HEALTHCARE & LIFE SCIENCES REVIEW

PHARMA BOARDROOM

THE GREAT PIONEER *PAGE 23*

SWITZERLAND

FEBRUARY 2018

Acknowledgements

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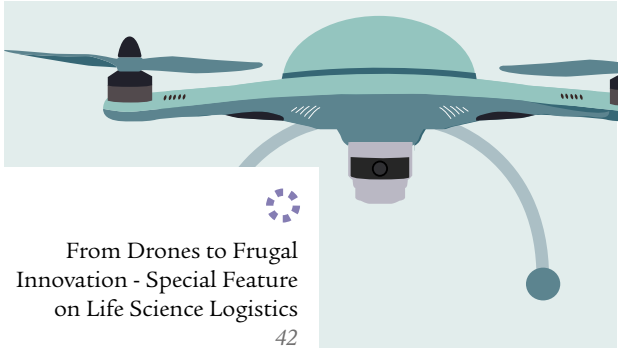
PHARMA BOARDROOM

Exclusive interview with Petra Doerr of Swissmedic
11

The Great Pioneer
Cover story
23



From Drones to Frugal Innovation - Special Feature on Life Science Logistics
42

CONTENTS
— February 2018

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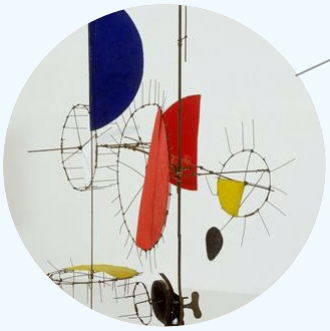

JOIN THE CONVERSATION

Switzerland

Additional full-feature interviews from our Switzerland 2018 Report can be accessed on PharmaBoardroom, the premier website for C-Level executives, consultants and state actors in the pharmaceuticals and life sciences sector, alongside hundreds of exclusive interviews featuring the main movers and shakers of the industry, free country reports and sector insights supplemented by the latest news from global markets.

AMPLIFIED CONTENT

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IN BRIEF

@Bilfinger

In his interview with @pharmaboardroom Stefan Frefel, CEO of Bilfinger Industrial Services Switzerland, outlines Bilfinger's core offering of #maintenance and #engineering services to the #pharmaceutical industry:

Read the interview

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Marc Funk - COO Pharma & Biotech - In 5 years, @LonzaGroup will be THE Partner of Choice. #Pharma #Switzerland

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CEO of #Idorsia Jean-Paul Clozel talks up his new company's prospects after the sale of #Actelion. #biotech

Read the interview

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Bruno Strigini, global CEO of #Novartis #Oncology discusses the company's new CAR-T therapy, #Kymriah @NovartisCancer

Read the interview

Preface

Building on our two recent reports on Switzerland, this special Part III edition of Healthcare & Life Sciences Review casts a broad eye over the myriad of niches and specializations within the sector in which Switzerland and Swiss companies excel.

Notable topicalities include Novartis Oncology's ground-breaking CAR-T therapy based on the exclusive insights of Bruno Strigini; how Swissmedic - the country's pharmaceutical regulator - is leading the world in terms of regulatory innovation; the story of Actelion's acquisition by J&J and the subsequent emergence of a new entity – Idorsia – led by the inimitable Jean-Paul Clozel; Switzerland's emergence as a destination for elite-level outsourced manufacturing; and the country's embrace of digitally disruptive technologies throughout the pharmaceutical value chain, as evinced by SwissPost's embrace of drones for drug deliveries.

Based on the insights of leaders and pioneers across the pharmaceutical value chain - from regulators to global affiliate heads and the founders of innovative local SMEs – HCLS Review Switzerland 2018 paints a picture of a country and an industry very much at the forefront of global innovation.

Innovation…

"Switzerland is the world's most innovative country." "It leads the ranking for the seventh consecutive year." These statements are taken from the Global Innovation Index, a report produced in collaboration between Cornell University, INSEAD and the World Intellectual Property Organization (WIPO).

In this environment, the Swiss pharmaceutical industry finds excellent conditions for continued success. Pharmaceutical products account for more than 38 percent of all Swiss exports – equivalent to CHF 80 billion in 2016. In addition, the Swiss pharmaceutical industry employs more than 45,000 people.

