



4
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CZECH CHEMICAL AND PHARMACEUTICAL INDUSTRY

Supplement of Czech Business and Trade

■ Interview: Helping to Establish Clear Market Rules

The Czech Association of Special Foods (CASF) was set up in the year 2000 to participate in the establishment of a balanced legislative framework for products supporting health. The CASF now represents 18 companies which account for about 50% of the Czech food supplements market. We asked Bohumil Hlavatý, the CASF Chief Executive, about problems faced by this branch of business.

Why was the Czech Association of Special Foods founded and what are its objectives?

The Czech Association of Special Foods was set up in order to defend the interests of food supplement producers and distributors who operate on the Czech market. We also want to establish an ethical and open market in food supplements. In order to achieve this goal, the CASF has an ethics commission composed of lawyers and other experts which helps the member firms in creating legal advertising. Intensive

communication with the state administration is necessary to build an open market. It is our advantage that we represent a half of the Czech market, it is easier for the decision-makers to negotiate with a representative of a whole segment rather than with separate firms.

Regarding food supplements, it is often said that the country's advertising legislation is strict or that the rules for food supplement advertising are not clear. If I do business in the sector, how do I learn whether "my advertising" is permissible?

The greatest stumbling block in our legal environment is that the certainty whether an advertisement is legal or not can be obtained only through a court verdict. There is no way of finding in advance whether an advertisement is legal or not. Companies usually solve this problem by addressing lawyers or our Ethics Commis-

sion. However, these institutions are unable to provide guarantees that an advertisement will not be fined.

Where should I be particularly careful? Can you give examples of a "correct" advertisement, and the false, deceptive advertising in this area?

Most often fines are imposed on advertisements because they do not show sufficiently in a visible way the obligatory information that the product is a food supplement. Unfortunately, no-one is able to state obligatorily what parameters this information is to have. Manufacturers are also frequently fined for their products trying to make the impression of a medicinal preparation. This can be an interpretation for information that a product is available in pharmacies. But they account for the sale of 80% of all food supplements. I certainly recommend to avoid formulations such as cures, helps to prevent specific diseases, and the like. If someone uses these words, they can be certain to be fined. On the other hand, such words as strengthens, revitalises, protects are tolerated.

If I, as an entrepreneur, want to introduce a new food supplement to the market, what should I do?

If you are not a manufacturer and want to start importing a food supplement, then the first thing to do is to check whether the manufacturer's product is certified at least according to the HACCP system. However, quality manufacturers of food supplements increasingly work at present already within the GMP standards which meet the requirements of pharmaceuticals production. If you are in doubt, I recommend you to consult the content of your preparation with the National Institute of Public Health, and in case of a controversial composition, with the State Institute for Drug Control. When this is done, you can request notification from the Ministry of Health, where you must submit, in addition to an opinion from the NIPH, and SIDC where required, also analyses from an accredited laboratory for chemical and microbial safety, and texts on packaging which comply with the laws currently in force.



