Expert interview

The great untapped potential of herbal medicines

Baden-Württemberg is home to a large number of companies that produce herbal medicines, i.e. preparations made from plant extracts rather than pure compounds. In an interview with Dr. Ariane Pott from BIOPRO Baden-Württemberg, Professor Dr. Michael Wink, Director of the Institute of Pharmacy and Molecular Biotechnology at the University of Heidelberg, explains how these special extracts are placed on the market and how they differ from medicines made from pure compounds.

How are new herbal medicines placed on the market?

For the pharmaceutical industry it only makes sense to spend time and money on developing a new drug if the application of the drug, the compound from which it is made or the process used to make it can be patent protected. Since drug development is fairly costly, the pharmaceutical industry is only interested in developing completely new active drug ingredients, as only these are patentable. The pharmaceutical industry is not generally that interested in medicinal plants as they do not contain a single definable and completely new active ingredient. Phytopharmaceutical producers are also well aware of the patent protection problem and solve it by developing special extracts with production processes that they can protect with a patent. They “invent” a special method to enrich or remove substances from an extract, so that the extract becomes something special. This invention can then be protected with a patent. These extracts are tested in clinical trials, approval is sought and, all being well, granted, as happens with standard drugs. Although this special manufacturing process enables manufacturers to protect their plant-based product, other manufacturers can easily find a way around it.

How do the regulatory requirements for herbal medicines, i.e. extracts, differ from those for synthetic drugs?

EU legislation accommodates the producers of herbal medicines to a large extent. For example, if a WHO or other monograph demonstrates that the plant for which regulatory approval is sought is a well-known medicinal plant, and expert monographs confirm the plant’s efficacy, only one to two small clinical trials are needed for the particular medicine to obtain a “well established use” marketing authorisation. The applicant needs to demonstrate the quality of the product, but does not need to carry out the comprehensive clinical trials that are mandatory for chemical drugs. The extensive WHO, ESCOP* and HMPC** monograph collections list significantly more medicinal plants than there are preparations with the “well established use” authorisation on the market. The EU has introduced a European directive for a simplified registration of traditional herbal medicinal products. Manufacturers seeking approval for so-called THMP (traditional herbal medicine products) have to demonstrate that these products have been used for medical application for a period of least 30 years, including at least 15 years in the EU. The applicant also needs to demonstrate the efficacy of the herbal medicine for which approval is sought, and that it does not have any adverse effects. The majority of herbal medicine producers therefore use THMPs. However, the drawback of this option is that the product cannot be protected with a patent. The first company that places a THMP-based product on the market does all the registration work, and all those that come after can simply reproduce the product.

How do you see the future of herbal medicine research and development?
As potential progress in this sector is hampered by patenting, I believe that herbal medicines will most likely always remain a niche market. Although plants contain a large number of interesting active ingredients that act against multi-resistant bacteria or infectious diseases for example, the majority of plant-based drugs will not be granted marketing authorisation for the simple reason that industry is not interested in this process for economic reasons. A large number of innovations are therefore lost. Researchers like myself publish like world champions, but our results are not translated into new drugs.

Then of course, there are the customers who want to use herbal medicines. There is a very good market for traditional medicine manufacturers. But innovations are very rare. The companies usually revert back to what they know from Chinese and traditional European medicine. This covers several thousand plants. And that is plenty to be getting on with. However, as far as the biodiversity of plants is concerned - we're talking about over 350,000 plant species - there is still a lot of untapped potential.

What is the potential?

There are a few medical problems, such as multi-resistant bacteria, which have been on the rise for years. In Europe, around 25,000 people die every year from sepsis caused by bacteria resistant to most standard antibiotics, and the number will continue rising, that's for sure. There are different reasons why bacteria become resistant to antibiotics, including the abuse of antibiotics (e.g. in animal breeding) and insufficient treatment duration. Pharmaceutical research is faced with the problem of finding active ingredients that are also effective against multi-resistant bacteria. And this is what we are working on here in Heidelberg. We are looking into whether there are any interesting antimicrobials in plants. And the answer is yes, there are quite a few that have similar effects to microbial antibiotics. If the isolated herbal compounds (secondary metabolites, antimicrobial peptides (AMPs)) are combined with other natural substances or with antibiotics, it will be possible to combat almost all multi-resistant bacteria. We are looking for substance combinations that have a synergistic effect. Combining an antimicrobial substance with another one with a different target can lead to a huge increase in effectiveness.

But we will have a hard time finding a pharmaceutical producer interested in developing and registering combinations with herbal compounds or extracts, mainly for financial reasons. The compounds are often known active ingredients that are difficult to patent, even for a new and exciting indication. However, in view of the urgency of the problem, I believe that governments will at some stage understand that public research institutes will have to look at developing economically less interesting active ingredients because they are in great medical demand.

WS EGB 761® (Tebonin® marketed by Dr. Willmar Schwabe GmbH & Co. KG) is an extract made from Ginkgo biloba leaves.
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* European Scientific Cooperative on Phytotherapy
** Committee on Herbal Medicinal Products
Fighting diseases with plant-derived active compounds

Herbal medicines have a long tradition in Germany. In an interview with Dr. Ariane Pott from BIOPRO Baden-Württemberg GmbH, Professor Dr. Michael Wink, Director of the Institute of Pharmacy and Molecular Biotechnology at the University of Heidelberg, highlighted that plants produce compounds that are effective against microorganisms and that can also be put to good use in the treatment of human diseases.