Report on twinning

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Florin Zubascu, journalist working for Science|Business, Brussels paid a 4-day visit in Warsaw due to Pharma Day which took place on April 25th. Florin assisted BASTION team in organization of the event, prepared press release about the meeting and ran interviews with participants.

Press Release

http://www.sciencebusiness.net/news/76557/Poland-looks-to-spur-translation-of-its-medical-research

Poland looks to spur translation of its medical research

While it has a high reputation for the quality of its basic medical research, Poland lacks the means to translate this into the clinic. International collaboration is needed to help build this infrastructure

By Florin Zubascu

Poland's medical researchers have plenty of good ideas and the intellectual capacity to pursue them, but they are having a hard time translating research outputs into the clinic.

The reasons behind this are varied, but delegates at last month's Pharma Day in Warsaw agree: what the country needs right now is to come up with strategies for spurring more international collaboration.

The meeting, organised by the Medical University of Warsaw and BASTION, a project set up to reduce the time from scientific discovery to clinical application, brought together top Polish medical scientists and biotech companies to discuss how to stimulate translational research in oncology and enhance cooperation between science and industry.

Funding the "wrong projects"

In addition to EU funding, Poland has several national funding mechanisms designed to stimulate translational research, noted Izabela Rzepczyńska, deputy head of unit at the Polish National Centre for

Research and Development (NCBiR). Ultimately, it is up to medical researchers to brave the step of applying for funds through these mechanisms, she said.

The national strategy programme, Strategmed, which is just about to launch its second call this year, offers the opportunity of getting access to the big money and for building consortia between academia and industry representatives. Another important programme, Innomed, is offering funding opportunities for science and industry collaborations. 35 per cent of its total budget of €72 million comes from industry, and its first call was launched last year.

However, researchers and academics complain about the quality of evaluation in these programmes. Zbigniew Gaciong, head of Internal Medicine, Hypertension and Vascular Diseases, at the Medical University of Warsaw argued that "many projects do not have innovative potential and won't have any patents as an output. Many papers in high-impact journals yes, but not much innovation will come out of them. There will be no translation and no commercial benefits", Gaciong said.

Magda Chlebus, Director of Science Policy at the European Federation of Pharmaceutical Industries and Associations, argued that basic science is relevant as well. "Not all science must be innovative or with commercial potential. Basic science is not about innovation but it plays an enabling role", Chlebus said.

A more active role for the government

Piotr Rutkowski, Director Representative for Clinical Trials at Maria Sklodwoska-Curie Memorial Cancer Center and Institute of Oncology, highlighted the mismatch between the number of clinical trials run by academia and the number of trials sponsored by the industry. "Unfortunately in Poland we have only commercially-sponsored trials," he said.

In 2013 there was only one academic clinical trial in the field of oncology registered in Poland, while in the EU as a whole, 40 percent of clinical trials are academic.

"We should promote and facilitate more clinical trials coming from academia, because the best ideas come from there," Rutkowski said.

The Polish Ministry for Health should allocate funds and offer legal support for academic clinical trials, which are easier and cheaper to perform than industry-sponsored trials, Rutkowski suggested.

International collaboration – Poland's weak point

Jakub Golab, BASTION project coordinator and head of the Department of Immunology at MUW, said "Poland should put greater focus on developing infrastructures to facilitate collaborations with more advanced research institutes in Europe and to bring more experienced researchers into the country". While BASTION has an impressive track record, with two patent applications for new diagnostic tools in oncology, and 74 peer-reviewed articles published since 2012, that is not enough to get the industry more interested in investing.

Patryk Mikucki, Hub Director for Study Management and Operations at AstraZeneca, said research in Poland is impressive, but from the perspective of a big pharmaceutical company, Poland is not the

favourite place in which to invest in research. “In order to be successful internationally, Poland has to choose a niche where it can be the best and the research community needs to build a common voice and to be perceived as one group”, Mikucki said.

Money is not the biggest problem. Before even thinking about funding, Poland has to create functional interfaces between academia and the industry, Mikucki told the meeting. “Local biotech companies can in some ways act as an interface between academia and big pharma, but people need to forget for a while about personal conflicts and come together as one group”, he said.

Precarious IP management

Collaboration certainly does not happen overnight, and there are obstacles that make it hard for biotech companies to get involved in partnerships, said Wojciech Czardybon, head of Discovery Chemistry at Selvita. “The biggest obstacle in the way of industry-academia collaborations is the lack of basic knowledge about IP protection”, he said.

Universities should take further steps in training students and researchers in the basics of IP protection and protect potentially valuable results. Companies automatically lose interest in investing in a project with an unclear IP position.

It is vital to teach students about IP and to develop mechanisms for improving IP protection, Czardybon said.

