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Special issue on Phytopharmaceuticals

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Editorial…

Phytopharmaceutical is a new class of drug which is conceptualize in India and implemented already. "Phytopharmaceutical drug" includes purified and standardised fraction with defined minimum four bio-active or phytochemical compounds (qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include administration by parenteral route.'

This class have more scientific inputs than herbal or AYUSH class of drugs. For development of this category of drug it requires to go through clinical trial which is an abbreviated form of trials required for development of modern medicines. This class of drugs are regulated by the same regulation as modern drugs are regulated.

The first of its kind a plant derived product named ACQH is under clinical trial conducting by Sun jointly with some research organizations after obtaining permission for conducting clinical trial for COVID from DCGI.

Hope this trial will be successful and a product be available for the patients.

Dr. Subhash C. Mandal, Ph.D. -Editor

From Secretary's desk

Dear Friends,

A warm welcome to the special issue of our SFE-newsletter on "phytopharmaceuticals"!

Many congratulations to the editorial team for their contributions to release this newsletter regularly even during this tough time.

On behalf of the newsletter team, I appreciate the efforts of article contributors, without whom our newsletter would not be possible.

Our newsletter is a group effort and rely on contributions from all SFE-members for the content. So, let's contribute to our own newsletter. We want to know what projects you're working on. What's new with you and your organization. Let's make it a successful mode of exchanging scientific knowledge in the field of ethnopharmacology.

I personally thank the members of the executive and editorial board of the newsletter, coordinators for the local chapters and all SFE-India members for their contributions to the society and the webinar series.

Stay safe, stay healthy.

Prof. Pulok K. Mukherjee, FWAST, FRSC, FNASc
Secretary, SFE - India

Featured article by Dr. C.K. Katiyar

Phytopharmaceuticals: An overview for the Pharmaceutical professionals

Dr. C. K. Katiyar
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Origin of most of the pharmaceutical drugs can be traced back to herbs and other natural products. Foundation of most of the traditional medical systems is also based upon the same. But due to intense scientific inputs and research pharmaceutical sector made its way much farther in terms of business as compared to traditional systems of medicine like AYUSH in India due to disproportionate investments on their scientific investigation, validation and research to provide evidence-based medicine. Conceptualization and introduction of Phytopharmaceutical as a new category of drug is

one step to inculcate higher level of science in medicinal plant-based products.There is a little-known history and background to Phytopharmaceutical drugs in India. Attracted by faster growth than Pharmaceutical drugs, few big Pharmaceutical companies forayed into herbal drug area. Soon they realized that potential of growth was low due to following reasons-

- Lack of interest of Modern Medicine physicians in prescribing Herbal drugs
- Lack or insufficient investment in R&D of herbal drugs to validate the claims of efficacy
- Lack of faith in quality of herbal drugs
- Loose regulatory provisions for licensing of new AYUSH products and broad non implementation of whatever rules were there
- Lack of Patent for herbal drugs working as disincentive to invest in this area
- Ban on cross prescription by Hon'ble Supreme Court of India limiting its promotion either through OTC route or through AYUSH Practitioners only.

During such scenario two great visionaries and stalwarts, Dr Nitya Anand, former Director, CSIR-CDRI, Lucknow and Prof SS Handa, former Director, CSIR- IIIM Jammu had a meeting some where in the year 2004 along with author of this article Dr CK Katiyar, who was Director of Herbal Drug Research at Ranbaxy Research Labs, Gurgaon at that time, to discuss how to expand the herbal medicine sector despite having all the above limitations.

After few meetings following action plan was developed:

- Re introduce quality monographs of herbal drugs in Indian Pharmacopoeia
- Push the Central Government to create a new category of Food Supplements on the lines of USFDA and
- Create a new category of drugs under Rule 122 E of Drugs and Cosmetics Act and Rules as Phytopharmaceuticals. This category would comprise of science-based derivative of herbal origin following pharmaceutical new drug development route of Sch Y.

Since topic of present article is Phytopharmaceutical, we would keep the discussion limited to this subject only.

The group met several times and discussed that Drug discovery has undergone multiple shifts in approaches in the current and past century. It started from natural products and later on shifted to combinatorial chemistry approach. With the advent of tools like computing, bio-informatics and independent Computer Aided Drug Design (CADD)process of new drug discovery underwent a sea change and the expenditure of new drug development also escalated and ranges between $648 Million USD to $2.7 billion USD.

