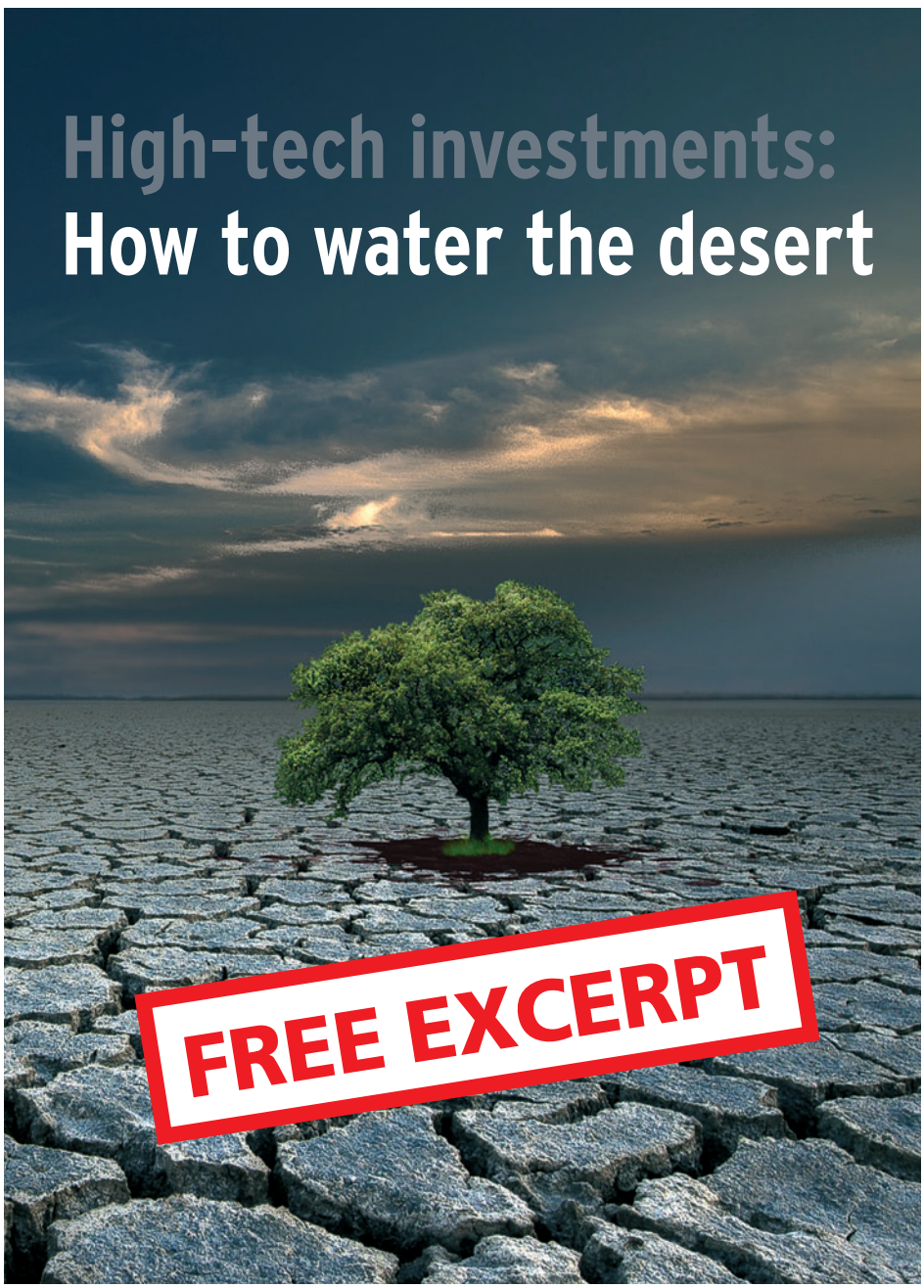
№ 5 | Volume 13 | 2014 | 10.00 € | ISSN 1618-8276 | A 60711 | BIOCOM

European Biotechnology

Science & Industry News



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EDITORIAL

Don't misinterpret the results of the referendum

Domenico Alexakis, CEO, Swiss Biotech Association

Domenico Alexakis is the CEO of the Swiss Biotech Association. He joined the organisation in 2003, and performs his duties in a part-time mandate. Alexakis was the co-founder of Swiss Biotech™, a brand programme that supports the positioning of biotechnology globally with changing partners. The entrepreneur holds operational mandates for other institutions, and also manages projects for clients in the fields of Innovation, Business Development and Economic Development. Before setting up his company Bridge Plus AG, Alexakis worked for Dow Chemical in various marketing departments. He holds degrees in communications and marketing.

