



SYNERGIA

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UPDATES

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NAAC
GRADE A

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WITH A GRADE**
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APPROVALS

BRAND NAME (ACTIVE INGREDIENT)	INDICATION	SPONSOR	APPROVAL
Trulance (Plecanatide)	Chronic idiopathic constipation	Synergy Pharmaceuticals	January 2017
Rhofade (Oxymetazoline HCl)	Facial erythema associated with rosacea	Allergan	January 2017
Parsabiv (Etelcalcetide)	Secondary hyperparathyroidism in adults with chronic kidney disease on hemodialysis	Amgen	February 2017
Siliq (Brodalumab)	Plaque psoriasis	Valeant Pharmaceuticals	February 2017
Xermelo (Telotristat ethyl)	Carcinoid syndrome diarrhea	Lexicon Pharmaceuticals	February 2017
Qtern (Dapagliflozin and saxagliptin)	Inadequately controlled type II diabetes	AstraZeneca	February 2017
Emflaza (Deflazacort)	Duchenne muscular dystrophy	Marathon Pharmaceuticals	February 2017
Kisqali (Ribociclib)	Postmenopausal women with a type of advanced breast cancer	Novartis Pharmaceuticals	March 2017
Bavencio (Avelumab)	Merkel cell carcinoma	Merck	March 2017
Dupixent (Dupilumab)	Atopic dermatitis	Regeneron Pharmaceuticals	March 2017
Symproic (Naldemedine)	Opioid-induced constipation	Shionogi	March 2017
Ocrevus (Ocrelizumab)	Multiple sclerosis	Genentech	March 2017
Xadago (Safinamide)	Parkinson's disease	Newron Pharmaceuticals	March 2017
Zejula (Niraparib)	Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer	Tesaro	March 2017

SOURCE: Centerwatch, USFDA, Current as on 31st December 2017, Compiled by Patel Trushitkumar B, Pharm D Intern

DISCLAIMER

SYNERGIA ("publication") intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with this publication or Krupanidhi College of Pharmacy, Bangalore shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration and not be construed as an endorsement.



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EXPERT REVIEW

B I O S I M I L A R S : A N I N S I G H T

Biosimilars are a new class of drugs intended to offer similar safety and efficacy to the reference biologicals that are off-patent. Biosimilars are biological products which are highly similar to the reference biologic product, but not the same as they may differ slightly in structure however with no clinically significant difference. Biologicals are large molecules derived using biotechnology for their use in the treatment, diagnosis or prevention of diseases. Biologicals are one of the important inventions to manage and treat difficult, rare, serious and life threatening conditions like cancer and autoimmune diseases. They have become an essential part of medical practice. Globally patients have received new treatment options in many therapy areas as more than 80 biologics have been launched over the past decade. The first recombinant product for human use, human insulin (Humulin®), was approved in the US in 1982. Following the approval of first biopharmaceutical, eight other products came into existence in that decade. There was a considerable rise in the number of approvals throughout the 1990s as the industry was getting experienced. Since 1995, approval rates have remained remarkably constant. It's forecasted that by 2022 about 50% of the Top 100 products in the market will be biologics owing it to the use of biotechnology.

Continued research and understanding on genetics and cell processes results in identification of new biologic targets leading to better understanding of diseases and thereby have newer targeted therapies.

Biologics are distinct from small molecules in several attributes. Biologics are big and very complex molecules, often 200 to 1,000 times the size of more common small molecule drugs. A typical monoclonal antibody will be measuring about 150,000 daltons, while aspirin, a small molecule is roughly about 180 daltons. Biologics in contrast to the small molecule have minimal safety issues due to the high target specificity and well understood mechanisms.

The success of biologics and their spiraling costs, timed with patent expiries, have led biopharmaceutical companies to develop biosimilar products. Patents on several bestselling biological products will expire by 2020. Biosimilars have the potential to increase access and provide lower-cost options for treatment of several conditions. As a result biosimilars are expected to become an important economic and therapeutic driver of the Indian pharmaceutical market.

Biosimilars are differently addressed by different regulatory bodies.