Whole world is grappling with the scientific issue on how to increase the productivity of

Pharmaceutical R&D. These couples with emergence of new disorders and viruses complicate the issues further.It was deliberated that in order to enhance the productivity of Indian Pharmaceutical R&D Indian Pharma industry should make use of its own traditional Indian system of medicine to take the leads to develop new drugs out of them to beat the difficult trends. However, the major obstacle felt was that after isolation of one compound and trying to make it druggable they again might fall in the same trap of single target. While looking at the method of use of traditional medicine it has been observed that most of the plants are used either as such or as extract, which contains multiple compounds. This gave an opportunity to shift from single target approach to extract / fraction of extract for multiple target approach. This led to prolonged discussion within the industry and between the industry and Government of India.

Central Drugs Standards Control Organization (CDSCO) constituted a committee of experts to review the proposal and provide its recommendations on the subject.Following regulatory and statutory procedures the proposed addition to the D & C Rules as approved by DTAB, created provisions of defining phytopharmaceuticals and schedule providing requirement of scientific data on quality, safety and efficacy for the same. This should not be confused with Ayurvedic drugs for the following reasons.

- Phytopharmaceuticals can be from a botanical (medicinal plant) from any part of the globe while Ayurvedic herbs are limited to the books approved under First Schedule of Drugs and Cosmetics Rules.
- Phytopharmaceuticals proposal does not simply depend on traditional knowledge but goes beyond to include scientific validation and development of drugs.
- Phytopharmaceuticals would promote innovations and development of new drugs from Botanicals in a scientific way, and would give boost to research in drug development for national Laboratories and Pharmaceutical research labs in India.
- Phytopharmaceuticals as proposed above permits development as a drug under chapter IV of Drugs and Cosmetics Rules, adopting the Drug Development Technologies involving modern techniques of Solvent Extraction, Fractionation, Potentiating steps, add-back techniques, modern extraction techniques like CO2 based extraction, freeze-drying, Formulation Developments, and many other techniques. Stress on high degree of characterization of the plant-based ingredient as a Phytopharmaceutical is a requirement that is not generally asked for any Traditional medicine (TM.). Adoption of these techniques using formulation agents, dosage form technologies are not permitted in Ayurvedic Drugs.Ayurvedic Drugs are regulated differently and need to meet the requirements given in authoritative texts recognized in the schedule and also have to be processed using methods given in such texts.
- Phytopharmaceuticals would need to be mandatorily evaluatedfor safety (toxicology) and efficacythrough wellconducted human clinical trials on lines similar tosynthetic compound-based drugs.Such mandatory requirements do not apply to Ayurvedic medicines.Information on possible mechanism of action also is a requirement, not generally known in TM.
- Phytopharmaceuticals when approved by Drug Controller General of India would have the

same status for marketing as that given for a synthetic compound-based drug.

- Such Phytopharmaceutical drugs would be prescribed by MBBS qualified Doctors, which is not the case for Ayurvedic drugs. It has high potential and will help patients get good quality, well studied drugs from Plant origin for many conditions for which Allopathic drugs are not available as of today.

After more than a decade long interaction, Phytopharmaceutical was introduced as new drug under Rule 122 E of Drugs and Cosmetics Rule through a Gazette Notification no. G.S.R.918(E) dated 30th November 2015 (1).

As per the Gazette Notification the Phytopharmaceutical drug has been defined as:
"Phytopharmaceutical drug" includes purified and standardised fraction with defined minimum four bio-active or phyto-chemical compounds (qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include administration by parenteral route.'.

By introducing Phytopharmaceutical as drug, India has become first country in the world to create this new class of drugs.It may be argued that Botanical drug is USA is also defined on similar lines but it permits the use of the product for the traditional use indication only and focus is more towards traceability.Phytopharmaceutical on the contrary is a category of new drug and need to undergo the similar rigour of drug development as new chemical entity.Sometimes there is confusion as to how Phytopharmaceutical is different from Ayurvedic medicines. The Gazette Notification (1) citing the studies required to be submitted as part of dossier for application of Phytopharmaceutical as new drug under Rule 122 E is reproduced below for the benefit of those who are interested. It provides the route of development of the drug in quite detail including requirements of pre clinical as well as clinical studies from Phase I to Phase IV.

