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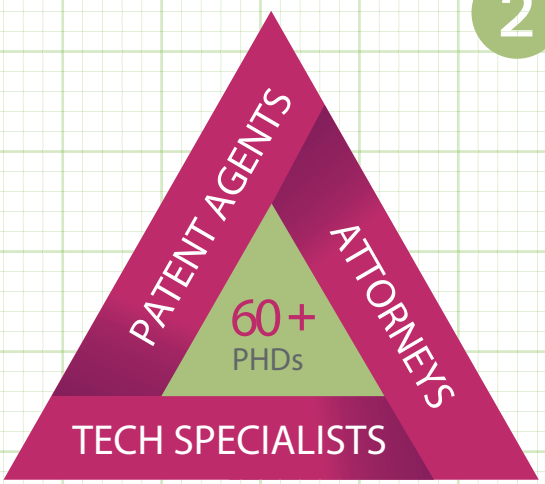

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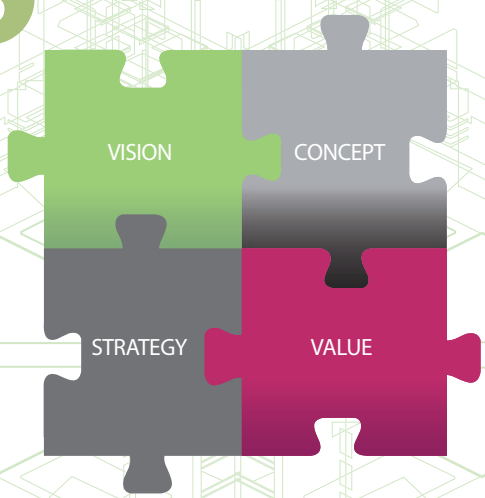

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INTRO

EDITORIAL

Efficient R&D networks based on innovation ecosystems

Roberto Gradnik, President of European Biopharmaceutical Enterprises, EBE

Roberto Gradnik, Strategic Board Advisor and former Chief Executive Officer of Stallergenes, has also been the President of the European Biopharmaceuticals Enterprises (EBE) since January 2012. From 2004-2010 he served as President of the Italian biotech industry association Assobiotec. Trained as a physician, Gradnik has more than 25 years of experience in the pharmaceuticals and biotechnology sectors. Prior to his current post, he held senior positions at BASF subsidiary Knoll Group and Serono/Merck Serono.

Research and innovation models are changing dramatically. The emergence of platforms such as advanced therapeutics is accelerating a change from innovation within big centres and universities to smaller, decentralised and more focused units. Innovation is always highest where there is freedom to be creative. An EBE member company CEO whom I know put it very succinctly: "The moment my CSO knows what's going on in the lab, we are no longer creating new innovation." The biopharmaceutical ecosystem has grown infinitely more diverse, with a wide variety of participants contributing to nearly every aspect of development. Networks and collaborative research establishments were originally seen as a supplement to innovation, but now they have begun generating more core innovation, and are viewed as essential. Considering the fact that most European healthcare biotech companies in the fragmented European innovation landscape are SMEs (70% of the 2,000 healthcare biotech companies in Europe have less than 50 employees), we now desperately need efficient networks of innovators from science, business and public institutions to facilitate funding and enablement. There has been a paradigm shift in attitudes towards generating innovation, and this means that all stakeholders need to begin working together much more closely – all the way from the lab to the shelves of pharmacies.

The ultimate drivers in this scenario, of course, are the return on investment and the return on health. We have seen a high return on the funding and time committed to networks that have a specific focus, with the understanding that innovation now no longer necessarily comes from our own laboratories.

A critical point is that both partners in a partnership have to benefit. Networks help to foster mutual trust, particularly where historically there has been a mutual mistrust, a situation largely born of differences in operational cultures. But the Innovative Medicines Initiative (IMI) and its successful continuation have demonstrated that these cultural gaps can also be overcome for the greater benefit of patients. Needless to say, partnerships need to demonstrate win-win, and public authorities can help encourage that. Partnerships can work to create a platform of mutual trust and benefit, just as the IMI forges programmes that foster innovation with reduced politics, creating a foundation for increased trust to flourish.