Conditions favoring innovation include a stable and reliable political environment. For a highly regulated sector such as pharmaceuticals, a legal and regulatory framework needs to be in place that fulfills its prime objective - safeguarding patients' health and safety - but at the same time does not put an unnecessary regulatory burden on companies developing innovative medicinal products, potentially addressing unmet medical needs and saving lives. The Swiss Federal Council is well aware of the relevance of the sector and in 2013 approved a master plan entitled 'Federal measures to strengthen biomedical research and technology.' Innovation is described as a key term in the master plan. It is also mentions that there is a target conflict between promotion of innovation and product market regulation.

How could this target conflict be solved - or at least minimized?

The pharmaceutical industry develops products globally. In order to regulate pharmaceuticals appropriately, cooperation between regulatory authorities is paramount. Unnecessary burden can be avoided by internationally harmonizing the requirements for the authorization and surveillance of these products.

It is the mandate of the International Council on Harmonisation (ICH; www.ich.org) to develop such internationally harmonized guidelines for innovative medicinal products for human use.

More recently, the International Coalition of Medicines Regulatory Authorities (ICMRA; www.icmra.org) has decided to include "Innovation" as one of their work streams with three sub-projects: cooperation with regard to methodologies and best practices for horizon scanning, sharing outcomes from horizon scanning activities as well as exchanging experiences on innovative procedures for the authorization of pharmaceuticals.

In conclusion, it can be stated that even though regulation may be seen as an obstacle for innovation, regulators are open to innovative approaches in order to minimize the negative impact it may have – obviously without losing sight of the protection of patients' health and well-being.

An independent, competent and efficient regulator can even be a locational factor, considering the fact that products manufactured or exported under its regime are trusted to a high standard – for Switzerland this would be "Made – and controlled – in Switzerland"!

I hope you enjoy reading this issue's features on innovative perspectives and recent developments in Switzerland.

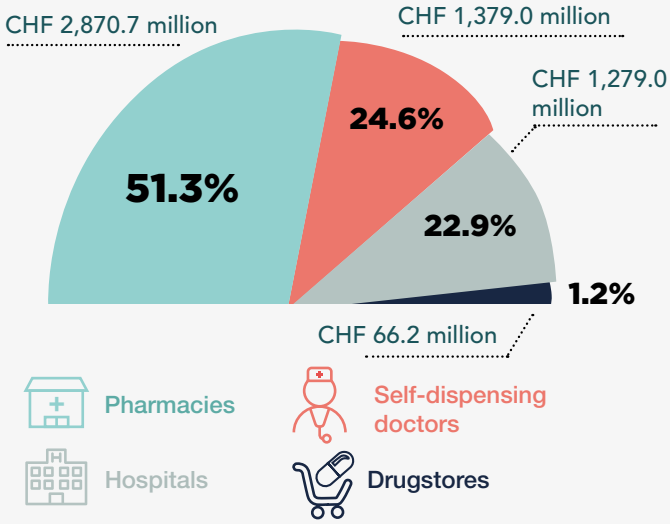
Petra Doerr, head of sector Communication & Networking, deputy executive director, Swissmedic

PHARMA BOARDROOM

swissmedic

PHARMACEUTICAL MARKET IN SWITZERLAND BY VALUE

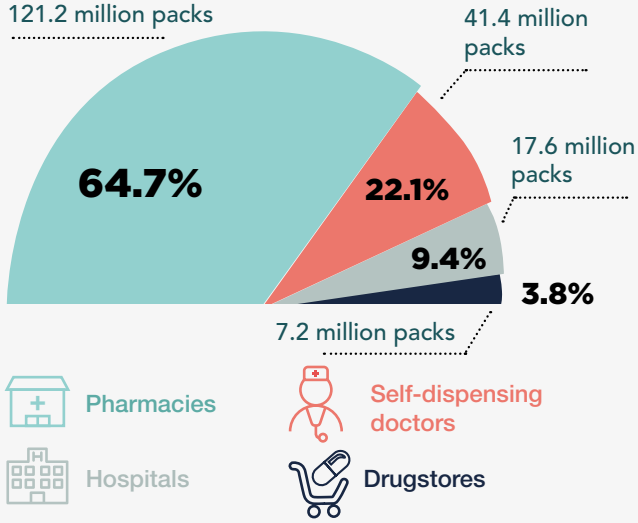
MARKET VALUE 2016: CHF 5,594.8
(AT EX-FACTORY PRICES, 100%)



Source: Interpharma

PHARMACEUTICAL MARKET IN SWITZERLAND BY VOLUME

MARKET VALUE 2016: 187. MILLION PACKS (100%)