"**APPENDIX I B**
DATA TO BE SUBMITTED ALONG WITH APPLICATION TO CONDUCT CLINICAL TRIAL OR IMPORT OR
MANUFACTURE OF A PHYTOPHARMACEUTICAL DRUG IN THE COUNTRY[(6)]

PART-I

1.1 A brief description or summary of the phytopharmaceutical drug giving the botanical name of the plant (including vernacular or spiritual name, wherever applicable), formulation and route or administration, dosages, therapeutic class for which it is indicated and the claims to be made for the phytopharmaceutical product.

1.2 Published literature including information on plant or product or phytopharmaceutical

drug, as a traditional medicine or as an ethno medicine and provide reference to books and other documents, regarding composition, process prescribed, dose or method of usage, proportion of the active ingredients in such traditional preparations per dose or per day's consumption and uses.

1.3 Information on any contraindications, side effects mentioned in traditional medicine or ethno medicine literature or reports on current usage of the formulation

1.4 Published scientific reports in respect of safety and pharmacological studies relevant for the phytopharmaceutical drug intended to be marketed –

a) Where the process and usages are similar or same to the product known in traditional medicine or ethno medicine; and

b) Where process and usages is different from that known in traditional medicine or ethno medicine.

1.5 Information on any contraindications, side effects mentioned or reported in any of the studies, information on side effects and adverse reactions reported during current usage of the phytopharmaceutical in the last three years, wherever applicable.

1.6 Present usage of the phytopharmaceutical drug,-to establish history of usages, provide details of the product, manufacturer, quantum sold, extent or exposure on human population and number of years for which the product is being sold.

2. Human or clinical pharmacology information:

2.1Published scientific reports in respect of pharmacologicalstudies including human studies or clinical studies or epidemiological studies, relevant for the phytopharmaceutical drug intended to be marketed-

a) where the process and usages are similar or same to the product known in traditional medicine or ethno medicine or ethno medicine; and

b) where process or usage is different from that known in traditional medicine or ethno medicine.

2.2Pharmacodynamic information (if available)

2.3 Monographs, if any, published on the plant or product or extract or phytopharmaceutical. (copies of all publications, along with english translation to be attached).

PART – II

Data generated by applicant

3.**Identification, authentication and source of plant used for extraction and fractionation:**

3.1Taxonomical identity of the plant used as a source of the phytopharmaceutical drug giving botanical name of genus, species and family, followed by the authority citation (taxonomist's name who named the species), the variety or the cultivar (if any) needs to be mentioned.

3.2Morphological and anatomical description giving diagnostic features and a photograph of the plant or plant part for further confirmation of identity and authenticity. (Furnish certificate of confirmation of

botanical identity by a qualified
taxonomist).

3.3Natural habitat and geographical distribution of the plant and also mention whether the part of the plant used is renewable or destructive and the source whether cultivated or wild

3.4Season or time of collection

3.5Source of the plant including its geographical location and season or time of collection

3.6A statement indicating whether the species is any of the following, namely: -

a) determined to be endangered or threatened under the Endangered Species Act or the Convention on International Trade in Endangered species (CITES) of wild Fauna and Flora)
b) entitled to special protection under the Biological Diversity Act, 2002 (18 of 2003).
c) Any known genotypic, chemotypic and ecotypic variability of species

3.7A list of grower or supplier (including names and addresses) and information on the following items for each grower or supplier, if available or identified already, includinginformation of primary processing, namely: -

a) harvest location
b) growth conditions
c) stage of plant growth at harvest
d) harvesting time
e) collection, washing, drying and storage conditions
f) handling, garbling and transportation
g) grinding, pulverising of the plant material; and
h) sieving for getting uniform particle size of powdered plant material

3.8Quality specifications, namely: -

a) foreign matter
b) total ash
c) acid insoluble ash
d) pesticide residue
e) heavy metal contamination
f)microbial load
g) chromatographic fingerprint profile with phytochemical reference marker
h) assay for bio-active or phytochemical compounds; and
i) chromatographic fingerprint of a sample as per test method given under quality control of the phytopharmaceutical drug (photo documentation)

3.9An undertaking to supply specimen sample of plant duly labelled and photocopy of the certificate of identify confirmationissued by a qualified taxonomist along with drawings or photographs of the diagnostic morphological
and histological features of the botanical raw material used for the confirmation of authenticity.