Marcin Szumowski, CEO and President of OncoArendi Therapeutics, echoed this. “Even though more and more researchers understand IP protection issues and some of them are doing a good job of protecting their IP, there are a lot of cases where these functions are run by assistant lawyers or by the legal departments of universities and this is not very effective”, Szumowski said.

Poland has the building blocks, but it will take time to put them together

In a short period of time Poland has made a giant leap forward, thanks to NCBiR, the National Science Council and units within universities which are committed to transferring IP to the market and commercialising it. “Both science and industry are becoming more and more successful, but they can do more”, said Gaciong. Overall, there are reasons to be optimistic about the future of science-industry collaboration but perhaps there is a need to move faster, because certainly the west is not going to wait for Poland to catch up.

In order to become an international success, Poland has to speak a common voice and keep the ideas flowing, otherwise it will be hard to attract big international money.

You can find more details about the BASTION project by clicking here or by sending an email to Karolina Dzwonek, Innovation Manager at BASTION.

Multilateral collaboration infrastructures are urgently needed by Polish medical researchers who want to capitalise on their scientific results

At the end of April, top Polish medical scientists and biotech companies gathered in Warsaw to discuss how to stimulate translational research in oncology and enhance cooperation between science and industry. The event was organised by the Medical University of Warsaw and BASTION, a multidisciplinary science project which aims to reduce the time from scientific discovery to clinical application. At the event, Science|Business interviewed Magda Chlebus, Director of Science Policy at the European Federation of Pharmaceutical Industries and Associations.

Q: How can Poland enhance collaboration between industry and academia, and how can Polish researchers capitalise on their scientific results?

A: I think that the fact that the business model in the pharmaceutical industry is evolving and is changing is not yet fully appreciated. Before, companies were conducting most R&D in house. Today the industry is externalising more and more and this also offers more opportunities for collaboration with academia and SMEs. The research ecosystem - interactions between all players, sectors and stakeholders - is more dynamic, and every party - public and private - plays an important role in the biomedical research processes.

Also, there should be some sort of "glue" to facilitate the interactions and to help in moving results from the very early stages of research, through development, to the different partners in the ecosystem, until a therapy reaches the patients.

Q: What would that glue be? Better communications? Networking? Targeted policies?

A: It would be a combination of factors. Certainly a better understanding of the environment, a better understanding of the value universities can offer, a better understanding of the intellectual property rules and what IP can offer and what it cannot, and making IP an asset rather than a barrier for collaboration, are important.

It is also important to go beyond national collaborations. In this case, European funded projects can be considered one of the glues that help bringing people together. The Innovative Medicines Initiative 2 that will be launched in July 2014, is a very good example of a collaboration where you have academics, patients, industry, regulators and payers, working together to take early discoveries through development and to the patient, in a collaborative way. Translational research does not happen bilaterally – it needs to bring many stakeholders together.

Q: Do you think this approach can succeed here in Poland?

A: It will eventually. At present it is essential to break the silos and create more opportunities for people to work together and build trust. They should learn more from each other and create common objectives and agendas, in order to understand what they have to offer to each other, what is the win-win situation. There is no effective mechanism to support such dialogue yet and there is also lack of self-confidence.

However, there are initiatives and projects, such as Bastion, which can help in moving things forward.

Q: Do you think Polish scientists are fearful of collaborating with industry?

A: There are more and more academics on the boards of pharmaceutical companies, and more and more collaborations between pharmaceutical companies and academia - because this is the only way of bringing excellent research results to the market. Usually, those who express fears are those who have little or no experience of collaboration.

The industry is in the midst of a process of changing its business models, of externalising its research, and great ideas are generated in collaboration with many different individuals. Academia should look for collaboration opportunities rather than just becoming outsourced service providers.

Q: How can academics protect their IP and profit from it? It seems that in Poland this issue requires more attention

A: From what I heard today, my impression is that Poland needs to catch up: there is probably not sufficient understanding of the benefits that well managed IP can offer. Technology transfer offices are not developed sufficiently. This sector, and this area of knowledge and expertise needs to be upgraded.

Q: How can the concept of multilateralism be made to fit with the need for a single voice for collaboration?

A: It actually fits very well because biomedical research is just one big ecosystem. Every partner, every stakeholder in this ecosystem has a role to play, but they all have a common objective: doing research that ultimately benefits patients.

Research funding agencies in Poland are urged to invest in the "right" projects

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Q: Do you think that Polish scientists fear to collaborate with industry?

A: There is a well-known and well described association between pharmaceutical companies and the academic community and nowadays I think this relationship follows strict rules in terms of funding, reimbursement, and so on. But some people hark back the same old story of how pharmaceutical companies manipulate physicians to write prescriptions for their drugs.