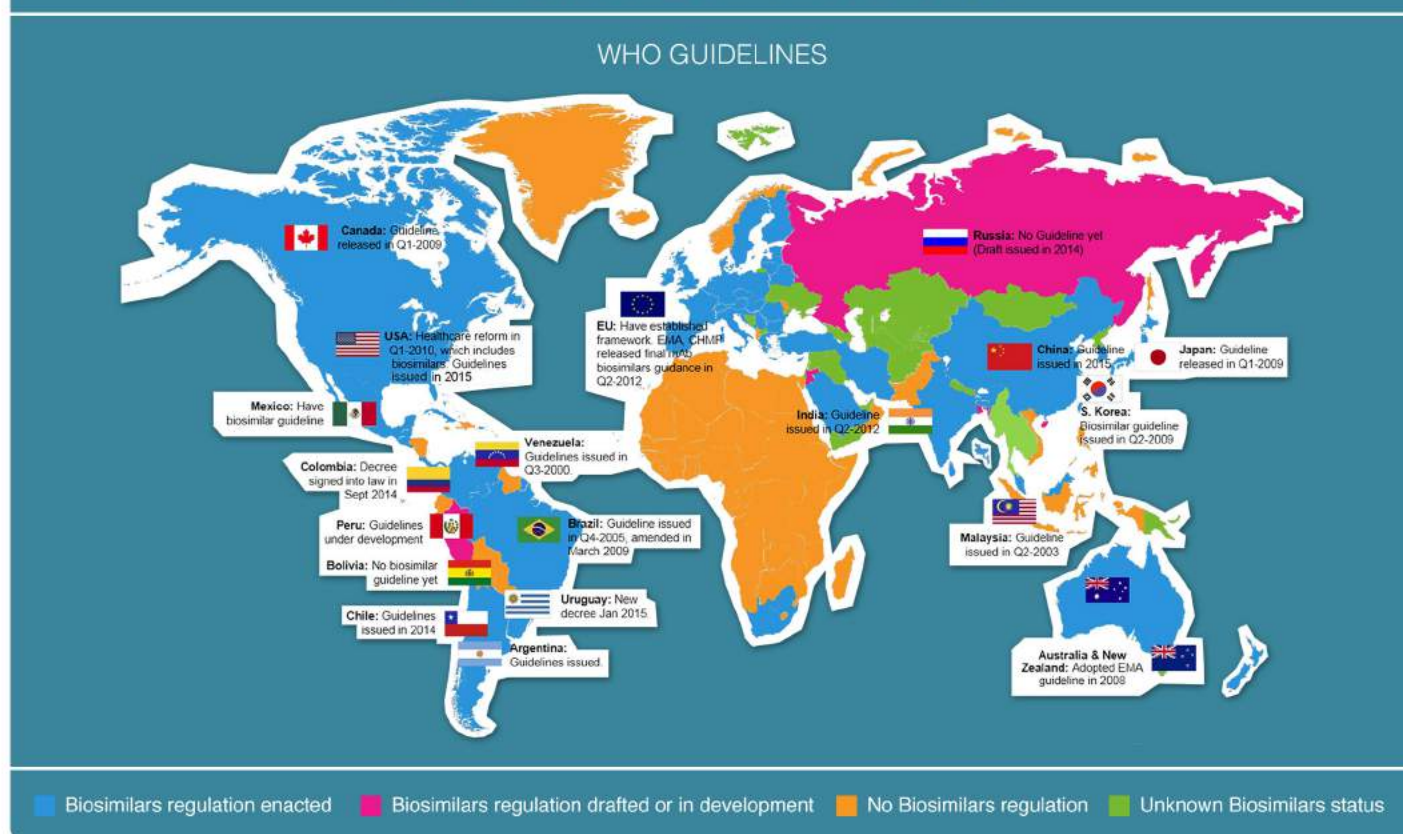
Regulatory Body	Terminologies used
United States Food and Drug Administration (US FDA)	Follow on Biologics
World Health Organization (WHO)	Similar Biotherapeutic Product
India	Similar Biologics
Europe	Biosimilar
Brazil	Follow on Biologics
Canada	Subsequent Entry Biologics
South Africa	Non-comparable Biologics
Japan	Follow on Biologics

SCENARIO IN INDIA:

