US dollars by marketing forecasters, particularly in Africa – Asian countries. According to AC Nielsen's report in 2009, more than \$432 million worth of skin products were purchased by Indians alone, annually. During such intervening years, the demand for skin products has skyrocketed.

Generally, it is not highlighted by industries regarding the health hazards related to the use of skin fairness products despite their heavy usage. The nature and concentration of ingredients used in skin products determine the severity of side effects. Despite a few cosmetic products being safe to use with lower risk, the majority of them contain dangerous ingredients like bleaching agents such as hydrogen peroxide, Hydroquinone and mercury. A

study by Agarwal et al., where 23 skin fairness creams were tested, revealed that 50% of face creams with steroids are dangerous to the skin. Periodically, the level of mercury in face creams has been increased in recent times.

Commonly used ingredients in fairness creams include betamethasone, Hydrogen peroxide, Alpha-hydroxy acids, Allison, Clobetasol, Vitamin C (ascorbic acid), Vitamin A, Ammoniated mercury chloride, Tretinoin and Calomel. Products consisting of ingredients like mercury, steroids of Hydroquinone are known to cause the most common side effects such as irritation, inflammation, thinning of the skin, peeling and scarring. Also, when used during breastfeeding and pregnancy, it can lead to liver, kidney or nerve damage in newborn babies. Skin – bleaching ingredients are known to cause viral, Bacterial, Fungal and Parasitic infections.



Various systemic and cutaneous side effects are caused by popular skin whitening products and the most effective Hydroquinone. Most of them include 70% of patients with contact dermatitis, PIH, allergic contact dermatitis and hypopigmentation. Others like peripheral neuropathy, decreased skin elasticity, impaired wound healing, wound dehiscence precisely after abdominal procedures like caesarian section or hysterectomy, nail discolouration, conjunctival pigmentation, corneal melanosis and degeneration and pseudo yellow – nail syndrome on long term use. Trimethylaminuria, or Fish odour syndrome, which is characterized by odour similar to the rotten fish body to eliminate trimethylamine in urine, vagina, sweat and saliva, is a specific side effect caused by chronic use of Hydroquinone. It was suggested that hydroquinone use is associated with squamous cell carcinoma, but all cases reported a history of prior or concomitant TC use.

Multiple dermatological and systemic side effects are related to the use of Topical Corticosteroids (TCs) as skin whitening agents. Some of the cutaneous complications associated with TC application are allergic contact dermatitis, periorbital dermatitis, Rosacea, Acne vulgaris, hypertrichosis, striae atrophica, telangiectasias, skin atrophy and viral warts. Also, it causes a plucked chicken-like appearance on the skin, which is seen in pseudo – pseudo xanthome elasticum, which is a rare side effect. It was believed that high-dose TCs (>50 g/wk of clobetasol propionate) is associated with adrenal suppression, but later even low-dose (7.5 g/wk) also caused the same in patients. Vulnerable Individuals are at high risk for developing adrenal suppression due to damaged skin barriers. Squamous cell carcinoma and avascular necrosis of the femoral head are two less – common side effects of TCs. TC users are at high risk of developing cellulitis, erysipelas, folliculitis, dermatophytosis and scabies. The increase in the use of highly potent formulations in thin skin (face, armpits and groin) can subsequently increase the risk of adverse reactions. Tinea incognito, Tinea faciei and Tinea corporis are common dermatophyte infections that can be caused.

The form of mercury and the rate of administration define the type of kidney injury associated with mercury. Neurotoxicity characterized as erethism, tremor,

peripheral neuropathy, metallic taste, anxiety, psychosis, depression and memory loss are associated with Organic and metallic mercury, which are lipophilic, whereas inorganic mercury rarely causes neurotoxicity. In contrast, all types of mercury are associated with developing a glomerular renal disease or tubular disease. Based on the length of exposure, acute exposure causes tubular (acute tubular necrosis), whereas chronic exposure causes glomerular injury. Allergic contact dermatitis, purpura, nail discolouration, flushing, erythroderma and gingivostomatitis are the most common mercuric complications. Mercury, with the capacity to cross the placenta, is related to prenatal and postnatal intoxication when pregnant women used soap containing mercury stated by Ladizinski et al. In addition, glomerular lesions are observed in 50% of young African – Kenya women using mercury-containing skin products.

