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Research of Natural Health Products is Lacking – Right?

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Introduction

In May 1994, while working in marketing for BASF Pharmaceuticals in Germany, I was prescribed a product called Sinupret® for chronic sinusitis by my family physician. The product was behind the counter in the local pharmacy and was reimbursed by my health insurance. After some months, my sinusitis was gone and I was intrigued about the product, its regulation and most particularly the research behind it.

In reading the Sinupret® packet I discovered to my surprise that it was a herbal medicine. Convinced, with my pharma background, that there would be little evidence for such a product I asked our medical information department to conduct a literature review of all clinical trials for herbal medicines in all languages. A week later I received 4 thick lever arch files of abstracts of tens of thousands of clinical trials on hundreds of products. This delivery changed my life!

Evidence is Product Specific

When you consider the complex multi-active constituents, the variability of nature and the difficult manufacturing process it is obvious that the evidence for natural health products is product specific. We don't expect to get the same product (or pay the same) when we buy a grand cru wine or a bunch of grapes. The lever arch files were of clinical trials on specific products, not substances.

Anti-Evidence Environment

Unfortunately, in most countries there are limited ways to differentiate Natural Health Products based on their specific evidence. The patent driven monopoly which underpins synthetic pharma research is limited for natural health, and regulatory authorities have struggled to keep on top of claim justification and the complex controls needed to ensure reproducible products. For example, few countries require transparency on how the products are really made reproducibly and sustainably; for herbal medicines example, that they follow both Good Agricultural and Collection Practices (GACP) and medicine level Good Manufacturing practices (GMP) in their production. Good Clinical Practice (GCP) for clinical trials of herbal medicine products are not a consistent requirement globally either. Disturbingly very few clinical trials published today follow the CONSORT elaboration for reporting of trials of herbal interventions, published 15 years ago [1].

For the industry, this lack of differentiation means there are limited to zero incentives for serious research on their products. In fact, it is worse than that, as the researching companies effectively fund the innovation of everyone else, who can "borrow" the evidence to support their, *different* products.

Why Do We Bother with Research at All?

If this were the whole story there wouldn't be any research on finished products, but it still takes place. Why? In the commoditised market where companies can "borrow" evidence from other companies, there is still a battle to differentiate. This can be by adding ingredients (which might be a market advantage for a few months), by lower prices (and likely lower quality) or by marketing stories. Some limited research can be useful for telling a story about the product or the credentials of

the company which can enhance the brand. The investment in limited research is enough to gain some short-term marketing promotion.

There is a small but growing community of innovator companies who really want to take the risks and make investments to serious research into their products too. Sadly, if successful with the research outcomes demonstrated through investment and responsible innovation, these companies are all too easily drowned out by bigger commodity players who have broad distribution and easy access for patients.

For the sector as a whole there is a lot of benefit to more research. Natural health products offer important alternatives to other medical approaches, and in some cases the best solution for patients [2]. Huge numbers of people already take natural health products (in a recent survey in Canada 85% of respondents take at least 1 Natural Health Product [3]) and so improving the evidence base of the sector is a huge public health matter.

However, the lack of understanding that evidence is product specific is a substantial brake on innovation.

The Race to Nowhere in Natural Medicine Research Today

Given the public health implications of the anti-evidence environment, philanthropic or governmental financial support of the sector could be the way forward. Unfortunately, over recent times there has been a substantial trend to investment in research of isolated components of natural medicines, as such research attracts grants. In a recent premium research conference in the sector, the Congress and Annual Meeting of the Society for Medicinal Plant and Natural Product Research (GA) in Innsbruck in 2019, only 3% of research presented was on clinical research of finished products (15 out of 493 posters presented were human clinical trials) [4]. Research on such isolated substances almost never leads to products, and if it does a full synthetic product development and patent is needed to do so. Therefore, sadly for natural health products we are in a race to nowhere with research on isolated components.

What Can Industry Do for the Future of Research?

Those in the industry who are attempting to do serious research of their finished products need to shout it from the rooftops. These companies are otherwise taking all the risks and funding the research and marketing stories of their often larger and better distributed competitors. Innovation can, and should, start with building the evidence for the reproducibility of the products. Research can include post-market systematic collection of evidence and doesn't necessarily need to rely only on randomised controlled studies in highly selected patient groups, which although ideal carries high costs and high risks. Irrespective of the type of evidence, that this evidence is product specific is a key truth for the future of a healthy industry and better acceptance and credibility of the sector in mainstream healthcare.

Role of Regulatory, Clinical, Publishing and Scientific Communities

The ecosystem of the natural health industry is now in place to build a collaborative approach for an improved evidence base for the sector.

Regulators, who are understandably prioritising safety and quality, need to continue to build pathways to encourage specific evidence products to be differentiated. Product specific claims are beginning to emerge, and the evidence bar is raised in these circumstances. Consumers need help to identify the value of such products and the, sometimes subtle, changes in allowed claims. Also policing of health claims and other compliance needs to be continually improved.

The health professional community are getting more active in discussing the natural health product use of their patients and educating themselves so that they can provide constructive, informed advice on specific product use. Yet, many "mainstream" health professionals remain sceptical and ask for scientific evidence using pharma standards that cannot be applied to natural health products.

The publishing community is improving the reporting of clinical trials on natural health products so that the methods section accurately describes the specific product used [1], and the avoidance of misleading publicity on the clinical value of a "*substance*" rather than the specific, and carefully made, product used in the clinical trial.

As the industry moves to a new era of research and evidence-based use, the scientific community have a particular role to play in mapping out standards and a constructive path forward based on the latest science.

Informed Choice and Public Health

The billions of people around the world who routinely take natural health products are largely unaware of the variability of the product quality and health outcomes they achieve. Their choices are unlikely to be informed by evidence, but by marketing spend, availability and price. This is clearly anti-innovation and means that

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public health benefits for billions of people might not be reliable.

The enormous potential benefit of natural health products to human health is illustrated by the fact that Royal Botanic Gardens in Kew have documented 33,443 plants with medicinal actions [5]. Even as I found in May 1994, research is not lacking, and there is far more available today. But the reproducibility of the products and the evidence for the health outcomes they deliver need urgent improvement to unlock this enormous potential benefit.

In conclusion, perhaps it isn't the research that is lacking but that scientifically researched products are difficult to identify in the marketplace. And why not adopt a global standard for consumers and health professionals to inform choice and help people find Natural Health Products with specific evidence?

List of Abbreviations Used

CONSORT: consolidated standards of reporting trials
GA: gesellschaft für arzneipflanzenforschung society for medicinal plant and natural product research
GCP: good clinical practice
GACP: good agricultural and collection practices
GMP: good manufacturing practices

Conflicts of Interest

NP is Chair of the board of the Natural Health Science Foundation, a New York not-for-profit that encourages innovation through supporting informed choice and education around specific evidence NHPs. He is Chair of Metavate Consulting, a research consultancy specialising in advising manufacturers how to develop new natural health products and claims. He is the founder, and until 2019 was the CEO, of Soho Flordis International, a distributor and manufacturer of NHPs in 55+ countries.

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