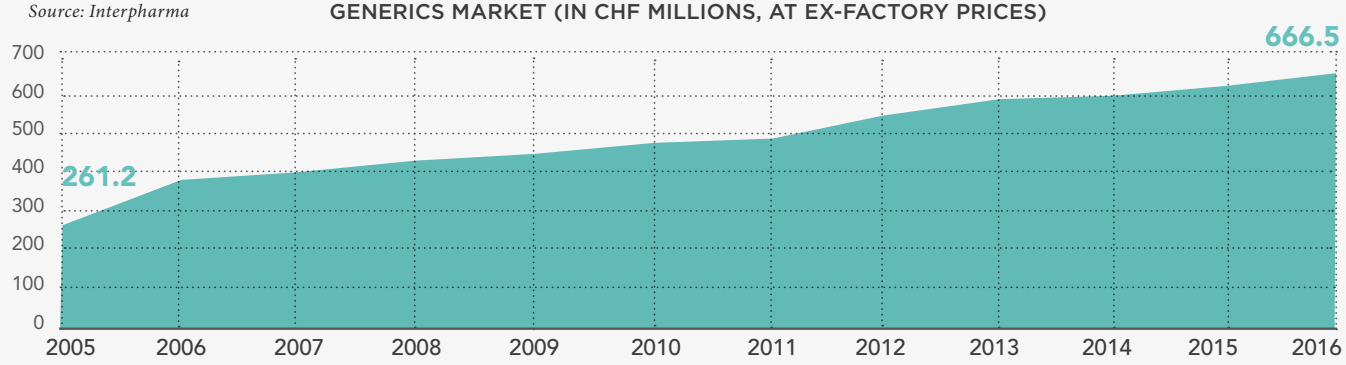


Source: Interpharma

GENERICS MARKET

Source: Interpharma

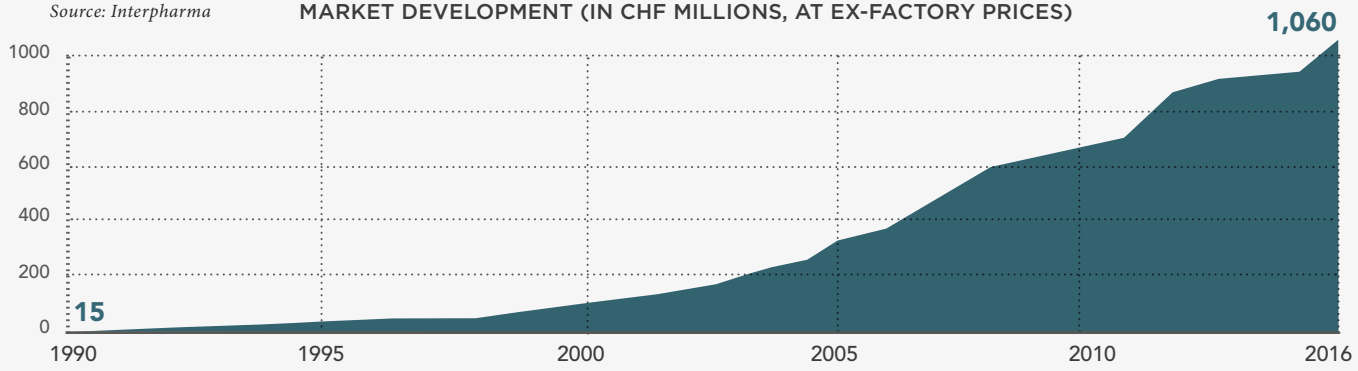
GENERICS MARKET (IN CHF MILLIONS, AT EX-FACTORY PRICES)