Although 61% of the Indian dermatologic market focuses on skin-lightening products, Studies assessing its prevalence could not be found. In India, the demand for skin whitening initiated long ago with people having fairer complexions who belonged to higher castes of Hinduism's social hierarchy. In addition, Great Britain, which was lightly skinned, made strength, fairness and supremacy an interconnection when it invaded India. Even today, when we go through newspaper matrimonial advertisements, it is evident that fairness is considered a superior status and beauty. While all these decades the fairness obsession remained on women, now it targets men through various marketing ways such as television, internet advertisements, newspapers and messages like "Men are more attractive and successful with lighter skin".

It has become common to use fairness creams. Albeit mercury, lead and arsenic acid are present in the four most common brands with much fewer quantities than those of permissible limits; the long-term toxic effects are yet to be understood. Thus, it necessitates precautionary use of such products because lower levels of chronic use may result in complications. Therefore, a change in mindset regarding the prejudice of inferiority of dark skin and the use of such toxic ingredients in fairness creams by stakeholders is in need of the hour. Further evidence is required to overrule the health issues that may develop due to heavy metal exposure in skin products.

Awareness alone is not a successful practice to prevent such health issues. Also, it remains a pressing consideration of how socio-cultural context can understand these health risks. It is of great importance that these behavioral changes are demanding to address adverse health issues related to skin products. Therefore, one of the themes suggested with regards to the skin whitening topic is health beliefs. An increase in awareness can decrease the abuse of these toxic agents. It is necessary to have control the overuse of skin whitening and bleaching products, and particularly women have to be educated regarding the complications.

Dr. A Pramod Kumar
Associate Professor
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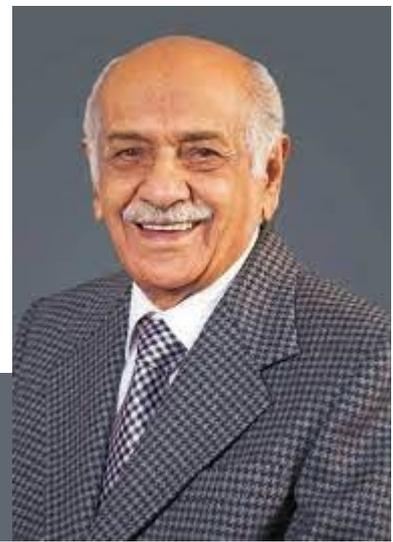


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INSPIRATIONAL PHARMACIST



Dr. B.D Miglani,
Father of Hospital Pharmacy in India
(1929-2017)

Dr. Bhagavan Das Miglani simplified as B. D Miglani has contributed tremendously to the progression of the pharmacy profession in India copiously. He is attributed as a founding father in hospital pharmacy, was a prominent pharmaceutical consultant and educationist who endured revolutionization in the pharma sector in India.

Miglani was Born in the former Pakistani village of Sahani in the Bhakkar tehsil in September 1929. He graduated B.Pharm in 1950 from Punjab university and later took M.Pharm and Ph.D in pharmacy from the identical university.

In 1963, he invited hospital pharmacists and others interested in the growth of hospital pharmacy in India to meet in Piani on December 29, 1963, during the 15th Indian Pharmaceutical Congress, to discuss the possibility of establishing an Indian Society of Hospital Pharmacists. The meeting decided to launch the IHPA, and a preparatory committee was formed to finish the constitution. Dr. Miglani established the Indian Hospital Pharmacists' Association in 1963, laid the groundwork, and served as General Secretary (1964-1971), President (1972-1973), and Patron of the IHP Association. The Indian Journal of Hospital Pharmacy was founded by Dr. Miglani (1964-2007). Dr. Miglani has made important contributions to the field of pharmacy and has received several awards and distinctions. The Indian Pharmacy Graduate Association, Delhi, presented him with the Lifetime Achievement Award (Nagpur). Aside from that, he has earned other accolades from a variety of organizations. He was a member of the Advisory Board of the Indian Journal of Pharmacy Practice from its establishment in 2008 until his death. He also instigated M.pharm hospital pharmacy Dipsar, New Delhi.

Dr. Miglani concluded with some wise words for newcomers to the pharmaceutical industry, saying, "Present-day pharmacy professionals have to be committed, dedicated and should work with a missionary spirit. The pharmacist's sole objective should be to provide quality services for the welfare of the patient community by taking the challenging job of providing drugs of quality at a reasonable cost and providing counselling to patients. We should get rid of the menace of greed and corruption.

Shifa Taj
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