During the Swiss Biotech Day in Zurich, the Swiss Biotech Report 2014 highlighted the most important innovation drivers in the country's industry and summarised the sector's most relevant topics. And the report's breadth highlighted a key fact. Although most citizens remain largely unaware of the impact biotech is having on our lives outside of healthcare, the field is now central to a very wide range of sectors – from environmental protection to the food industry.

Innovation drivers and financing were of course major issues at the Swiss Biotech Day. However, the hottest topic of all was the country's recent referendum vote on mass immigration. The Swiss constitution will now have to be revised to include a statement reflecting that the country wants to control the flow of immigrants. The EU decision to suspend Switzerland from Horizon 2020 as a direct consequence of the vote certainly gave rise to plenty of discussion. Current policies, however, will remain in place for the next three years, which at least creates security in planning. Now this time period has to be used wisely to find the best possible solutions for the future. Preserving the innovative power of this research-intensive sector is vital to keeping the industry's engine running – both inside and outside the country. To achieve that, the sector needs access to the most important research networks and skilled specialists with the best possible training. The mass immigration vote creates additional hurdles that threaten to slow down the momentum of the biotech sector. However, both the Swiss federation and its cantons understand that the Life Sciences are of utmost importance, and policymakers are expected to continue to give priority to the sector.

Some commentaries suggest that Switzerland is now against a foreign work force. Nothing could be farther from the truth. For generations, Switzerland's economic success has been built on fruitful academic and industrial exchange with people from all over the world. In a recent publication, the director of the leading think-tank Avenir Suisse compared the country's immigration statistics from 2007–2012 with its neighbours. Per capita over those six years, Switzerland welcomed nearly three times as many immigrants as Austria, twice as many as Italy, and around nine times more than France or Germany. Based on its relative size, the Confederetia Helvetica therefore does very well indeed. But emotionally it is a fact: smaller countries feel that big immigration numbers dilute feelings of national identification.

Whilst direct democracy has led to many sound decisions in the past, the current situation is proving to be a challenging consensual process. Progressive forces want to find a balanced solution. The process itself is necessary and mandatory, but it doesn't have to heed the voices demanding 'immediate' decisions that are often based on personal motives and views.

Because the country needs to innovate, I am confident Switzerland's liberal conditions will continue to hold true in the future. Not many industry sectors are as well connected globally as biotechnology. Relationship-building spans continents, and different cultures and the ways they mingle are certainly more fruitful than the path of isolation. It is therefore of utmost importance for Switzerland to quickly regain its status in Horizon 2020, continuing the overwhelmingly positive work begun in the EU's 7th Framework Programme.

European Biotechnology News is published in co-operation with the following organisations:

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Imprint European Biotechnology News is published monthly by: BIOCOM AG, Lützowstr. 33–36, D-10785 Berlin, Germany, Tel.: +49-30-264921-0, Fax: +49-30-264921-11, E-Mail: service@eurobiotechnews.eu; Internet: **www.eurobiotechnews.eu**, Publisher: Andreas Mietzsch, Editorial Team: Thomas Gabrielczyk (Managing Editor), Derrick Williams (Co-editor), Dr. Patrick Dieckhoff, Uta Mommert, Dr. Martin Laqua, Benjamin Stolzenberg; Advertising: Oliver Schnell, +49-30-2649-2145, Christian Böhm, +49-30-2649-2149; Distribution: Marcus Laschke, +49-30-2649-2148; Printed at: Druckhaus Humburg, Bremen; Graphic Design: Michaela Reblin. European Biotechnology Science & Industry News is only regularly available through subscription at BIOCOM AG. Annual subscription fees: € 100.00, Students € 50.00 (subject to proof of enrolment). Prices include VAT, postage & packaging. Ordered subscriptions can be cancelled within 2 weeks directly at BIOCOM AG. The subscription is initially valid for one year. Subscriptions will be renewed automatically for one more year, respectively, unless they are cancelled at least 6 weeks before the date of expiry. Failures of delivery which BIOCOM AG is not responsible for do not entitle the subscriber to delivery or reimbursement of pre-paid fees. Seat of court is Berlin, Germany. As regards contents: individually named articles are published within the sole responsibility of their respective authors.

