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NORTH-EAST REGION'S SMART SPECIALIZATION STRATEGY

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**CASE STUDY – BIOTECHNOLOGY SECTOR IN NORTH-EAST
REGION, Romania**

i. SMART potential specialization sector

Biotechnology is the science that studies bio-productive processes based on culturing of cells and tissues of plant, animal or microbial origin. This multidisciplinary science integrates expertise in biological sciences, such as microbiology, cell and molecular biology, immunology, genetics and more, in order to use living microorganisms, and other cell or tissues types of plant or animal origin, for obtaining useful products in agriculture, animal husbandry, food, medicine, pharmaceutical industry.

Biotechnology comprises basically several sub-disciplines: medical biotechnology and gene therapy (production of antibodies); pharmaceutical biotechnology (to produce bioactive compounds - vitamins, proteins, antibodies); agricultural biotechnology (production of new organisms with different characteristics that can be traded for food); marine biotechnology (study of active compounds and their use in industry, production of medicines) or green (to produce compounds biodegradable).

In this case study there will be references to medical biotechnology and pharmaceuticals, with particularity in the North-East.

According to Eurostat, the pharmaceutical industry is part of the technology-intensive industries with high added value and require skilled labour. It is an industry that requires a diversified economic environment in which the entrepreneurial discovery process to be permanent.

Thus, it is necessary that regions to discover those areas of research and innovation that will excel. In this learning process, entrepreneurs will play an important role in identifying promising areas of specialization in the future.

Regarding business representatives, in 2011 were registered in North-East Region, only 8 companies out of a total of 121 registered nationally. Most of them (5 companies) were active in Iasi and 3 in Neamt County.

Company	County	Locality	No of employees 2011	Turnover 2011	No. of employees 2012	Turnover 2012	NACE
Antibiotice SA	IS	Iași	1450	281847455	1465	304731950	2110
Fitterman Pharma	IS	Iași	120	40486745	135	68338967	2120
Docs Art SRL	NT	Piatra Neamț	0	1835	-	10229	2120
Centrul de Cercetare și prelucrare a plantelor medicinale Plantavorel SA	NT	Piatra Neamț	84	3810205	73	4246645	2120
Honey & Investment Pharm SRL	NT	Ruginoasa	1	108029	0	567732	2120
Ircon SRL	IS	Iași	28	6830412	28	8525078	2120
Vanelli SRL	IS	Iași	71	8992206	43	6203469	2120
Hyperion SA	IS	Iași	16	1743343	21	2789224	2120

Source: List of companies in Romania, 2013

According to the distribution of companies per size, in the region operates only one large firm, the rest being small and medium enterprises, and micro enterprises with up to 9 employees.

It was noticed a concentration of companies particularly in 2012 - "Manufacture of pharmaceutical preparations". Aggregated results of these companies are insignificant, accounting for only 0.43% of the total number of employees in this area and 0.48% of the turnover of the North-East Region. The company "Antibiotice SA" is the leading Romanian producer of generic drugs. The firm also is the only

pharmaceutical company in Romania with a portfolio of active pharmaceutical ingredients obtained through biosynthesis and may introduce new manufacturing products of own biotechnological research or acquisition of license.

This economic sector is considered to be a strategic one, in particular for Iasi, Botosani and Neamt counties.

In 2011, the trade balance for pharmaceutical products in the North-East Region was positive, registering a surplus of 5.485 thousand euros, and in 2012 it rose to 5.875 thousand euros, due to higher exports of the company ANTIBIOTICE S.A. Iasi, which exceeded 20 million. RON annually. Thus, North-East Region recorded a comparative advantage in terms of this group of products.

In addition to the companies mentioned above, another category of actors are research institutes. Among these, **Biological Research Institute** promotes fundamental and applied research in cutting-edge fields such as molecular and cellular biology, biotechnology, biodiversity, bioinformatics and bioanalysis. One of the competences of this institute is bioanalysis - use of modern methods and techniques for the analysis of biological samples, drugs and their metabolites.

Antibiotics Research Centre is a modern research unit within the Antibiotice SA Company which aims to develop new drugs, having three distinct divisions: pharmaceutical development, centre for drug evaluation and Regulatory Affairs.

A third category of factors is represented by universities. **University of Medicine and Pharmacy "Gr. T. Popa"** recorded a total of 307 PhD students in the Doctoral School UMF Iasi, some of these in research of pharmaceutical biotechnology.



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Within this university it was founded The Centre for Biomedical Research Gr.T.Popa which aims to promote multidisciplinary research in life sciences (biomedical, behavioural sciences).

Also within UMF Iasi is the **Platform and clinical research on the mechanisms of non-oncological and oncology research and physio-pharmacology**. This association of algeziologie unites in doctors, pharmacists, biological biotechnology could contribute to the development of pharmaceutical and medical products.

