Innovative Thought Forum

Key discussions and takeaways from webinar on

"Protocol for development of new drugs and clinical trials of new, repurposed and existing drugs of AYUSH"

organised by Innovative Thought Forum (ITF) and Arogya Bharati (AB)

26th May 2020

1st Floor, A-7, Safal Profitaire, Corporate Road, Near Prahladnagar Garden, Ahmedabad – 380 015.

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Programme

- Welcome Note by S B Dangayach, Founder Trustee, ITF & National Vice President, AB
- Opening remarks by Vd. Ramesh Gautam, Karyadhyaksh, Arogya Bharati
- Insight on subject of the day with preamble on need for recalibrating Drug Development Protocol for AYUSH by Padma Shri Dr.V. Prakash, Former Director, CFTRI

Talk by Experts (5 minutes each)

- Approach to R & D in AYUSH"
  By Dr N N Mehrotra, Retd Addl Director; CDRI, Lucknow
- WHO Perspective of AYUSH"
  By Dr Geetha Krishnan, WHO (AYUSH) Officer at Geneva
- "Crux of WHO document on safety of Homoeopathy"
  By Dr R K Manchanda, Director AYUSH, Government of Delhi
- "Application of Biomarkers in Drug Development"
  By Prabodha Swain, Ph.D
- Preclinical Model for validation of AYUSH products"
  By Prof (Dr) Rakesh Rawal, Life Science Dept, Gujarat University & former Sr Scientific officer at Gujarat Cancer Research Institute, Ahmedabad
- "Revalidating role of ICMR in AYUSH Drug Development & Clinical Trials"
  By Prof (Vd) Hitesh Jani, Former Principal & Dean, Jamnagar Ayurved College with special interests in LokAyurved, Garbhsanskar & Gau Vigyan (Panchgavya)
- "Patient Centered Outcome Research (PCOR) for AYUSH products as alternative to clinical trials"
  By Dr Sanjeev Acharya,Principal ,SSR college of Pharmacy
- "Drug Proving & Clinical trials in Homoeopathy"
  By Dr Prashant Tamboli, Research Head, Dr M L Dhawale Memorial Homoeopathic Institute
- "Industry Perspective on Challenges of New Homoeopathy Drug Development"
  By Dr Valavan, Head, Medical Affairs, Dr Willmar Schwabe (India) Ltd.
- Significance of clinical trials of herbal formulations"
  By Dr Subodh Adesara, Former Commissioner, FDCA, Gujarat State
- "can we modernized and innovate regulation while respecting the particularity of AYUSH system ?"
  By Dr Robert Van Haselen, Director world Integrated Medicine Forum, Deputy Director of the Royal London homeopathic hospital

Discussion Invitees (2-3 minutes each)

- Dr Surendra Bhatt, Ph.D in Medicinal Organic Chemistry,Having worked in basic research on Antibiotics from Soil Organism & Ayurvedic Industry on drug standardization, validation, toxicity studies, preclinical & clinical Trials

- Prof (Dr) Maruti Sarma, Community Medicine & Public Health Expert, Telangana
- Dr Rajesh Shah, Life Force Foundation, Mumbai
- Mr Sanjay Shah, Unikal Consultants ,International expert in medical devices

Q & A

- Take away message by Dr. V. Prakash
- Closing remarks by Vd. Ramesh Gautam

Important Points

Ayurveda and Bharatiya Parampara fundamental to sustainable health in India

Successful protocols over 5000 years based on epidemiology and documentation in many books and scriptures for practice of Ayurveda and traditional knowledge

AYUSH misunderstood by many as only Ayurveda whereas it is acronym for "Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy

Lot of action in allopathy with 500 clinical trials for C 19 in different places. Most for repurposing as new drug development in allopathy very costly and time consuming

Following acts and rules applicable to drug development and cilinical trials in India

- Drugs and cosmetics act, 1940 with amendments
- Drugs and cosmetics rules, 1945 with amendments
- New drugs and clinical trial rules(NDCTR) of 2019
- CCRAS Guidelines for clinical evaluations of Ayurvedic interventions covering ASU (Ayurveda, Siddha and Unani)

Homoeopathy bracketed with allopathy for development and clinical trials though fundamentally different than allopathy in principle and science of action

GOI has relied on allopathy in public and private health since independence with nominal and symbolic support to AYUSH. Sensing grave limitations of allopathy, GOI has permitted AYUSH for proposals for clinical trials vide gazette of 21/4/20 for C19. As of now 4 projects approved. More on way.

FDA of U S A has permitted use of HCQ and Remdesivir for C19 following limited trials on patients prompting other nations incl India to assess and allow repurposed drugs outside bounds of the act or rules

WHO now pragmatic and wishes to give weightage to safety and efficacy supported by rational studies than xenology. Also becoming solution centric, pathy agnostic and patient centric as long as safety and efficacy parameters are met. Supporting evidence building work all over the world in space of traditional medicines. Also encouraging cohort studies on many prophylactic solutions given in India thru AYUSH

Recognizing need to look at safety of manufacturing of Homoeopathic medicines, WHO published a document in 2009.