First biosimilar was approved for marketing in India in 2000 which was for treatment of Hepatitis B. About 75% of biosimilar market is shared by India, with about 30 biosimilar products marketed out of 40 biological products¹⁵For the first time CDSCO, in collaboration with the Department of Biotechnology (DBT), issued in 2012 the Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India (Guidelines). The Guidelines had detailed the regulatory requirements, such as data requirements for the manufacturing, characterization, preclinical studies and clinical trials, for receiving marketing authorization of similar biologics. The Guidelines are applicable for similar biologics developed in or imported into India. This guidance was revised in August 2016 jointly by CDSCO and DBT in consultation with stakeholder experts from industry associations, leading scientific institutions, and laboratories. The revision was done with the objective of keeping pace with ever changing global standards and to streamline the regulatory process for the authorization of similar biologics in India. The revision has factored and taken into consideration the recent guidelines from EMA on Similar Biological medicinal products, 2014, as well as the current WHO guidelines on the quality, safety, and

efficacy of bio-therapeutic protein products prepared by r-DNA technology so as to ensure the product meets acceptable levels of safety, efficacy, and quality. The most major changes, is on the option of reference biologic. If the reference biologic is not marketed in India, it can be licensed in any ICH country. On post-marketing studies the guidance clarifies that these are intended to further reduce the residual risk of the Similar Biologic and which now includes a timeline for such studies. The post marketing safety data is expected through a pre-defined single arm study of generally, more than 200 evaluable patients and compared to historical data of the Reference product. The study should be completed preferably within 2 years of the marketing permission / manufacturing license unless otherwise justified. If the sponsor conducts pre-approval studies that included more than 100 patients on the proposed Similar Biologic drug, the number of patients in phase IV study can be reduced accordingly so that the safety data (from both Phase III and IV) is derived from a minimum of 300 patients treated with the Similar Biologics.

REGULATORY GUIDELINES - GLOBAL SCENARIO



Infographic courtesy: Biosimilars: Rationale and current regulatory landscape. Semin Arthritis Rheum. 2016 Apr; 45 (5 Suppl):S1-10. doi: 10.1016/j.semarthrit.2016.01.001. Epub 2016 Jan 21.

TOXIC EPIDERMAL NECROSIS (TEN)

TEN is a potentially life-threatening dermatologic disorder. TEN is believed to be an immune-related cytotoxic reaction. TEN can be induced by drugs including antibiotics, Antiepileptic drugs, Nonsteroidal anti-inflammatory drugs, Allopurinol, corticosteroids and the antiretroviral drugs.

Here is a case report that describes a 63 year old man with comorbidities, presented to the hospital with complaints of high grade fever with headache/joint pain/myalgia. With due consent and a provisional diagnosis of Acute Febrile illness-Enteric/Viral, he was admitted to the hospital for further evaluation. His initial laboratory workup revealed thrombocytopenia with negative for dengue/widal being normal. Patient was treated with IV empirical antibiotics, PPI's, antipyretics along with his previous medications. During the next 4 days of hospital stay, He persisted to be febrile with daily spikes and hence further laboratory work-up into malaria, leptospirosis, brucella, rickettsial was done which reported to be negative. Despite an aggressive management, Platelet started to drop to 22,000 along with leucopenia/high LDH/CRP. Due to severe chills associated with fever and lab reports of high LDH, a probability of complicated malaria was considered, Antimalarials was started with persistence of fever spikes, Antibiotics were changed to Meropenem, and Doxycycline was added for atypical fever including Scrub typhus.

After a day, the patient worsened in the form of hypotension, multiple petechial rashes and few bullous lesions, sub conjunctival haemorrhage with pedal oedema, decreased urine output and laboratory reports of leucopenia/thrombocytopenia/high CRP with metabolic acidosis. Due to high risk for morbidity. He was shifted to MICU for further management. In view of his dermatological changes possibility of Doxycycline induced Adverse Drug Reaction(ADR) was considered and immediately the drug was stopped. Then consulted dermatologist for skin lesions of bullae/ distal-infarctions, evaluated and possibility of Drug induced Toxic

Epidermal Necrolysis, with Septic Emboli of digital gangrene was diagnosed. With dermatological lesions of multiple blisters, multiple digital infarctions and multiple petechial lesions, a vasculitic syndrome with underlying sepsis was considered and relevant investigation was sent for, including ANA/p-ANCA/C-ANCA/ Complement levels- all which reported to be non diagnostic. With rising WBC counts to about 25,950/ cu. mm Antibiotic coverage was changed over to Vancomycin and Meropenem with renal dosing as per the sessions of dialysis.

