

GLOBALISATION OF AYURVEDA CHALLENGES AHEAD

By

Dr. Vishal Gulati, Chairman IAF, UK

Over the last few decades Ayurveda has not emerged as one of the oldest and most comprehensive traditional healing system and a powerful source of knowledge and commerce, instead it has been sidelined and relegated to the secondary league with other food additives and health food league. Not only is it unfortunate to see a serious art and science to be sidelined but is becoming clear that most governments around the world are wising up to the 'back door' entry of traditional medicine and it is only a matter of time before these avenues will be closed. Should we wait for it to happen and then lament? I don't think so. What is needed is the determination and dynamism to counter this challenge and to promote Ayurveda so it can reach its full potential. The strategy for such a process will need at least two components, one will be legislative and regulatory which will require interfacing with global governments (please refer to Mr. Praful Patel's paper) and the other component will be scientific which will essentially look at the ways in which Ayurveda can demonstrate its strength in a language that the world can understand.

Before Ayurveda or any other alternative and complimentary system of medicine are accepted globally they will have to a number of challenges. Many of these challenges are common to any other alternative health care system while others are uniquely related to the holistic rather than reductionist approach of Ayurveda. Some of the issues and challenges in this area are discussed below as a guide to what they are and how they may be countered.

Safety: Complete satisfaction that a medical preparation is safe to be dispensed to patients is the prime concern of regulatory bodies around the world. This is not an easy task. Any doubt on the safety of a preparation will lead to rejection of that preparation at the regulatory level. A number of arguments are put forward to defend Ayurveda such as 'it is a system which uses natural ingredients'. Such an argument is not sufficient to convince regulatory agencies. Natural products such as bacterial toxins, snake venom and many poisonous plant extracts kill hundreds of people to show us that everything that is natural is safe; on the other hand a large number of substances that are artificially synthesised are safe for humans. Always remember that arguments of safety have to be made by comparison of like for like. Most drugs that make it through this test are given to animals at doses that are many times higher than humans to prove safety. Other arguments such as – 'regulatory authorities approved thalidomide and Baycol, our product is safer than that' are also unhelpful because even though the FDA approved Baycol it is the manufacturer, Bayer, who is paying out the damages worth over 2 billion dollars! If we want to capture large markets we also have to take responsibility.

Efficacy: While safety is the primary concern of the regulatory agencies efficacy is not far behind. This is particularly important in the context of medications that are targeted into areas where effective treatments already exist. Barriers to entry in these areas are high; they are typically hypertension, diabetes etc. Traditionally low hurdle indications such as cancers are also becoming more challenging. Initially those indications that require smaller trials may be useful.

Claims: Ayurvedic preparations often make very wide and general claims. Regulatory authorities are very sensitive to such claims.

"JointCare" claims include: "strong disinfecting properties", "antibacterial, antiviral, and analgesic activity", "rheumatoid arthritis", "an overall improvement was recorded in 70% of patients with rheumatoid arthritis. Swelling and tenderness of the joints was greatly lowered. ... Results are equally impressive in case of knee injuries which responded very well to JointCare treatment", "for many elderly people suffering from chronic and painful deterioration of their joints, JointCare has remarkable anti-inflammatory properties", "The conclusion was that JointCare is an effective agent in Rheumatoid Arthritis", "relieving discomfort caused by morning stiffness", and "... have recognized the value of natural products such as JointCare in the treatment of low back pain, one of the most common chronic orthopedic problems";

The above medication makes a large number of claims but was rejected by the FDA in 1998 because the makers of this drug were not able to satisfy most of these claims. In mainstream medicine, it is very common in the pharmaceutical industry to start with very small claims and get the drug approved and then waits for other claims to be verified. Many pharmaceutical companies are taking advantage of orphan drug indications and fast track approvals. Approaching the regulatory authorities with half-baked data to support wide claims can only harm the industry in terms of perception. The FDA archive is littered with thousands of such failures not because these drugs don't work but because they were filed wrongly!

Directions: A leaflet in any regulated drug explains how the drug works and how it should be taken. Often no such information accompanies Ayurvedic medicines. Information on what food it interacts with and what other drugs can and cannot be taken are essential components of a drug label.