IMI2

Money to boost pharma R&D

Strasbourg/Brussels – The European Parliament has greenlighted the €3.45bn IMI2 (Innovative Medicines Initiative 2) public private partnership (PPP) to boost research into improved medicines. In mid-April, MEPs confirmed the initiative's strategic research agenda, which aims to identify predictors of drug safety and efficacy (biomarkers), as well as improve target validation, clinical trials endpoints/designs and patient-tailored adherence programmes in five therapeutic fields of high medical need in the next 10 years: neurodegeneration, infections, metabolic disorders, immune-mediated diseases and translational safety.

While the European Commission will support the EU's largest PPP with €1.73bn from its Horizon 2020 budget, members of the EU pharma association EFPIA have earmarked in-kind contributions of €1.5bn from their internal R&D budgets to improve Big Pharma's R&D output. SMEs involved in IMI2 will contribute up to an additional €225m.

Ambitious goals

The first Innovative Medicines Initiative, which ran from 2007-2013, funded 40 projects with a budget of €2bn. IMI2 has set the bar high for the next decade, with companies aiming to classify at least four more diseases using molecular instead of histology markers, thereby boosting the development of personalised treatments. Furthermore, IMI2 researchers want to improve preclinical model predictability by up to 10%, and will attempt to define novel surrogate endpoints for at least four diseases. Additionally, real-time monitoring of disease-relevant markers should improve risk/benefit assessment of new drug regimens. Finally, new trial designs that allow for real-world data collection in at least two diseases should help decrease clinical development costs.

Heard in Brussels

Your data protection mission … should you choose to accept it

Brussels – There are sinister moves in the world of data protection, and I need to mobilise you – my crack squad of guerrilla scientists. The EC is showing its ugly face, and it's going to impact you. A new data protection regulation is being pushed through by the Commission, and it isn't fighting fair. This is a regulation, not a directive like the one it replaces, and will be implemented word for word into national law, overwriting years of carefully developed legislation that protects consumers and science.

The regulation frankly sucks, and could have been written by a bunch of monkeys with typewriters. It potentially restricts access to data on a huge scale for research, and displays a profound lack of legal clarity or understanding of data use in science. It is so badly written that it will create legal uncertainty around any research carried out using pseudonimised or sensitive data, threatening products or processes from such research – a real killer for investment and exploitation. It will affect all research, so don't feel smug if you are reading this from a university.

The 'ugly face' is the strange situation where amendments from worried national governments appear to be sliding out of text prepared by the European Commission, which is very kindly helping out the current Presidency with some extra admin 'support'. Parliament is also confusing the scandal of data access by government security agencies with the use of data in research, and will vote through a draconian regulation that does nothing to stop the NSA reading your email and everything to stop you using data derived from patients, biobanks, etc.

Many governments oppose this, but run the risk of generating headlines about failing to protect their citizens. As we are close to elections, there is an almost tragic

Claire Skentelbery,
Secretary General of the European Biotechnology Network

resignation to the fact that this regulation will come into effect, and efforts are being aimed at damage limitation rather than creating something genuinely useful. It is like replacing a brain surgeon with a child holding a blunt spoon. It didn't always go right before, but it sure as hell is going to go wrong now.

This is a ridiculous and dangerous situation. European Commission, please listen to national concerns and improve this regulation. Make it legally strong, bring in specific, more sophisticated reference to the use of data in science, and listen to the countries that have spent years developing exactly this kind of legislation – they know what they are talking about. You are supposed to serve Europe, not impose your own underdeveloped opinions through a misuse of process.

And you, my fearless warriors, contact your MEP, your national government and your newspapers and tell them what this regulation will do to science in Europe. Make them bold enough to do something about it while they still can. If not, then the last one out of the lab should turn out the lights.