Plastic-Surgeon recommended for skin biopsy for cultures and pathological diagnostics was sent for, which revealed no significant findings. From clinical symptoms and signs, multiple thrombotic infarctions, increased LDH and persistent thrombocytopenia, a probable diagnosis of Thrombotic Thrombocytopenia Purpura was considered and with discussion involving the Nephrologist/ Haematologist/ Dermatologist/ Intensivist, empirical treatment with Parenteral Steroids + plasmapheresis concurrent with haemodialysis was considered and initiated. Patient was shifted out of the MICU, for continuation of further management, further reports of blood C/S and Pus cultures obtained from blisters/wounds, detected Klebsiella abd as per the sensitivity, parenteral Colistin was started with renal dosing for five days

With due consent and under aseptic precautions, Patient underwent wound debridement + Split-skin grafting of right forearm with amputation of 1. Partial right thumb 2.Right great toe 3.All toes of left foot, with no intra-op complications. In view of wound debridement, graft placement and digit amputation with intermittent fever spikes, colistin along with cefoperazone + sulbactam was continued for five more days with alternative-day renal monitoring. With regular aseptic dressings, metabolic/renal monitoring, precautionary care of central I/V cannulations, physiotherapy, mobilisations and bowel-bladder training was continued. With no further fever spikes, normal WBC counts and improved wound healing with healthy granulation tissue, Colistin was stopped after 2 weeks of duration. With no fresh clinical symptoms, haemodynamic status, acceptable condition and advised for regular follow up with wound care, He is now being discharged with oral medications.



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WELLNESS AT HOME



Today herbs are catching a lot of attention due to their very nature of cure: simple, no side effects, no chemicals, inexpensive, plus the ability of being able to cure yourself. This trend for resorting to home remedies is not new. In fact, they have their origin in ancient times. Traditionally, in India, plants with medicinal value were grown in home gardens. Some simple Home Remedies are as following:

1	CUTS AND WOUNDS	The fresh gel of Kumari (Aloe vera) can be applied externally which gives a soothing effect and helps in fast healing. Application of Haridra (turmeric) powder in cuts and bruises arrests bleeding.	 Aloe Vera	or	 Turmeric		
2	BURNS	Application of pure honey help in fast healing. The paste of Bhringaraja (Eclipta alba) leaves also heals the wound due to burns and scalds. The paste of Shatavari (Asparagus racemosus) leaves is applied to alleviate burningsensation.	 Bhringaraja	or	 Shatavari		
3	INSOMNIA	Application of oil to the soles and massaging before going to bed will induce sleep.	 Pada abhyanga				
4	MIGRAINE	Application of herbal pastes like Sandalwood, camphor, Jatamansi (Nardostachys jatamansi) the nasal drops of saffron with ghee is effective remedy ofmigraine.	 Sandalwood	or	 Camphor	or	 Jatamansi
5	STOMATITIS	Gargle with decoction of Dhanyaka (Coriandrum sativum).	 Dhanyaka seeds	 Dhanyaka	 Dhanyaka leaf		
6	SORE EYES AND CONJUNCTIVITIS	Take one teaspoon of Haridra powder boil it with a cup of water. Strain and use it as eye wash. Eye wash with Triphala is helpful.	 Glass of water	+	 Turmeric		



Tulsi Leaves

+



Ginger

Warm some milk, add turmeric and drink it. Take the juice of ginger, crush tulsi leaves to it and add honey & consume to get relief from a cough.

COLD AND COUGH

7



Sandalwood

+



Saffron

Apply paste of Chandhana (Santalum album) mixed with little quantity of camphor and saffron on forehead, it relieves headache.

HEADACHE

8



Boiled water

+



Jeeraka

Consume boiled water with Jeera.

STOMACH ACHE

9



Raisins



Vajrasana



Dhanurasana

Soak 6-8 raisins in hot water. When cool, crush well and strain. When given routinely even to little infants, it helps to regulate bowel movement. Some yogasanas like Pawan mukta asana, Vajrasana, Dhanurasana also relives constipation.

CONSTIPATION

10



Neem twigs

or



Sesame oil

Brushing the teeth with Neem twig is beneficial. Gargle with decoction of Neem leaves and it controls dental infections. Massage the receding gum with sesame oil, it strengthens the teeth and gums.

