Phinn®
PHARMANAGER INNOVATION

REGULATORY DATABASE FOR SCIENTIFIC INNOVATION

Understand
Anticipate
Innovate
Intelligent
Smart
Clarity
User-friendliness
Simplicity
Speed
Accessibility

Backed by ten years' experience in the field of scientific and regulatory consulting, Pharmanager Development designed Phinn®, the only intelligence and innovation tool of its kind in the world. Phinn® was launched at the latest Vitafoods Europe Conference. In less than five minutes, it provides access to all the regulatory, scientific and technical characteristics of some 1,500 ingredients.

The tool was developed on the basis of an observation: Pharmanager Development's regulatory and scientific expertise was supported by a database. But the database had become extremely (overly?) extensive, and could only *"be understood and used by a regulatory expert"*, comments Jean-Christophe Mano, co-founder, alongside François Baranger, of Pharmanager Development. Yet a regulatory database really only fully comes into its own if it can be accessed by non-regulatory specialists – the R&D department, for example.

A network of expertise

To make the database accessible, Pharmanager Development turned to two companies, each with its own specialist field.
A consultant was brought in to handle the IT aspects of the project – a judicious choice enabling the creation of intelligent search engines inspired by those incorporated in the latest generation of websites.
Pharmanager also called upon the services of Nutrikéo – both companies have previously collaborated on a number of different projects – to play the role of layman with a view to defining the required functionality of the Phinn® database.
A second layer of expertise specific to Pharmanager Development: the advice of its consultants, as well as the publication of a weekly newsletter covering between

4 and 12 topical issues, each presented with a headline, a summary and an explanation.

A guided pathway...

What are formulators, R&D engineers, company regulatory affairs managers and developers looking for?
The developers created the new database by putting themselves in the shoes of each of these people, anticipating their needs and prioritising their requests. Designed as a guided pathway for both ingredients and additives. Accessing the database leads to a number of different pathway options, depending on the various angles of attack: the marketing positioning of a food supplement (cholesterol, slimming, vision, etc.), ingredients, claims, countries, etc.

Firstly, development avenues.

A company seeking to launch an anti-stress formula, for example, needs to have access to ingredients that have been granted a claim, to those with claims pending and to those whose claims have been rejected. Opinions and justifications can be accessed, as can clinical studies, the scientific literature, etc.
This depth of analysis is *"tailored to pave the way for future successes, but also to avoid formulation pitfalls"*, maintains Jean-Christophe Mano.

Secondly, ingredients.

Damiana for example. Clicking on the name of this plant brings up a comprehensive data sheet, prioritised to provide the information required for the development of a product containing it: is this plant authorised and in which countries? What part of the plant can be used? For what applications (supplement or foodstuff)? Which substances within it need to be monitored? What are the restrictions for its use? Regulatory texts concerning the plant are also presented, as well as the recommendations of European and national authorities.
Insofar as it is a plant, the claims liable to be associated with the plant (even when their evaluation is pending) are also presented via the EFSA's Access database. These claims are accompanied by instructions for use.
A second example: red yeast rice, for which a positive opinion for a health claim (maintenance of cholesterol) was issued by the EFSA. In a newsletter of 18 March 2016, Pharmanager Development had stated that Germany had begun re-evaluating the dose for which the claim had been granted (10 mg/d). As far as the German authorities were concerned, a product providing more than 5 mg/d of yeast is a medicine. So what strategic market approach should a food supplement player adopt with respect to the market? Should it continue to propose formulas providing 10 mg/d of yeast? 5 mg/d?
Pharmanager Development's consultants contribute their expertise right through the process via Phinn®, giving their opinions. They believe that there is a real risk in Germany of a supplement providing between 5 and 10 mg/d of yeast being requalified as a medicine. And this risk is considerable for amounts in excess of 10 mg/d.

Monitoring of Novel Foods and additives

A «step by step» approach is also proposed for other regulatory categories. Additives for example. The filters applied are different. Searches are carried out by additive category: colours, emulsifiers, etc. Each has its own associated comprehensive data sheet. Novel Foods. For these too, specific filters are used to untangle the complexity of the regulations. Let's take the example of lycopene. Tomato extract is not a Novel Food when it is used as a food supplement, but it is when it is used in a foodstuff. As for synthetic lycopene, it is a Novel Food in both product categories. ■

REGULATORY SUPPORT

A tool for monitoring and anticipating European regulations, with comments from Pharmanager Development's experts:
- Consultation of national and European regulatory texts
- Access to the positive and negative lists of each country
- Access to European projects currently under consideration

SCIENTIFIC SUPPORT

A tool for verifying and supporting projects:
- Collection of scientific reports for each reference of ingredients (clinical studies, safety of use, bioavailability, etc.)
- Monthly review of positive clinical studies related to health claims
- EFSA reports and opinions

A UNIQUE DATABASE

- A tool for formulating, developing and innovating
- More than 1,500 ingredients, around ten added every month
- Summary of scientific and regulatory data for each active ingredient.
- Updated weekly

THE STRENGTHS OF PHINN®

A reliable database
- Pharmanager's regulatory and scientific expertise
- Data analysed and commented on by Pharmanager's consultants

An exhaustive database
- Regulatory information from more than 40 countries
- More than 1,200 plants in the ingredients database

An updated database
- Software updated weekly
- Weekly newsletter

A user-friendly database
- Multiple search criteria
- Information accessible in a few clicks (time-saving)

Assistance
- Free training
- Consultation included (1 hour/month)

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