Reductionist v/s holistic: This fundamental distinction between allopathy and ayurveda continues to the two systems on a divergent path. I am not going to take a view on which is better or worse but I firmly believe that reconciliation is essential for progress. While there has been some work in this direction in the way of isolation of active ingredients and head to head comparison between medications from different systems a lot more needs to be done. I see such studies to be just a test of the actual medication and not that of a system. It is common for some drugs to not succeed the first time; AstraZeneca's Iressa for cancer is the most recent example. More such studies will need to be don't not only to measure the efficacy of individual drugs but also to enhance our understanding of the substances that we are working with. I would much rather work with a system that enhances its knowledge rather

that one that relies on ancient texts. During the process of studying this we will become wiser about the science and will be able to make better choices to allow us to move forward.

It is currently not clear if the FDA or the MCA will approve mixtures for therapy. Although both these organisations have voiced commitments to supporting alternative and complimentary medicine no product with such a profile been approved so far.

Standardisation: When a product is presented for approval it needs to be standardised so the regulatory authorities are certain about the composition of the substance. This allows the regulators to match future batches against purity etc. This is typically difficult when a holistic method of treatment is used. Of course these guidelines are made to support the mainstream pharmaceutical industry which used the 'active ingredient' approach while Ayurveda uses a composition of mixtures approach where it is not possible to isolate an active ingredient and the sum total of effect of the medication is dependent on the interactions between the patient body and all the ingredients of the medication. This poses a potential problem relating to standardisation. Even if it was possible to standardise mixture individual plants grown and harvested, stored and transported in different conditions are known to have different properties. New technologies are helping other traditional healthcare systems. Elaborate, software based 'supply chain integrity' management is in place in many such houses where it is possible to track where and in what conditions a plant was grown, what crop was grown on the field before that. What the climate was like while it grew, when and under what conditions the herb was harvested, its storage, its transport etc is documented end to end and can be tracked at a touch of a button. The manufacturer in this case not only has this information on record but also is able to determine the conditions that will yield a good product. Once a preparation is made it can further be standardised like it has been done by NMR spectroscopy by some in the UK. Traces of NMR spectrum allow the manufacturer, regulator and even a customer to distinguish between preparations. I will mention this again in the intellectual property issues.

Intellectual Property: There are issues of ownership, protection and further advancement of intellectual property of Ayurvedic science. The body of knowledge of Ayurveda that exists today is a fruit of thousands of years of research and practice. No one body can lay claim on such a valuable asset and this knowledge base should be used for common good. Having said that, we will have to be very naive to ignore the fact that future innovations need to be protected. Any individual step that makes the Ayurvedic practice more effective, fruitful and cost effective should be protected to stimulate creativity. In many cases intellectual property around the actual product will need to be protected to give the people here who work hard enough incentive. Such protection is expensive but drug companies would not be spending 100s of millions on intellectual property if it weren't worth it.

Branding: Even prescription products need branding today. Every time I go to the USA, I am struck by the number of adverts on television about prescription drugs. These are targeted not at those who write these prescription but to patients who suffer from these diseases so they can ask their doctors to prescribe the latest drug. Many of these battles are won and lost in living rooms across America everyday. Ayurveda will need to be branded – as a positive brand and then individual products will be branded. These days even branding takes the help of science. It is easier to sell shoes if you can tell the customers that it has been designed using a patented

scientific method (e.g.; Nike) and you sell more shampoo if it has some active ingredient that is known to make hair healthier! It shouldn't be difficult for a 5000-year-old science to do so once we are able to get our act together.

There are opportunities and only we will be blamed for missing them. Our Yogis invented Yoga thousands of years ago. We forgot about it and it was rediscovered in the West and we re-imported it as YOGA. Today it is hard to find a Yoga teacher in London who has any training whatsoever in the actual practice in Yoga. Not many books about Yoga are written by Indian experts. Ayurved has already turned into Ayurveda!! We shouldn't wait until we have to buy Ayurvedic drugs from a multinational pharmaceutical company!!