This is nonsense because we are talking about collaborations that may be fruitful for both sides. There is a win-win situation and we all know that the industry cannot function by itself. They need an influx from external associates, mostly from universities. When you look at countries like the US – on the campus of Harvard University you have buildings of Merck, Sharp & Dohme (MSD), Astra Zeneca and the Sandoz Institute. But in countries like Poland people think that collaboration between academia and the industry leads to bribing physicians to write prescriptions.

Of course, this is a sell-buy situation: you want to buy with a low price and sell with a high price. Indeed, pharmaceutical companies can buy IP from Polish universities at a very low price – but this is where negotiations should come in. Maybe scientists and researchers are not the most appropriate people to

deal with the industry. Universities need specialised services that deal with IP and commercialisation, and that protect the interests of the university and of the scientists.

Q: Why do you think that for big pharmaceutical companies, Poland is not the favourite place to invest in research?

A: Our local companies invest in the country but because they are generic companies, they are not looking for new molecules so they fund simple studies like bio availability, some chemical studies on molecules, and clinical studies on synthesis of molecules and so on.

But I agree that big pharmaceutical companies are not interested in investing in Poland for a very simple reason: big companies consider the investment as a part of the offset. They simply say they can return 2 to 5 per cent of their profits as investment in local R&D.

These companies want something in return and I think they cannot be blamed for that. For example, MSD was about to open research lab in Poland and the talks were in an advanced stage and local people from MSD were working very hard to finalise the deal, but eventually they got a very straight-forward response: if the investment policy on the MSD programmes was not changed, then there would be no investment. Business, as they say, has no feelings.

Q: Could smart specialisation help to improve translational research?

A: I think it's a great idea. Of course it also has a danger: you can be too specialised and go into a *cul de sac.* But I think that if we could concentrate on some specific areas, like big pharma – after all companies do not have drugs for everything. Usually they have some divisions that specialise in certain areas.

We're relatively a big country and we have a lot of everything. At the moment Poland should definitely specialise in doing research and drug development for cancer and infectious diseases. But maybe we should also look for common medical problems, such as arteriosclerosis.

Q: How would you evaluate the quality of projects funded by the Polish government?

A: A lot of state-funded projects are not innovative enough: I think that the process of reviewing proposals should be different and the reviewers should take more responsibility. When you base your decisions only on reviewers you have to realise that in a country like Poland we have very few researchers who are experts in their respective fields. So, when you write a proposal there are three

options: it will be reviewed by your friend, by your enemy or by [someone who is] ignorant. None of these options are good.

The reviewing process has to change. I am quite convinced that this can be done by people from the National Centre for Research and Development. They could go over the projects and evaluate the potential for innovation because many reviewers are not very well prepared and they don't have enough knowledge to figure out whether the projects they review have any commercial potential.

It is easy to assess the scientific value of a project, or its originality, but you will need specialised people to spot innovative projects. Of course, spotting innovation is like Russian roulette - but only prepared people are lucky.

Q: In your opinion, what's the most important obstacle to transferring academic research to the market?

A: Normally, this transfer should go smoothly. From a legal point of view there are no barriers that cannot be overcome. If a project is truly innovative companies would line up to invest in it immediately.

Q: So you think the problem is making and funding innovation and the process of going to the market depends on the industry's readiness to invest?

A: First, the most important problem is related to funding: money is not allocated to the right people. In the reviewing process, innovation is not a priority because funding decisions are based on research experience, publication records, and on the scientific value of the project, but not on its potential for innovation.

Second, our universities are not prepared to process the transition from bench to the bedside because of legal issues, difficulties in drafting contracts and so on. And the universities need to be better negotiators. This process of negotiations and legal work creates a lot of problems in Poland. There is a lack of people and institutions with the skills and knowledge to do it.

Q: What about of the Polish pharmaceutical industry?

A: These companies don't suffer of a lack of ideas, but from a lack of resources. They have many projects but they don't have enough resources to work on all of them and they can't develop projects for every researcher that comes up with a good idea.

Q: Do you think that the national funding agency is able to reform, to simplify procedures and to facilitate collaboration?

A: I still hope that will happen. But I am deeply convinced that there is a will from the side of the director of the national funding agency to do this. I have no doubt that there is a sincere will to do this. But you know, this might be just wishful thinking.

Poland has the building blocks for world class translational medicine but not all stakeholders are on the same page yet

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Q: What do you think Poland needs to do to be more successful at translating research to the market and what is missing in terms of academia-industry collaboration?

A: I've been in biotech and drug development for a lot of years and the biggest problem between academic and industry collaboration is that there is a disconnect between what everybody wants to do. Each party can have different goals that, on the surface, may seem conflicting. And it's quite interesting that if you can sit down with people and be upfront about what you want and they're upfront about what they want, it's easier to come to a collaboration that's much more fruitful. It's hard to do that in a formal way, it has to be through good communication.