MARKET OF BIOTECH AND GENE TECH PRODUCTS

Source: Interpharma

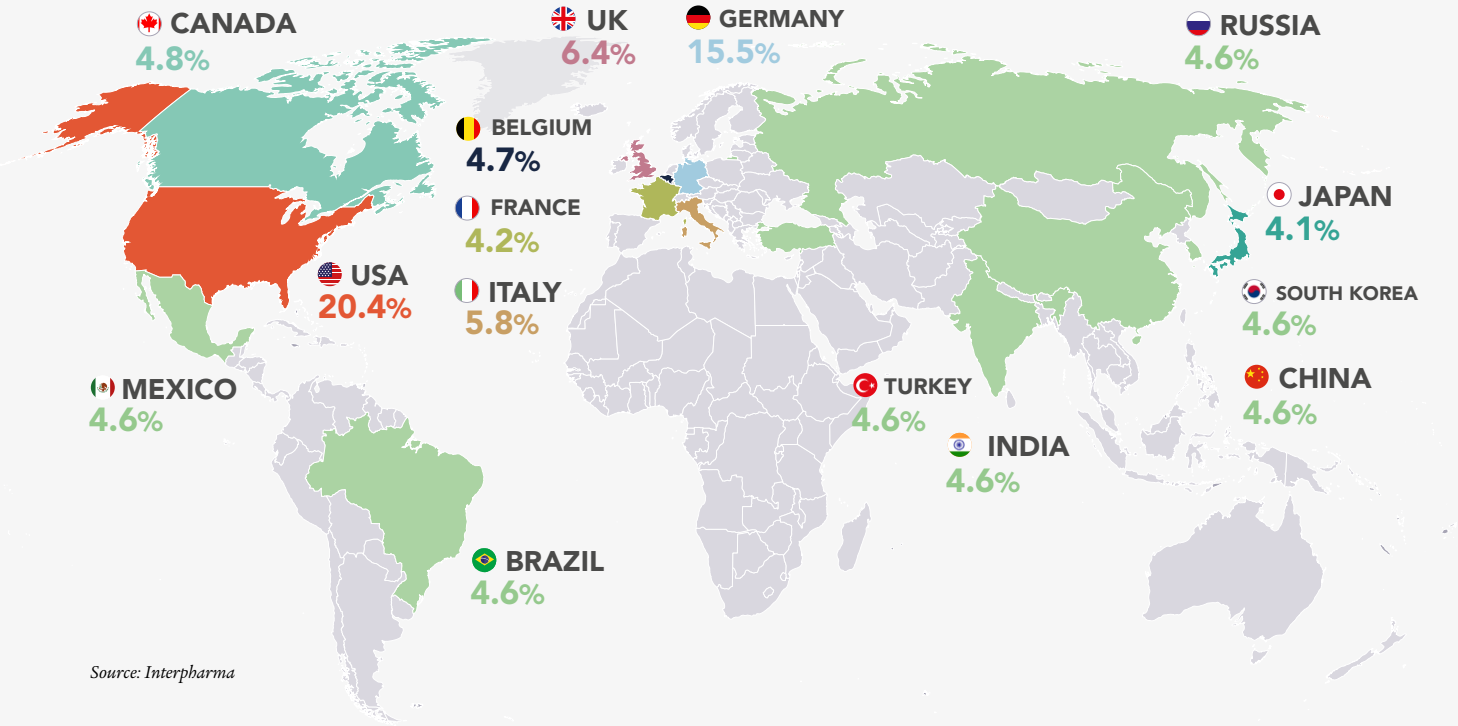
MARKET DEVELOPMENT (IN CHF MILLIONS, AT EX-FACTORY PRICES)



EXPORTS OF PHARMACEUTICAL PRODUCTS

EXPORT VOLUME IN 2016: CHF 80.4 BILLION (100%) 38.2% OF ALL SWISS EXPORTS

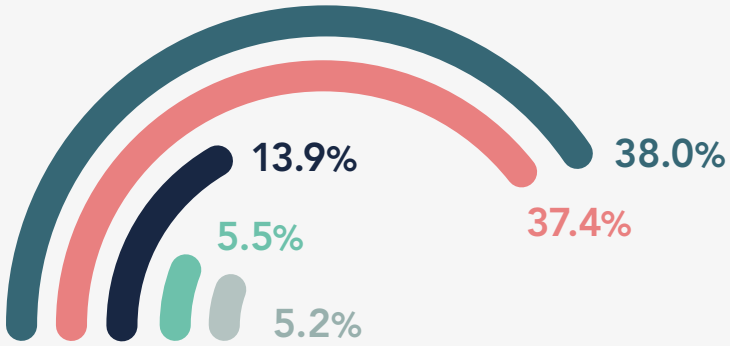
NON-EU (49.1%)		EU (50.9%)	
OTHER COUNTRIES	12.8%	REST OF EUROPE	14.3%
REST OF EUROPE	2.4%		



Source: Interpharma

INTERPHARMA COMPANIES: SPENDING ON R&D WORLDWIDE

GLOBAL R&D EXPENDITURE OF INTERPHARMA COMPANIES, 2016* CHF 18,221 MILLION (100%)