To support all of these aspects, EBE recently launched a partnership with the European Biotechnology Network (EBN) to facilitate EBE member companies' access to diverse networks and funding opportunities across Europe. This move is aimed at helping them to build partnerships out of their comfort zone, and deliver disruptive innovation in the future. I am delighted with this collaboration, not least because it truly demonstrates the delivery power of efficient networking.

As we move forward through 2014, the two networks will bring their members together through the auspices of Horizon 2020, the IMI, and many other funding opportunities, allowing them to discover common goals around which they can combine their specialist technology platforms. From SMEs to large companies to universities – the lure of creating exciting science and business is the perfect catalyst for partnership. And as barriers between sectors and organisations fall, the results can only be positive for participants and Europe as a whole.

CIRCULATION

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AGRIBIOTECH

Permit denied

Brussels – Although more and more EU Member States are considering opting out of planting GMO acreage on their own territory, the new opportunity to ban GM crops isn't slowing down attempts to import them. At the end of May, three applications for the import of genetically engineered soybean strains did not receive the required qualified majority in the Standing Committee on the Food Chain and Animal Health (SCFCAH). The decision on whether to approve a herbicide-tolerant soybean from BASF (BPS-CV127-9) and two soybeans that lead to beneficial fatty acid profiles (Pioneer's soybean 305423 and Monsanto's Mon88705) have been now been forwarded to the Appeals Committee. If it is unable to reach the required majority, the Commission can decide to approve on its own.

HEALTHCARE BUDGETS

e-Ageing

Brussels/Athens – EU Health Commissioner Tonio Borg has called for more use of wireless devices in monitoring chronic diseases. Speaking in mid-May at the eHealth Forum 2014 in Athens, he said telemedicine and the current 100,000 healthcare apps on mobile phones are tools that can help promote eHealth. According to estimates from the European Commission (EC), the impact of mobile health (mHealth) on EU healthcare systems could be significant. EC Vice-President Neelie Kroes says mHealth could save €99bn annually by 2017 if its potential is fully unlocked. In April, Kroes launched the MobiGuide project, which provides personalised clinical-guideline-based guidance outside clinical environments to cardiac and diabetes patients. "mHealth has great potential to empower citizens to manage their own health and stay healthy longer, to trigger greater quality of care and comfort for patients, and to assist health professionals in their work," said Borg.

Heard in Brussels

Europe's hungry biotech sector

Brussels – The launch of Horizon2020 and close of the first deadlines in February has shown the appetite of Europe's researchers from industry and academia for funding. A huge number of applications were received, particularly for the two-stage applications, where success rates are as low as 4% for some topics. And pass rates could remain low even at Stage 2.

A silver lining

This is scary news at first glance, but we have to look at it in multiple ways. First, these were the first deadlines after a break between FP7 and H2020, so people had been waiting awhile for the Framework carousel to start turning again. Second, the two-stage application process opens the door to a huge number of speculative attempts at Stage 1, where the application is short. In some ways it's annoying to think a half-developed idea could beat a carefully crafted effort. Indeed, exactly that has happened to enough EBN Member proposals.

Feeding the European fire

When you look at the big picture, however, you have to feel positive. Horizon 2020 is highly focussed on exploitation and raised impact. If evaluators are spoiled for choice with proposals that can deliver economic returns from biotech, then we can't complain too much. Goodness knows Europe needs to deliver money back into the system from maturing biotechnology. I'm not talking about the kind of money that comes from the acquisition of an SME for a fraction of the public money that has been poured into making it ripe for purchase, but the genuine maturation of value within Europe. These short Stage 1 proposals also enable people new to EC funding to dip a toe in the water. Much better a failed Stage 1 proposal

Claire Skentelbery,
Secretary General of the European Biotechnology Network

that gets you thinking about working in partnership and moving your technology forward than no effort at all because a full proposal was too difficult. Failed Stage 1 proposals need to keep their chins up – after all, you've started a journey, found some new friends and there are many adventures that beckon.

From small beginnings

The big question coming up is how the new SME Instrument performs. Part of me trembles at the thought of how many applications are cooking and how many will be disappointed. The rest of me is excited – at last, something to drive SMEs forward, masters of their own destiny! We're cautiously circling the first deadlines in June, and I would imagine that the EC is also waiting with terror in its heart so see what the application process yields, and whether they'll have to get extra USB sticks out of the cupboard to store all the applications. If you feel any tremors in cyberspace on June 25, you will know the SME Instrument has delivered a bouncing big baby into the nervous arms of its midwife.