A few years ago with a different company we were trying to do a collaboration with a group in the US and their only goal was to publish, but they thought I didn't want them to. I have no problems with researchers publishing anything that comes out of my collaborations with them. As long as I get to

protect it, I am actually happy about them publishing. As soon as we agreed on a process for IP and publishing, the collaboration was very fruitful.

It's hard to do that unless you have this component of communications between industry and academia to understand what the goals are. Each research institute has a goal, each company has a goal and they have different reasons for getting into a collaboration. Unless you get the chance to sit with them and talk it's usually not going anywhere. That's the problem.

Q: Do you think that researchers should do more than just focus on publishing? Do you think they should have a more active role in IP protection and transferring results to the market?

A: That's their job. I mean, what's the goal of an academic researcher? It's to publish and innovate. It all depends on what the arrangements are, but once it gets to a publication standpoint if you want to move it forward that's going to be the company's job. An academic's job is to innovate.

It's very important that the goals of any collaboration are clear upfront. But, it's hard for academic researchers to say " I am going to follow this plan and no more because they don't know if they want to go any farther, explore a different facet of the research, etc. And because they're afraid they're not going to have enough industrial support, which is important to them, it can be unclear unless goals are stated upfront.

Q: So, who should take care of the IP side?

A: The company. Always. IP is one of the largest assets to a life scienece company and IP management is a key component to business longevity.

Q: But teaching researchers about IP would still be necessary?

A: Everybody should be able to understand what IP is and what can be considered as IP. But I'd prefer to manage the IP and let the researchers do the work. It makes more sense. I'm a big proponent of the company managing the IP – not necessarily owning it but at least managing it.

Q: Do you think there is a conflict between academic researchers and industry in Poland?

A: That's a struggle everywhere. I don't thing that's just here. Small biotech companies come from academia and most people involved don't necessarily understand the entire drug development process.

Small biotech companies can do two things: try and learn the entire drug development process and then hire in others to be able to do it, or do it themselves, which can lead to failure. Or they just do the things that they're really good at and hope to sell that output.

Academic researchers want to publish. They want to do work and tell the world about it. Small biotech companies want to do work and figure out how to exploit it, and in some cases feel that it should never be talked about because they feel the competition is too high. I think that's false because as long as I have my IP strategy solved, publishing is actually very good from the company standpoint.

If I am a small biotech company and looking for another investor or partner like a large pharmaceutical company, and I am looking for a pay-out they're not going to know anything about this and I have to go to them fresh.

Publications solve this problem. If for the three years that I've been working on it they've been reading papers on this new pathway or drug candidate, when I am going to them they're already going to understand. Half my job has been done by the academics who have been publishing their work. Publishing is good for both sides.

Q: What stops companies and academics in Poland taking this pragmatic view?

A: Experience. It's a relatively young industry here. There is not a lot of expertise that has been built up both on the business and research side. The research is fantastic, always has been. The universities are well equipped, the academic staff are amazing, their support staff are better than most other universities. They have access to technologists and you name it, they can do a lot of really good work. But Poland is the same as many other countries.

There are three things that make biotech industry get moving. One is the science, second is the people, and third is the money. I think the people are already here and I don't want to suggest that they don't know what they're doing.

But, the problem is the money. In the US there is access to the really big money. When you plan to go really big funding is key and the company needs to understand where that money might come from. The US is the largest biotech public market. It makes sense to access this..

It's kind of interesting because I am working on both sides of the fence right now and I am trying to understand how I might be able to use that to my advantage because I have a foot here in Poland and our goal is trying to build a start-up in Poland. We'd like to begin some of that basic research, some of that pre-clinical work, some of that innovation through a network of institutions here, along with our corporate entity in Poland. And then use Canada for being able to raise large dollars. I am not sure how I am going to do that yet but it's an advantage that we have a foot on both sides.

Venture capital is always a problem because it's a personal thing. Researchers don't understand why so many times get refused by venture capitalists – but that's because venture capitalists don't understand research. It's more difficult; raising money is hard work.

I think that will change over time. Biotech is new in Poland. It needs time to seep into the economy. But from what I have experienced, the ingedients (people and science) are here for a successful industry

Q: What could the government do to improve things on the policy side?

A: Canada has tried several different things. but there is no one or two strategies. I think there are certain things that can be done that make things easier to set up relationships between industry and academia. That would be a big step. If governments can help to make it a little bit easier for this relationship to happen that would probably do a lot more than investing in research or things of that nature. Money is always great, but money is not going to help if relationships cannot be built.

Poland, they've got the people. Absolutely. They've got the science. Now they need the money and the relationships. The building blocks are there. I think it just needs some time for people to understand how to build relationships – and that's going to be a very important part.

If the government can make academia and industry to work together through a flow of money or different types of regulation or support in other ways, that would be great. It's hard to pin down what the right formula would be, but support of any kind for building more relationships is always welcomed.