DENTAL CARE AND DENTAL INFECTION

11



Sesame oil

+



White mustard

Massage with tila taila (sesame oil) reduces dryness of skin. Paste of blacksesame, cumin seeds with white mustard makes the face glow and removes blemishes. Chandana is one of the best deodorants.

SKIN CARE

12



Jathi

or



Saffron

The paste of Jathi (Myristica fragrans) with milk is applied on face. Mix sandalwood powder with rose water and apply as a pack twice a day. Saffron is one of the main ingredients as valuable remedy for depigmentation of skin, pimples, and freckles.

ACNE

13

Fruit juice of Amla can be used for hair wash to prevent premature greying of hair. The fresh leaves of Bhringharaja juice blackens the hair, promotes hair growth and it is the best natural dye. Hair wash with decoction of triphala smoothens the hair. The paste of fresh leaves of fenugreek applied over scalp regularly before washing the hair cure dandruff.

HAIR CARE

14

Gargle with warm Haridra water 2-3 times a day relieves sore throat.

SORE THROAT

15

ALUMNI SPEAK

MY LIFE AS A CLINICAL PHARMACIST

The life of a typical Clinical Pharmacist isn't easy. Despite the gruelling workload and schedule, my years as a pharmacy student were some of the best of my life. I am fortunate enough to work with a multidisciplinary team of Doctors and other departments that teaches me something new each day. Clinical Pharmacists are a trusted link between patients and their doctors. This position affords me a unique perspective into many facets of healthcare. I, literally, learn something new every day and I am so appreciative of that. I am in the perfect position to strengthen the healthcare message by tailoring my recommendations to patients. I also have to make decisions in my work each day that can have a real impact on patient's lives. I evaluate drug interactions to avoid patient harm. I evaluate lab results and blood pressure readings, suggest the alternative safe medications which can be given to the patient based on the diagnosis, an extra safety net for clinicians at my organization, which allows me to recommend therapy changes to improve patient health. Medication Errors can happen in the hospital, at the doctor's office, at the pharmacy, or at home. This is one serious area where I take it so serious to avoid maximum Medication Errors in the hospital. I personally meet the concerned Doctors, Sr. Specialist, Resident Doctors and Junior Doctors of each department on a daily/ weekly basis informing them about the importance of medication errors and how to avoid such errors from arising in the medication drug chart and how effective it would bring about the change in patterns of prescribing medications as well as to the patient outcome effectively. Other clinical oriented activities that I go on about doing is, attending daily Doctors wardrounds, answering all drug related queries, attending the Pharmacy and Therapeutic Committee meet on a monthly basis, calculating the exact dose to be given, attending the doctors academic meeting, checking and signing all the crash- kart (emergency medications) in all departments. On a daily basis I help doctors avoid serious problems by alerting their physicians to overuse or inappropriate combinations of drugs and antibiotics. Patient counselling is one of the most vital role that we play importance in the profession we are in. It is not just the material we learned in colleges that makes a good Clinical Pharmacist. It is having the compassion to listen with a caring and concerned ear to let a person know that how they feel matters to someone. "Clinical Pharmacist – Doctor Relationship" is very challenging. Trust is essential when you are affecting the well-being of a doctor's patient. It takes time to build that trust, but once you are over that barrier, the relationship is very smooth and doctors begin to rely on you, because they know you can provide the same level of care in terms of drug therapy. Above all I take this very moment to step back and extend my gratitude to all my teachers who has taken considerable efforts in making me of who I am today.



Renoy Philip
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Aster CMI Hospital, Hebbal

INTERN NOTES

MY EXPERIENCE AS CLINICAL RESEARCH TRAINEE IN IMAGE CORE LAB

As a Pharm D intern, there are wide areas that we can expose ourselves to during the span of one year. I decided to begin my journey with gaining experience in the field of research and understanding the nitty-gritty of it. Honestly, at the start I did not know what to expect ahead. All the theoretical knowledge aside, it was obvious that my practical exposure would be much different than the visuals build up by the theories of it. I started my Internship from 1st of July for three months and kept my senses aware of anything that would come my way. To begin with, I was initially trained on the ICH-GCP guidelines and made to review protocols from various ongoing oncology trials at that moment. As the name suggests, Image Core Lab is basically involved in helping the ongoing clinical trials by providing interpretation of the radiographic findings during the study period. An area of radiology seems peculiar at first, but there were a lot of things to learn. To clarify on what my role there would be, I got exposure to scanning through various radiographic images like CT scan, PET-CT, MRI and so on. I was also trained to formulate the final reports after our radiologists there interpreted the images. Further more I also got a chance to know about the data management part of research and how Electronic Data Capture forms were filled under the guidance of the team lead and Clinical Research Associate there.