4. Process for extraction and subsequent fractionation and purification:

4.1Quality specifications and test methods for starting material

4.2Steps involved in processing

a) details of solvent used, extractive values, solvent residue tests or limits, physio-chemical tests, microbial loads, heavy metal contaminants, chromatographic finger print profile with phytochemical reference markers, assay for active constituents or characteristic markers, if active constituents are not known

b) characterisation of final purified fractions

c) data on bio-active constituent of final purified fraction

d) information on any excipients or diluents or stabiliser or preservative used, if any

4.3Details of packaging of the purified and characterised final product, storage conditions and labelling.

5. Formulation of phytopharmaceutical drug applied for:

5.1 Details of the composition, proportion of the final purified fraction with defined markers of phytopharmaceutical drug per unit dose, name and proportions of all excipients, stabilisers and any other agent used and packaging materials

5.2 Test for identification for the phytopharmaceutical drug

5.3 Quality specifications for active and inactive phytopharmaceutical chromatographic finger print profile with phytochemical reference marker and assay or active constituent or characteristic chemical marker

6. Manufacturing process of formulation:

6.1 The outline of the method of manufacture of the dosage form, along with environmental controls, in-process quality control tests and limits for acceptance

6.2 Details of all packaging materials used, packing steps and description of the final packs

6.3 Finished product's quality specifications, including tests specific for the dosage form, quality and chromatographic finger print profile with phytochemical reference marker and assay for active constituent or characteristic marker, if active constituents are not known.

7. Stability data:

7.1 Stability data of the phytopharmaceutical drug described at 4 above, stored at room temperature at 40+/-2 deg. C and humidity at 75%RH +/- 5% RH for 0,1,2,3 and 6 months.

7.2 Stability data of the phytopharmaceutical drug in dosage form or formulation stored at room temperature at 40+/-2 deg. C and humidity at 75%RH+/-5%RH for 0,1,2,3 and 6 months, in the pack intended for marketing

8. Safety and pharmacological information:

8.1 Data on safety and pharmacological studies to be provided

8.2 Animal toxicity and safety data:

a) 28 to 90 days repeat dose oral toxicity on two species of animals
b) In-vitro genotoxicity data (Ame's test and Chromosomal aberration test as per Schedule Y)
c) dermal toxicity tests for topical use products
d) teratogenicity study (only if phytopharmaceutical drug is intended for use during pregnancy)

9. Human studies:

9.1 Clinical trials for phytopharmaceutical drugs to be conducted as per applicable rules and guidelines for new drugs

9.2 For all phytopharmaceutical drugs data from phase I (to determine maximum tolerated dose and associated toxicities) and the protocols shall be submitted prior to performing the studies

9.3 Data of results of dose finding studies performed and the protocols shall be submitted prior to performing the studies Provided that in the case of phytopharmaceutical drug already marketed for more than five years or where there is adequate published evidence regarding the safety of the phytopharmaceutical drug, the studies may be abbreviated, modified or relaxed.

10. Confirmatory clinical trials:

10.1 Submit protocols for approval for any specific or special safety and efficacy study proposed specific to the phytopharmaceutical drug

10.2 Submit proposed protocol for approval for human clinical studies appropriate to generate or validate safety and efficacy data for the phytopharmaceutical dosage from or product as per applicable rules and guidelines.

10.3 Submit information on how the quality of the formulation would be maintained during the above studies

11. Regulatory status:

11.1 Status of the phytopharmaceutical drug marketed in any country under any category like functional food or dietary supplement or as traditional medicine or as an approved drug.