News

Food matters

Brussels – A 70% decline in cardiovascular deaths in Denmark following a ban of trans fats has provided more strong evidence that lifestyle and diet can significantly impact health outcomes. In April, the European Commission launched the first transnational call of its novel Joint Programming Initiative 'A Healthy Diet for a Healthy Life' (JPI HDHL). This funding round will focus on the validation of biomarkers that indicate nutritional effects in the development of foods. Selected projects will be announced in October. Kick-off is in December.

EU synergies

London – The European Chemicals Agency (ECHA) and European Medicines Agency (EMA) are joining forces in predictive toxicology, measuring the environmental impact of pharmaceuticals, and defining maximum residue limits for pharmacologically active substances. In mid-May, EMA chief Guido Rasi and ECHA-head Geert Dancet signed a memorandum of understanding on the partnership.

Taking the EC to court

Stockholm/Brussels – Sweden is sueing the European Commission for its delay in defining scientific criteria needed to identify and ban hormone-like substances in products that affect human health and the environment. According to Environment minister Lena Ek, the Commission missed a December 2013 deadline to provide testing criteria. To speed up the process, her government will now take the case to the European Court of Justice.

MEDICATION ERRORS

European agencies take action to address a widely perceived danger

London/Brussels – In the US, medication errors are estimated to cause a stunning 400,000 deaths a year, making them the third leading cause of death there. European data suggest that medical errors and healthcare-related adverse drug reactions (ADRs) occur in 8% to 12% of all hospitalisations, and cause about 850,000 adverse events a year. While accurate figures are hard to determine, four out of five EU citizens on average perceive medication errors as a prominent problem in their country, according to a 2006 Eurobarometer survey. What's more, medication errors are "the single most common preventable cause of adverse events in medication practice," according to the European Medicines Agency (EMA). Together with EU national competent authorities, the EMA agreed an action plan to address the problem in late April.

Based on discussions with over 200 stakeholders in the field, the agencies' strategy focuses on improving reporting of ADRs as a prerequisite for risk minimisation and prevention strategies. The action plan includes recommendations that are to be implemented by autumn of 2015, among them:

- the implementation of a good practices guide, including common rules for coding and reporting medication errors as well as data-sharing,
- the establishment of a good practice guide on risk minimisation and prevention of medication errors, including specific patient subgroups such as children and geriatric patients.
- the development of an EMA concept paper on the best use of the Medical Dictionary for Regulatory Activities (MedDRA) terminology to address medication-error specific coding, data retrieval and analysis issues.
- raising awareness and implementing a communication strategy as part of the European Commission's Joint Action 'Strengthening Collaboration for Operating Pharmacovigilance in Europe' (SCOPE)

The EMA and the national Agencies also want to improve contact between themselves as well as with patient/consumer groups as well as healthcare professionals to assess and systematically prevent risks associated with medication errors throughout a pharmaceutical product's entire lifecycle.

Table 1: Incidence of medication errors in Europe

Stage in the medication use system	Ambulatory care	Hospital	Comments
Prescribing	7.5%	0.3-9.1%	% of medication orders
Dispensing	0.08%	1.6-2.1%	% of medication orders
Administration	Not available		Direct observation studies:
		49.3%	– IV medicines dose prepared on wards
		5.1-47.5%	– Traditional floor stock or ward stock systems
		2.4-8.6%	– Ward stock system with original prescription and daily ward visits by pharmacists
		7.2-9.1%	– Patient prescription distribution systems
		10.5%	– Unit dose drug distribution manual system
		2.4-9.7%	– Unit dose drug distribution, computerised or automated system

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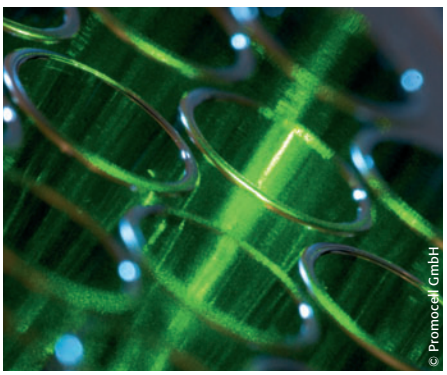

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