Many anomalies in the overall ecosystem for drug development

- Homoeopathic medicines controlled by DCGI and not by Ministry of AYUSH. Homoeopathy, with its core strength, has unique requirement of regulation and control due to its nature of medicine that is not fully understood by relevant people.
- Need for independent DTAB for Homoeopathy

- Overall control of ICMR, a specialist in biomedical or allopathic field over other councils in all vital aspects though individual councils may have drawn their own protocols
- Insistence on bioavailability and bioequivalence for new drugs in Homoeopathy in which these aspects are irrelevant due to ultra dilutions and principles Homoeopathy
- Complete control or domination of Min of Health and Family Welfare directly or indirectly through it's outfits with AYUSH having a very small or subordinate role

A few vital learnings from allopathy worth considering * Appropriate surrogate marker for ensuring quality and predictability of efficiency of any AYUSH drugs. Disease or pathway specific Biomarkers can be an important tool for assessing the efficacy of the therapy and also compare with other treatment modalities. Human specific molecular biomarkers can be analyzed using homologue marker in animals and vice versa

- Clinical trial cost exorbitant in new drug development. Patient-centered outcomes research (PCOR) may be the best way while maintaining safety standards
- Online platform for sharing data by desiring researchers and practitioners can reduce cost and time

High standards of quality in development and clinical research while factoring in unique characteristics of each medicinal science in AYUSH for winning customer confidence. Necessary changes in current rules to be effected for equitable opportunity to all .For example

- Method of "provings" in Homoeopathy to be incorporated in the rules
- Homoeopathic vaccines, known as nosodes, to be supported and mainstreamed after understanding it's innate character
- Learning and adapting good work being done in other countries in TCM (traditional and complementary medicine)

AYUSH to learn from medical devices field .A sub committee in DTAB now to independently oversee the sector .

COVID 19 has levelled field for all .Parameters of safety, ethical approval should be same for all systems as well outcome. Parameters of assessment should be to cut down complications, shortening the disease span, improving physiological and biochemistry parameters and better quality of life. Time for AYUSH to stand on it's own with suitable and rational changes from allopathy

Surgery, diagnostics, devices etc not allopathy but common adjuncts to all medicinal sciences. Very poor track record of discovery or development of new allopathic drugs due to complexities, costs and risks. Hence repurposing existing drugs the pragmatic way AYUSH has many safe and relatively harmless drugs as per respective pharmacopoeias that can be tested for safety and efficacy in short time use

Allopathy still at Annamay Kosh level. AYUSH covers part or full Panchkosh. Thus AYUSH "beyond science "

Lack of patient records and documentation major weakness of AYUSH. All it's practitioners to correct this weakness and diffidence urgently .

Entire public health system in the country driven by allopathy with literally no place for AYUSH. Similarly all pharmacy colleges allopathy centric .Likewise most regulators with allopathy background .Commercial interests linked to allopathy too.

Key takeaways

1 Following C19 Allopathy, Ayurveda and Homoeopathy at the same level. Keeping safety and efficacy parameters same for all, freedom to evolve suitable protocols for drugs and trials for AYUSH now necessar

2 Separate NDCTR and independent DTAB to be made for Homoeopathy soonest.

3 Need to make a common procedure for testing of repurposed drugs from all streams on COVID patients and other ailments

4 There should be proportionate funds, research and promotion of AYUSH as Allopathy so that AYUSH develops on it's own strength.

5 There should be documentation of the work being done to build rational evidence

6 In chapter 11 of the rules for new drugs and clinical trials (NDCTR),unapproved medicines can be imported or manufactured and used. This must be there in the rules for ASU. Govt hospitals or institutions should allow trials and use of Ayurveda and Homoeopathy drugs right away with safety issue not much of a concern in most of them.

7 Work towards a dominant role for AYUSH in health and wellness centres under Ayushman Bharat

8 Innovation and entrepreneurship to be encouraged in AYUSH to build sound business models

9 AYUSH with modern science has to be utilized. But science should not be obstacle to development of AYUSH. Open data clinical trial and pathy agnostic approach can be way forward

10 Bhartiya Swasthya Chintan needs to be strengthened to influence the future policy for favourable developments in AYUSH.

Actionable Points

1 Small team to work on separate NDCTR and independent DTAB for Homoeopathy

2 Simple and rational process for repurposing of existing AYUSH medicines for emergencies and normal conditions through patient centric observational research or other cost effective routes or processes.

3 Open platform creation for data for helping research at lower cost in short time

4 Involvement with Ayushman Bharat to secure dominant role for AYUSH in Health and Wellness centres across India

5 Conversion of ideas in AYUSH into business models

Legend

AYUSH- Ayurveda, Yoga, Unani, Siddha and Homoeopathy

ASU- Ayurveda, Siddha and Unani

DCGI- Drugs controller general of India

DTAB- Drugs technical advisory board

NDCTR- New drug and clinical trial rules

ICMR- Indian council of medical research

C 19- COVID 19

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