12. Marketing information:

12.1 Details of package insert or patient information sheet of the phytopharmaceutical drug to be marketed

12.2 Draft of the text for label and carton

13. Post marketing surveillance (PMS):

13.1 The applicant shall furnish periodic safety update reports every six months for the first

two years after approval the drug is granted

13.2 For subsequent two years the periodic safety update reports need to be submitted annually

14. Any other relevant information:

Any other relevant information which the applicant considers that itwill help in scientific evaluation of the application-

CURRENT STATUS

Since the time of amendment in Drugs and Cosmetics Rules, Central Drugs Standards Control Organisation (CDSCO) has received very few new drug applications under category of Phytopharmaceuticals.The reason is that most of the contenders might actually be at the development stage only.Few developments have taken place in the meantime as below:

i) Department of Bio-Technology, Ministry of Science and Technology, Government of India have started Phytopharmaceutical Mission for North East.

ii) Indian Council of Medical Research (ICMR) signed a MOU with Indian Ayurvedic Company, Emami Ltd. to develop a Phytopharmaceutical drug for pre-diabetes in collaborative manner.The product might enter clinical trials phase in 2020.

iii) Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR) and Department of Bio-Technology (DBT) have signed a tripartite agreement to develop Phytopharmaceutical drugs in certain therapeutic areas.A monitoring committee has been formed to review the status on regular intervals.

Phytopharmaceutical being new class of drug CDSCO has yet to develop full fledged mechanism for evaluation of the new drug application though a committee has already been formed for the purpose.

In all likelihood CSIR Indian Institute of Integrative Medicine, Jammu may be notified as drug testing lab (DTL) for Phytopharmaceutical on behalf of CDSCO.

We hope that introduction of Phytopharmaceutical would herald a new era in the field of new drug discovery by Indian Pharmaceutical R&D. Once we create few success stories whole World is likely to follow the path.

Acknowledgement: Author acknowledges help of Ms Arundhati Gupta, Executive Assistant at Emami Ltd for preparing the manuscript.

References:

1. Gazette Notification no. G.S.R.918(E) dated 30th November 2015, Drugs and Cosmetics Act, 8th Amendment Rules 2015, Ministry of Health and Family Welfare, Government of India

Webinar extracts

The Relevance of Ethnopharmocology in the Post Covid Era.

Sri. Shekhar Dutt, SM, IAS (Rtd)
Former Governor of Chhattisgarh State, Govt. of India

Covid 19 has brought in a completely different attitude of people as to the way they use to live before the advent of the virus. This is true of not only with the people of developed countries, but also with the people of less developed and developing countries. Indeed, the speed at which the Pandemic has affected people has surprised many governments who had no shortage of health care workers and doctors, no shortage of hospital beds and no shortage of medical equipment.

Once the virus came out of China, it played havoc in many developed countries like Italy, France, Germany, Spain, UK and USA. The Corona Virus travelled primarily through the people of different countries who became infected as they visited Wuhan, either on a business trip or as tourists. A very large number of people of the above-mentioned countries who were infected by this virus lost their lives. A number of other countries like Sweden, Belgium, Iran, Brazil and of course the country from which it originated i.e. China were badly affected and large numbers of patients died. Nobody, even the doctors, suspected the ferocity with which the virus attacked the infected human beings and incapacitated the patients by affecting the lungs. What is more worrying is that, at present, there is no universally agreed or accepted line of treatment, vaccine or curative medicine. However, the mortality rate has been much lower than that of some other Pandemics, which had visited the earth earlier, like Spanish Flu, SARS, and Bird Flu.

The major reason why the mortality rate has been lower is not because of some magical drug, but because of the body's inherent immunology system. In other words, the people who had their own immune system which was capable of resisting the Corona Virus survived the infection. The entire range of subjects and disciplines that cover Ethnopharmocolgy strengthens the ability of the human beings to fight the diseases emanating from natural causes. Ethnopharmocology has often been defined as "the interdisciplinary scientific exploration of the biologically active agents that are traditionally employed." In other words, the Ethnopharmocological approach is based on a body of work that spans several major disciplines such as botany, chemistry and pharmacology. The overall effect of these biologically active agents on the human body has been that of increasing the body's own immune system and mechanism. Therefore, in the context of the Post-Covid-19 Era a detailed and closer study of Ethnopharmocoloy is not only desirable but also, essential for mankind.