Nanomedic Cluster - Together to the Goal

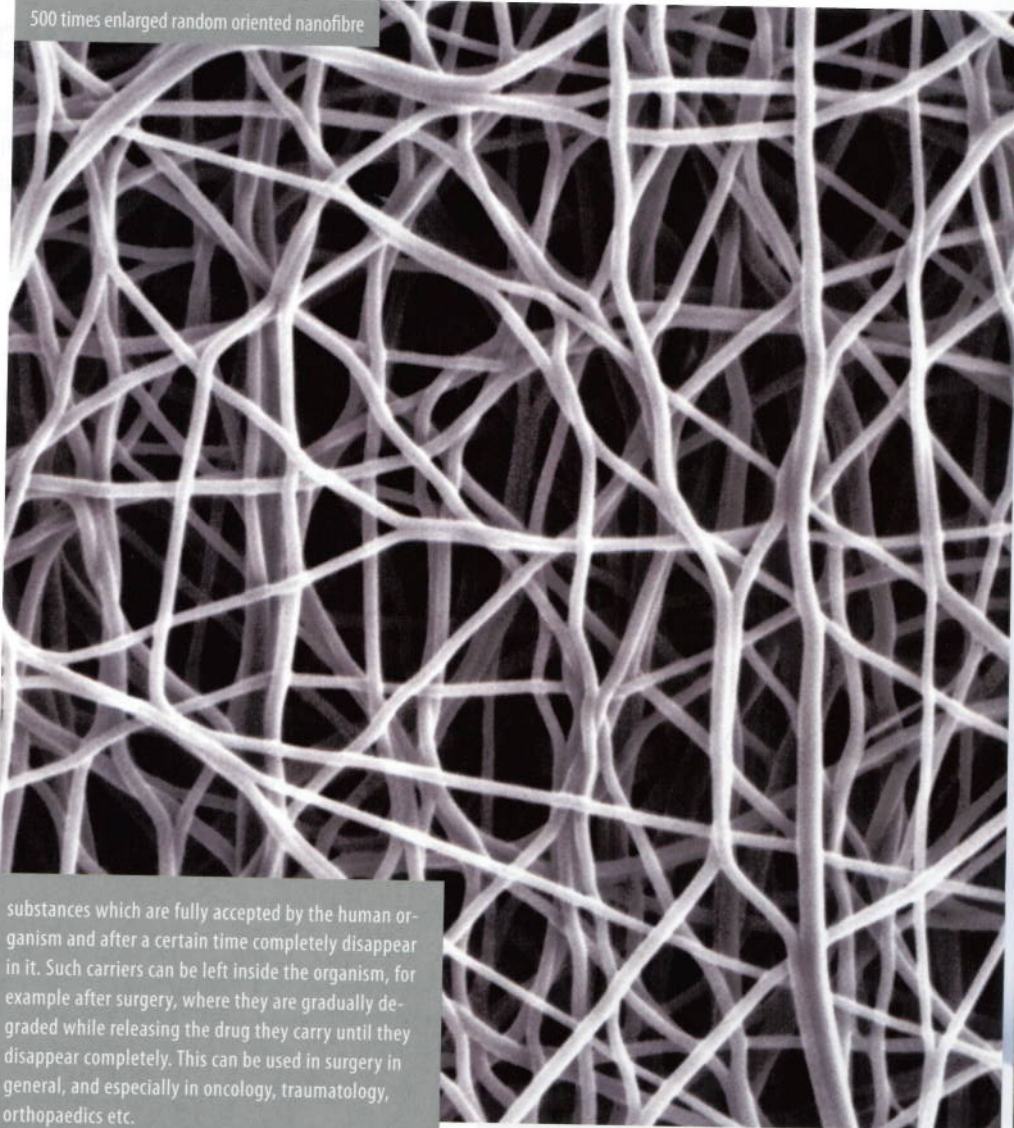
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The word cluster is heard ever more often in the Czech Republic. It is a modern way of linking entities which do not compete, but complement each other. This gives the members and the association as a whole better opportunity to manoeuvre and prerequisites for direct and indirect economic support from the state and social support in general. An example of a lucrative symbiosis of the entrepreneurial and scientific sectors is the Nanomedic Cluster.

The cluster is a grouping of companies, universities, and research institutes, which was established in the autumn of 2006 and at present its members are 18 small and medium-sized enterprises and six scientific sections of universities and academic institutes. The Pardubice Region acceded to the cluster in January 2010. From the beginning, the cluster has been presenting itself as a grouping of co-operating and non-competing entities which intend to develop and then manufacture and sell products of medical nanobiotechnologies.

This scientific term stands for preparations which are manufactured with the

500 times enlarged random oriented nanofibre



CLEAR OBJECTIVES

As soon as the cluster had been established, it defined five objectives on which their activities would be concentrated:

- Firstly, it is nano and microfibers of biopolymers, which will serve as covers of wounds and burns, or as supportive structures in different scaffolds.
- The second area are bandages (wound covers) with a biologically active component to cover wounds which are difficult to cure (bedsores, diabetic defects, and varicose ulcers).
- The third area are preparations for tissue engineering, a sort of artificial tissue to replace in the body natural tissues damaged by accident or illness.
- The fourth intention of the cluster is the development of drug carriers for targeted distribution or guided release. The basis of these systems should be substances which are fully accepted by the human organism and after a certain time completely disappear in it. Such carriers can be left inside the organism, for example after surgery, where they are gradually degraded while releasing the drug they carry until they disappear completely. This can be used in surgery in general, and especially in oncology, traumatology, orthopaedics etc.
- The last area of development are certain forms of therapy using various possibilities of manipulation of gene expression in the treatment of wounds and tissue engineering. In essence, this would mean that with use of the developed substances we could switch on or off certain genes which manage the creation of substances. For example, genes with positive influence on the healing of wounds would be switched on, and those with adverse influence would be switched off.