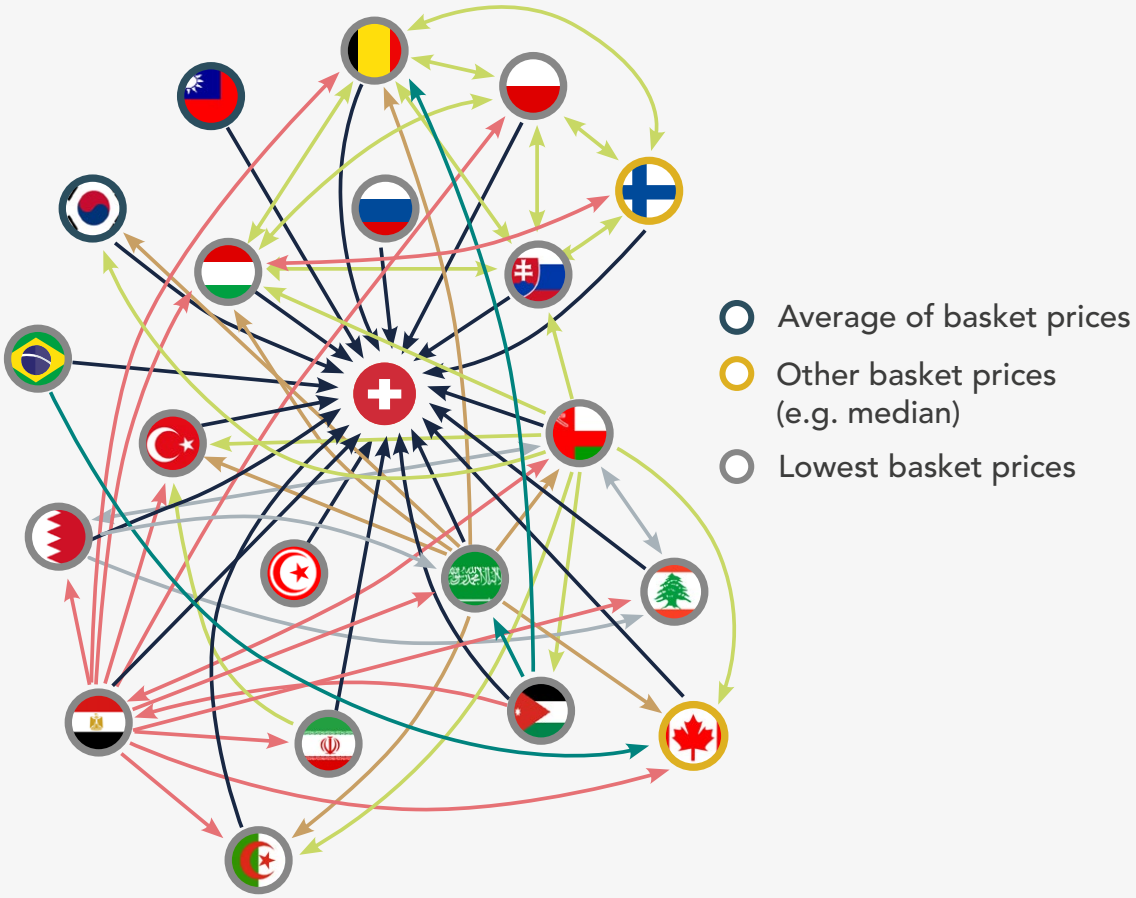
- OTHERS (CHF 998 MILLION)
- JAPAN (CHF 949 MILLION)
- REST OF EUROPE (CHF 2,524 MILLION)
- SWITZERLAND (CHF 6,822 MILLION)
- USA (CHF 6,928 MILLION)

*Based on data for R&D in pharmaceuticals from Actelion, Novartis, Roche, Merck and Vifor Pharma. The other Interpharma companies do not break down their R&D investments by country and were therefore not included.