Medicinal Plants Synergy: easier to say than to prove

Prof. Robert Verpoorte
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In the discussion on medicinal plants often synergy is used as an argument to explain activity, and even to argue that medicinal plants are superior to single pure compounds. But how much real evidence is there for synergy? Synergy simply means that 1+1>2. The basis of nature! To proof synergy between two compounds for a certain biological activity isobolograms are used in which one can see that the activity of the mixtures of two compounds is higher than the sum of the activities of these two compounds separately. Many studies on synergy apply this method to proof synergy of two compounds, however, this requires that one knows the active compound(s) of a medicinal plant. If these are not known it becomes difficult, particularly when in bioassay guided fractionation the activity is lost, e.g. when activity is fully dependent on the presence of two or more compounds. The only solution is a systems biology approach. By measuring the metabolic profile of different extracts of a medicinal plant or fractions thereof and combining that information with the results of the bioassays of these samples, one may identify the signals that correlate with activity. These signals may be due to one or more compounds. After identification of these compounds, e.g. after isolation via metabolomics guided fractionation, one can test these compounds for synergy.

If synergy would play an important role in medicinal plants, the synergistic effect is on the system as a whole, and thus synergy may have many forms, also depending on the parameter that is the measure for activity, e.g. is it the cure of a disease or the effect on a single target to name the extremes. That means for studies on synergism one should use preferably in-vivo bioassays, and if possible even apply this approach in clinical trials, as besides synergy also prodrugs may be present in medicinal plants.

Obviously such an approach is totally different from the currently accepted approaches to drug development which are based on the single target single compound paradigm. The fact that HIV now can be kept under control by using a combination of several drugs, are a first sign that a paradigm shift is on its way, bringing natural products and medicinal plants again to the forefront of drug discovery.

Modern pharmacognosy within the ambit of the 4th industrial revolution

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Pharmacognosy is a well-established discipline which aims to explore the quality, safety and efficacy of herbal raw materials and commercial products. The Fourth Industrial Revolution represents a fundamental change in the way we approach life and will inevitably also shape the future of scientific thinking and will permeate the theory and praxis of our research approach on medicinal plants. Like any science-based discipline, pharmacognosists would need to remain relevant and embrace modern technology in their research workflow. While several traditionally analytical approaches are currently in use for routine quality control in the food, agriculture and pharmaceutical industries, many conventional techniques may fall short on speed of analysis, holistic approach and cost-effectiveness due to the complex nature of herbal products. In the continued quest to develop protocols that are fast, non-destructive, easy to use and offer a comprehensive analysis of the whole plant metabolome, the potential of some novel analytical techniques such as vibrational spectroscopy, including mid- (MIR) and near-infrared (NIR), imaging technology and atmospheric solids analysis probe (ASAP) has been investigated. Furthermore, metabolomics will remain an important research approach to explore complex analytical datasets and the tandem integration of pharmacological data through biochemometrics will be pivotal in new evidence-based discoveries. Using several examples from the African flora we aim to demonstrate the application of modern technology to advance herbal medicines. As we enter the Fourth Industrial Revolution as a new chapter in human development, enabled by extraordinary technology advances, pharmacognosy should embrace this opportunity to advance the importance and relevance of the discipline.

Science based management of COVID-19 Pandemic

Dr. Ajay Parida
Director of Institute of Life Sciences (an autonomous institution of the Dept. of Biotechnology, Govt. of India), Bhubaneswar, India

The deadly outbreaks of viruses are of significant public health concern in India and worldwide. The ongoing SARS-CoV2 pandemic appears to be much more dangerous and lethal than any of the previous outbreaks infecting and killing several millions.

As countries begin to lift COVID-19-related activity restrictions,diagnostic testing remains extremely important. Identification of people infected with SARS-CoV-2 will help guide treatment of those individuals and indicate who needs to be isolated, and have their contacts traced and quarantined, to prevent the further spread of the disease. Despite being among only a handful of countries that have tested over a million people, India still has one of the lowest testing rates proportionate to its population. In Indian context, there are challenges in achieving desired levels of testing given the large population. While RT-PCR based tests have been primarily followed, it is limited by availability of well-equipped testing facilities and until now, India has primarily relied on government institutions and hospitals and these tests are relatively expensive. Several research institutions are near to developing antibody-based testing kits and once developed this will decrease the cost and help a greater coverage.

However, testing on its own will not stop the spread of SARSCoV-2. A combination of measures such as rapid diagnosis and immediate isolation of cases, rigorous tracking and precautionary self-isolation of close contacts has been the strategy being followed by many countries including India. Testing must be widely available and must cover all susceptible population. Currently, the Indian government follows a system of testing vulnerable population or patients requiring hospitalisation, as well as close contacts of positive patients and health care worker with symptoms.