use of biological systems; in this case the use of bacteria and yeasts, and their size and manner of formation rank them among nanotechnologies suitable for application in medicine. We can show this clearly by the following example: With the use of bacteria, we make hyaluronic acid,

which occurs in our body and so is a substance inherent in it. Since we produced this acid with the use of bacteria (it was actually produced by bacteria directly), we worked with typical instruments of biotechnologies. From this substance we make nanofibres to be used as carriers

for targeted drug delivery. In view of their size, nanofibres belong to the nanoworld and we produce them by nanotechnological techniques.

Rapid Success

Nanomedic Cluster has been operating for less than four years. This is a relatively short time in the branch of pharmacy, in which the development of new preparations is normally long. However, the cluster can boast of a number of achievements, which have so far reached the stage of application for patents and presentations at various congresses and symposiums, but will be applied in prac-

tice soon. In the first place, there are very thin fibres made from hyaluronic acid, a substance which occurs normally in the organism and is not regarded as alien to its nature. These fibres can serve as the carriers of drugs that speed up healing, provided they are given the form of textile used to cover wounds. No equipment for the manufacture of these fibres exists and so it has to be developed. The same substance was used to make nanofibres thinner than human hair and imperceptible to the naked eye. These will be used to form an artificial cartilage, which is also being developed in the cluster. In this case, too, the manufacturing equipment had to be developed, as that available on the market cannot make targeted fibres needed for the given purpose. Development has also been completed of a bandage with a biologically effective active layer, which accelerates the healing of varicose ulcers and problematic wounds of diabetic patients.

500 times enlarged oriented nanofibre



Co-operation in Practice

In order to meet its resolution to develop as well as manufacture new preparations, the cluster had to invite to its ranks enterprises which develop and produce machinery and equipment for the manufacture of new medical and curative preparations. And so a place in the cluster belongs to engineering companies cap-

able of designing and manufacturing new equipment and bringing it to excellence in co-operation with companies operating in measuring and regulation.

It was clear from the beginning that a problem in the realisation of the cluster strategy would not be lack of research and manufacturing technology or premises. The "bottleneck" could be expected in staffing, especially in research, development, and designing, and middle and senior management. Specialised education in the neoteric and fringe branch of medical nanobiotechnologies does not exist for the time being in the Czech Republic as it probably does not elsewhere. This was why the cluster set as one of its strategic intentions support for the establishment of a new multidiscipline study branch to educate experts in medical nanobiotechnology. The new study branch is planned at the Brno University of Technology with Bachelor's, and later also Master's and Doctoral programmes.

■ Poll of Successful Companies Operating in the Chemical and Pharmaceutical Industry

Export: 70% of the total turnover – mainly to Germany, Poland, Hungary, Slovakia, and Austria

Enaspol a.s. is a chemical company with a long tradition in research and production of surfactants, which are the basic materials for the manufacture of detergents and washing powders. Another production segment are construction chemicals (especially concrete plasticisers and superplasticisers), dispersing agents for dyes and pigments, and textile auxiliaries. Enaspol is located near the town of Teplice in North Bohemia.

Where do you see the biggest interest of your clients at this time?

We are a small producer of chemical substances, but clients can always rely on the quality of our products, timely and reliable supplies, possibility of finding complicated technical solutions with our experts, and help in the development of new products. Flexibility, reliability, and inventiveness are our biggest advantages. A good signal was the fact that the crisis did not weaken us

but forced us to rationalise production. Our attention is now focused on research and development where we invest increasing amounts of money. This enables us to place our chemical products in new branches with a promising future: the manufacture of plasterboard, self-levelling floors, and latex. Besides finding new uses of our old products, we are introducing new products which are sought for in the market. This was the main reason why we developed washing preparations for professional dishwashers, a number of paraffin emulsions, hydrotropic surfactants, and linen softeners.

How specifically is your company tackling the crisis impacts?

From the short-term point of view, we strive for strict and consistent checking of all cost items and ensuing reduction of the purposeless and superfluous ones, services in particular. In the case of raw materials, we seek the most advantageous purchase and payment terms. From the long-term view, care is paid to innovations and new acquisitions.

Enaspol a. s.

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Turnover: EUR 12 million
Number of employees: 68