My experience there was further enriched as I got exposure to medical device trial and understood the various phases that occur before a medical device or application can take its final shape. The training on RECIST 1.1. Criteria further added as feather on my hat, as I now understand how the Response of Solid Tumors to therapy are assessed in patients and can interpret where the response to be partial, complete or progressive based on it. To sum it up, it was a fulfilling and satisfying experience wherein I got to know of the ups and downs of a research environment. I also got an opportunity to learn and am now be able to scan through radio-graphic images surfacely (better than what I could previously) and this is definitely an added advantage for me that can come handy to improve my clinical services. All in all, it was a good dip into the huge ocean of clinical research and now as I surface, I am capable of choosing my options more thoughtfully. It is a different kind of experience outside the hospital world.

LATEST NEWS

Teleradiology Solutions (TRS) announced a collaboration with Massachusetts General Hospital (MGH) in Boston, one of the top-ranked hospitals in the US to offer 3D image post-processing services.



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THE **DOYENS**
GUARDIANS OF KNOWLEDGE



The Hindu conferred "THE DOYENS Guardians of Knowledge" award to Prof. Dr. Suresh Nagpal Founder Chairman of Krupanidhi Educational trust on 26 March 2017, at Bangalore. This award is instituted by the leading Indian newspaper The Hindu to honor the life time achievements of the pioneers who have very landscape of education in Karnataka, and for their contributions that brought a transformational change in this field.



The National Accreditation and assessment council (NAAC) the autonomous body of the UGC re-accredited KCP with A Grade for duration of 5 years. This re-accreditation by NAAC assures that the teaching learning process, systems and infrastructure in place at KCP are at par with the best in its class. Synergia congratulates the NAAC team faculty and the students of KCP who made this possible



EXPRESSIONS 2017



QbDCON - NATIONAL CONFERENCE ON RECENT DEVELOPMENTS, PRACTICAL AND REGULATORY ASPECTS OF QUALITY BY DESIGN

QbDCON was organized by Department of Quality Assurance, Krupanidhi College of Pharmacy, Bangalore on Saturday, 11 March 2017. QbDCON was sponsored by Rajiv Gandhi University of Health Sciences, Karnataka and the event was partnered by Centre for Pharmaceutical Professional Advancement, Krupanidhi College of Pharmacy. M/s. Vienni Training & Consulting LLC, Bangalore were the training partners of this event, represented by its founders M/S Ivy Louis and Vishal Sharma. The other resource persons were Mr. Sachin Mundade, Asst. VP Strides Shasun, Dr. K.L.K. Paranjyothy, eminent pharmaceutical consultant & Chandramouli R, Prof & HOD Department of Quality Assurance and the convener of this event.



TALENT'S DAY



DAY 1

EYE SCREENING CAMP IN MULLUR VILLAGE



DAY 2

PERSONAL HYGIENE EDUCATION IN GOVERNMENT PRIMARY SCHOOL, MULLUR



DAY 3

IMMUNIZATION AWARENESS AND EDUCATION TO MOTHERS IN MULLUR VILLAGE



DAY 4

SAPLINGS PLANTATION IN MULLUR GOVERNMENT PRIMARY SCHOOL



DAY 5

EYE CAMP FOLLOW UP IN MULLUR AND SURGERY AT GLOBE EYE FOUNDATION



DAY 6

PROMOTION OF PHYSICAL ACTIVITIES IN GOVERNMENT PRIMARY SCHOOL, MULLUR



KCP NSS UNIT RECEIVED "NATIONAL YOUNG LEADERS PROGRAMME AWARD" FROM RGUHS & MINISTRY OF YOUTH AFFAIRS AND SPORTS, GOVT OF KARNATAKA ON 24TH MARCH 2017.

TEAM SYNERGIA

PATRON: Dr. Suresh Nagpal, Mrs. Geetha Nagpal, Prof. Sunil Dhamangini, Ms. Neha Nagpal, Dr. Samuel Paul Isaac
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