While testing and identification of COVID-19 positives cases will continue in coming month, efforts are needed to augment testing capacities, more efforts are needed to initiate research efforts on development of diagnostics, therapeutics and vaccines to provide lasting solution to our fight against COVID-19. Development of mono- and poly- clonal antibodies, screening natural compounds and libraries and small molecules for identification of drug targets for COVID are among the priority areas. Study to understand the genomic architecture of the COVID-19 virus can provide us significant information on virus migration, phylogeny, virulence pattern as well as genomic changes over time. Study on the immune-profiles of symptomatic and asymptomatic individual will help us understand the immunity response in relation to viral infection. This basic information will enable us to fight COVID-19 pandemic effectively and efficiently.

Latest news

First Phytopharmaceutical Drug Approved for Clinical Trials targeting COVID-19 in India

Jul 2, 2020 | Covid-19, India, News, Phytopharmaceuticals

Sun Pharmaceuticals, an India pharmaceutical company, initiated a Phase 2 clinical trial to investigate AQCH, a phytopharmaceutical (plant derived) drug for treatment of COVID-19 cases. 12 research sites in India will evaluate the drug on 210 COVID-19 patients for what will be a treatment duration of 10 days. This is the first time a phytopharmaceutical drug has been approved for a clinical trial by the Drugs Controller General of India (DCGI) for COVID-19.

The Drug

AQHQ is a plant-derived phytopharmaceutical investigational product. The company secured approval by the DCGI in April of this year. Initially in development for the treatment of dengue, the drug evidenced broad antiviral effect in-vitro and is now under evaluation as a potential COVID-19 treatment. Sun has been collaborating with DBT-ICGE and CSIR-IIM since 2016 for the development of a phytopharmaceutical drug for dengue.

The Study

The results of this trial are expected by October 2020. Human safety study of AQCH has already been completed and the drug has been found safe at the recommended dose for Phase 2 study. The drug has shown anti-SARS-CoV-2 effects in in-vitro studies conducted in collaboration with International Center for Genetic Engineering and Biotechnology (ICGEB), Italy.

F. No. t. 11020/1/2020-DCC (AYUSH)

Government of India

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

Dated: 28th July, 2020.

ORDER

Whereas in the wake of COVID-19 outbreak, Ministry of AYUSH vide Gazette Notification No. L.11011/8/2020/AS dated 21st April, 2020 issued guidelines of the requirements to enable the conduct of research studies/clinical trials on Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) interventions on COVID19;

Whereas, as per Rule 158-B of the Drugs and Cosmetics Rules, 1945, proof of effectiveness for new indication or use is inter alia required for granting license/approval to manufacture for sale of Ayurvedic, Siddha and Unani medicines;

Whereas it has come to the notice of Central Government in the Ministry of AYUSH that approvals are being given for the medicinal products selected/registered for the clinical trials/research studies and spurious claims and misleading advertisements made in the media about the treatment of COVID-19 patients;

Therefore in order to make the process of product approval/licensing consistent at State/UT level for the purpose of effective quality control of Ayurvedic, Siddha, Unani and Homoeopathic medicines underwent clinical trials/research studies for COVID-19 and in exercise of the powers of Central Government, conferred under Section 33P of the Drugs and Cosmetics Act, 1940, it is hereby directed to all State/UT Licensing Authorities to forward license application of such formulations with details and results of the clinical trial/research study for verification by the Central Government in the Ministry of AYUSH. State/UT Licensing Authority shall grant the approval or license to manufacture for sale of any such formulation only after obtaining clearance from the Central Government.

Adviser (Ay.) and Head, ASU&H Drugs Policy Section

To

i) Principal Secretaries/Secretaries (Health/AYUSH) of all States/UTs.

ii) State Licensing Authorities/Drug Controllers of AYUSH

13th September, 2020

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
(EMR Division)

Post COVID management protocol

Background

COVID – 19 disease caused by SARS-CoV-2 Coronavirus is relatively a new disease, with fresh information being known on a dynamic basis about the natural history of the disease, especially in terms of post-recovery events.