The activity of scientific production of the University of Medicine and Pharmacy "Gr. T. Popa" is intense, so the number of published articles in 2011 was 41, 12% of the total number of articles published by research institutions in Iasi. None of the articles did not address the issue of pharmaceutical biotechnology.

Faculty of Biology of the University "A.I.Cuza" is active in the study of biotechnology, with both teachers and PhD students of the Doctoral School of the Faculty of Biology trained in this area of research, on topics in the field of biotechnology, such as biotechnology and microbial cell.

In the context of development of pharmaceutical and medical biotechnology, hospitals and institutes from the medical field have a very important role. **Iasi Regional Oncology Institute** cherishes the activity of research and development, establishing three research laboratories: molecular biology, radiology and imaging and radiotherapy. The laboratory of molecular biology allows multigene analysis at a compatible resolution with the application of customized therapies.

Between **Emergency County Hospital "St.Spiridon"** and the University of Medicine and Pharmacy "Gr. T. Popa" was created a common platform for research in molecular medicine with the following departments: functional genomics,

molecular imaging, flow cytometer and molecular biology for education. The department of molecular biology permit a deepen study of education areas such as medicine, biology, biochemistry, chemistry by using a methodology of investigation and use of techniques in the field of molecular medicine.

A concentration of business structures inaugurated in Iasi is "Future Hub Iasi". This structure of "Hub" type will be a liaison between four clusters structured in the following areas: transportation and logistics, pharmaceuticals and healthcare, academic, technology and IT services. The growth pole from the field of pharmacy will focus on pharmaceutical research and health services. Thus, within the pole will operate a network of research laboratories whose results will be taken into production by existing drugs factories.

ii. Clusters and smart specialization

Currently, there is no cluster to address and pharmaceutical and medical biotechnologies, the number of actors that could be involved in a regional cluster would be reduced. However, as part of the life sciences, there may be some common concerns with those of the cluster of medical-imaging ImagoMol Iasi.

It can be seen that there is a tendency for countries and regions to set the same priorities. All want to become a core development in biotechnology, nanotechnology and ICT by hosting clusters of excellence, business incubators and science parks and so on. But it is very important for regions to identify their best assets, peculiarities and to create a single strategic vision.



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A good practice example is one of Poland in the biopharmaceutical field. It started by identifying niches in the pharmaceutical through the process of innovation and the entrepreneurial discovery. Thus, were established the following niches: the development of new drugs - analysis of active ingredients and their manufacturing methods, creation of galenic formulas; creating proprietary technology generics.

In the second stage, it was created BIRTI (Baltic Innovative Research and Technology Infrastructure) - a platform for cross-border cooperation in order to coordinate the development of human resources and research infrastructure, development and innovation in all three Baltic states, focusing on development of RDI capacity and strengthening of excellence in the Baltic region.

The purpose of BIRTI is to create favourable conditions for the process of innovation, encouraging teamwork of scientists, engineers, designers, to develop competitive knowledge. The projects of this platform are: BioPharmAlliance - cluster in bio pharmacy and organic chemistry, NanoTechEnergy - cluster in the field of nanostructured materials and BaltSmartTech - smart technology cluster in Engineering and IT & C

The objective of the Cluster BioPharmAlliance is to complementary develop the existing infrastructure within institutions with scientific activity, to create a logistical base, of advanced research in biomedical and pharmaceutical research in order to create competitive products. Among the founding organizations are: Institute of Organic Synthesis, University of Latvia, Biomedical Research Centre, Riga Technical University, Institute for food safety, animal health and the environment, University Hospital Pauls Stradins etc.

Among the scientific activities can be included: bioinformatics, invention and research in the field of human medicine and veterinary bio pharmacy. However,

within the cluster have to be made some improvements in terms of quality of jobs: new doctoral programs, adult education programs, mobility between science centres and enterprises, international mobility.

From the composition of this cluster it could be observed the diversity of actors involved, but also their size. One such cluster in North-East Region could not reach a very high level of maturity, since it fails to reach a critical mass.

iii. Areas of competence in biotechnology

Given the specificity of this industry in the North-East Region, it was found the following niche:

Sector of origin	Main field	Directions to reconfigure sector	Support links
The pharmaceutical industry in North-East Region	Life sciences	Pharmaceutical biotechnology - Biopharmaceuticals (drugs produced using biotechnological methods) Medical biotechnology - microbial and cellular (obtaining of effective preparations with antitumor, antiviral, antimicrobial effects, vaccines, methods for early diagnosis of diseases)	1. Antibiotice SA 2. UMF Iași 3. Biological Research Institute 4. Faculty of Biology