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EMA

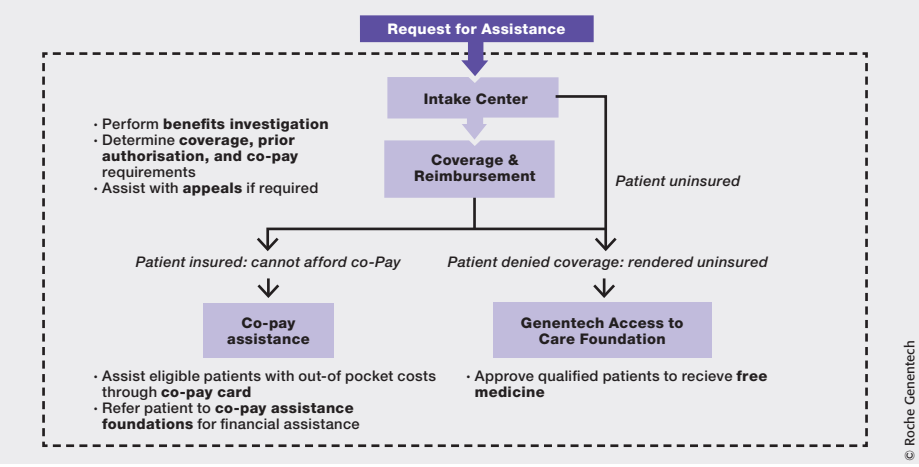
Costly failure in AE reporting?

London/Brussels/Basel – In mid-April, the European Medicines Agency (EMA) completed its inquiry into potential violations by Swiss-based Roche AG of its obligations to report adverse side effects of 19 centrally authorised medicines to the EU regulatory authority. The EMA's confidential report has now been sent to the European Commission, which will decide if Roche must pay penalties for not complying with the bloc's pharmacovigilance rules. Under the terms of the so-called EU PENALTY REGULATION (EC 658/2007), fines could amount to up to €640m – 5% of Roche's annual EU turnover in 2011. That's the financial year before British regulators (MHRA) discovered data pointing to up to 80,000 cases of unreported potential adverse effects (AEs) during a routine inspection of Roche Products Ltd. in Welwyn (see EUROBIOTECHNEWS 12/2013).

US records uncovered in the UK

Interestingly, the data found in the UK stem from US patient support programmes dating back to 1997, in which Roche has provided access to blockbusters such as Rituxan, Avastin or Herceptin for people who have no health insurance or were unable to afford the medicines. The records of adverse events (which include 15,161 deaths that are not necessarily linked to Roche products) did not provide any new safety signals that would question the medicines' authorisation. It is still unclear whether the reports only stem from patient support programmes such as GATCF (from Roche's US subsidiary Genentech) or the company's "Medical Needs Programme" (from Roche's former US headquarters in Nutley, which were closed in 2012).

According to the EMA, the cases tied to the patient support programmes were not the only potential adverse reaction complaints to go unreported by Roche. REUTERS reports that the agency says it has discovered another 23,000 unrelated reports in Roche's system, about 600 of them tied to clinical trials. Back in 2012, Roche claimed that "the non-reporting of these potentially adverse events was not intentional" and that it has updated its procedures so it can prevent similar incidents in the future. The Commission now has up to 18 months to request Roche to provide further information and ask the company to take a stand on its pharmacovigilance reporting system. It will then make a decision on the case.



Structure of Genentech's current patient support programmes.

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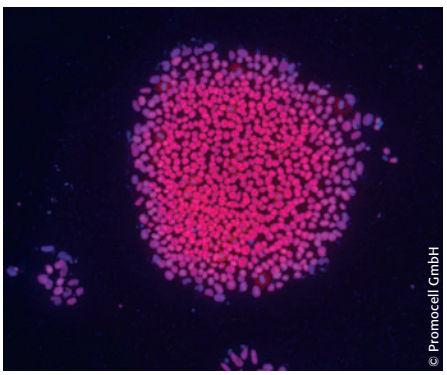

Heidelberg – Today, embryonic stem cells (ESC) and induced pluripotent stem cells (iPSC) represent the most significant types of pluripotent stem cells (PSC). In the beginning, ESC were cultured on feeder cell layers, primarily murine embryonic fibroblasts (MEF), in culture media containing fetal calf serum (FCS) – a poorly-defined, time-consuming and laborious culture technique.

Despite recent technical advancements, the established hPSC culture systems still share unfavourable properties. Most of them use supra-physiologically high amounts of growth factors and /or contain substances purified from human or animal origin. In addition, animal-derived and / or non-defined ECM is used. The PromoCell hPSC Growth Medium DXF eliminates these disadvantages:

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