After acute COVID-19 illness, recovered patients may continue to report wide variety of signs and symptoms including fatigue, body ache, cough, sore throat, difficulty in breathing, etc. As of now there is limited evidence of post-COVID sequalae and further research is required and is being actively pursued. A holistic approach is required for follow up care and well-being of all post-COVID recovering patients.

Scope

This document provides an integrated holistic approach for managing patients who have recovered enough from COVID for care at home. It is not meant to be used as preventive / curative therapy. The recovery period is likely to be longer for patients who suffered from more severe form of the disease and those with pre-existing illness.

Post-COVID Follow Up Protocol

(i) At individual level

- Continue COVID appropriate behaviour (use of mask, hand & respiratory hygiene, physical distancing).
- Drink adequate amount of warm water (if not contra-indicated).
- Take immunity promoting AYUSH medicine (details of medicines and their dosage is at **Annexure I**) – To be practiced and prescribed by a qualified practitioner of AYUSH.
- If health permits, regular household work to be done. Professional work to be resumed in graded manner.

- Mild/ moderate exercise

    - Daily practice of Yogasana, Pranayama and Meditation, as much as health permits or as prescribed.
    - Breathing exercises as prescribed by treating physician.
    - Daily morning or evening walk at a comfortable pace as tolerated.

- Balanced nutritious diet, preferably easy to digest freshly cooked soft diet.
- Have adequate sleep and rest.
- Avoid smoking and consumption of alcohol.
- Take regular medications as advised for COVID and also for managing comorbidities, if any. Doctor to be always informed about all medicines that the individual is taking (allopathic/AYUSH) so as to avoid prescription interaction.
- Self-health monitoring at home - temperature, blood pressure, blood sugar (especially, if diabetic), pulse oximetry etc. (if medically advised)
- If there is persistent dry cough / sore throat, do saline gargles and take steam inhalation. The addition of herbs/spices for gargling/steam inhalation (refer to Annexure I). Cough medications, should be taken on advice of medical doctor or qualified practitioner of Ayush.
- Look for early warning signs like high grade fever, breathlessness, $Sp0_2 <$ 95%, unexplained chest pain, new onset of confusion, focal weakness.

(ii) At the level of community

- Recovered individuals to share their positive experiences with their friends and relatives using social media, community leaders, opinion leaders, religious leaders for creating awareness, dispelling myths and stigma.
- Take support of community based self-help groups, civil society organizations, and qualified professionals for recovery and rehabilitation process (medical, social, occupational, livelihood).
- Seek psycho-social support from peers, community health workers, counsellor. If required seek mental health support service.
- Participate in group sessions of Yoga, Meditation etc. while taking all due precautions like physical distancing.

(iii) In healthcare facility setting

- The first follow-up visit (physical/telephonic) should be within 7 days after discharge, preferably at the hospital where he/she underwent treatment.
- Subsequent treatment/follow up visits may be with the nearest qualified allopathic/AYUSH practitioner/medical facility of other systems of medicine. Poly-therapy is to be avoided due to potential for unknown drug-drug interaction, which may lead to Serious Adverse Events (SAE) or Adverse Effects (AE).
- The patients who had undergone home isolation, if they complain of persisting symptoms, will visit the nearest health facility.
- Severe cases requiring critical care support will require more stringent follow up.

Annexure I

Immunity promoting AYUSH medicine (to be prescribed only by practioners permitted under law for prescribing the medicine/therapy under specific stream)

Ayush Kwath (150 ml; 1 cup) daily, Samshamani vati twice a day 500 mg (1 gm per day) or Giloy powder 1 -3 grams with luke warm water for 15 days, Ashwagandha 500 mg twice a day (1 gm per day) or Ashwagandha powder 1-3 grams twice daily for 15 days and Amla fruit one daily/Amla powder 1-3 grams once daily.

- Mulethi powder (in case of dry cough) 1- 3 gram with luke warm water twice daily
- Warm Milk with ½ teaspoonful Haldi in (morning/evening)
- Gargling with turmeric and salt
- Chyawanprash 1 teaspoonful (5 mg) once daily in morning (as per directions from Vaidya)

It is also suggested by the Ministry of AYUSH that the use of Chyawanprash in the morning (1 teaspoonful) with luke warm water/milk is highly recommended (under the direction of Registered Ayurveda physician) as in the clinical practice Chyawanprash is believed to be effective in post-recovery period.


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