Source: Interpharma

SWITZERLAND AS A PRICING REFERENCE COUNTRY

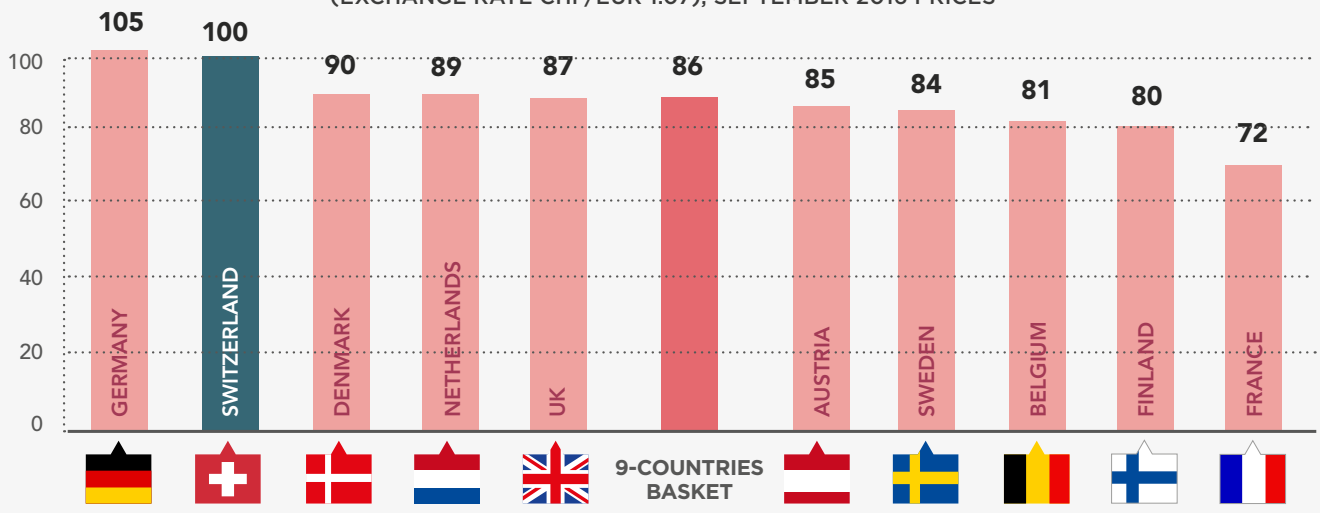
Source: Interpharma



COMPARISON OF DRUGS PRICES SWITZERLAND VS OTHER COUNTRIES

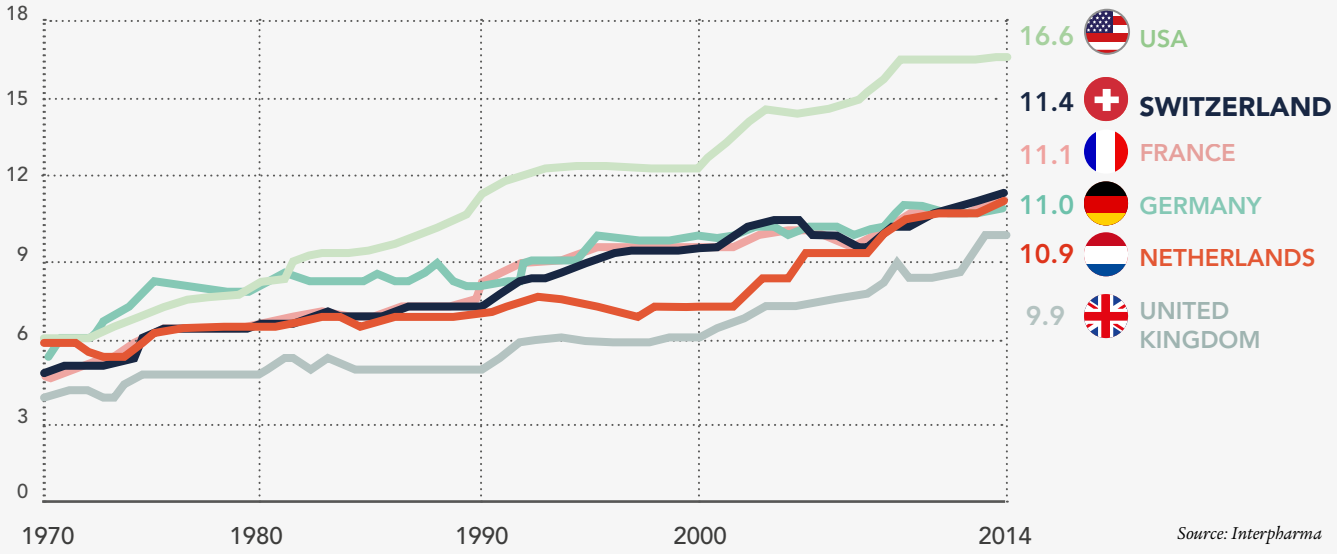
TOP 250 ORIGINAL PRODUCTS 9-COUNTRIES BASKET
(EXCHANGE RATE CHF/EUR 1.07), SEPTEMBER 2016 PRICES

Source: Interpharma



DEVELOPMENT OF HEALTHCARE SPENDING

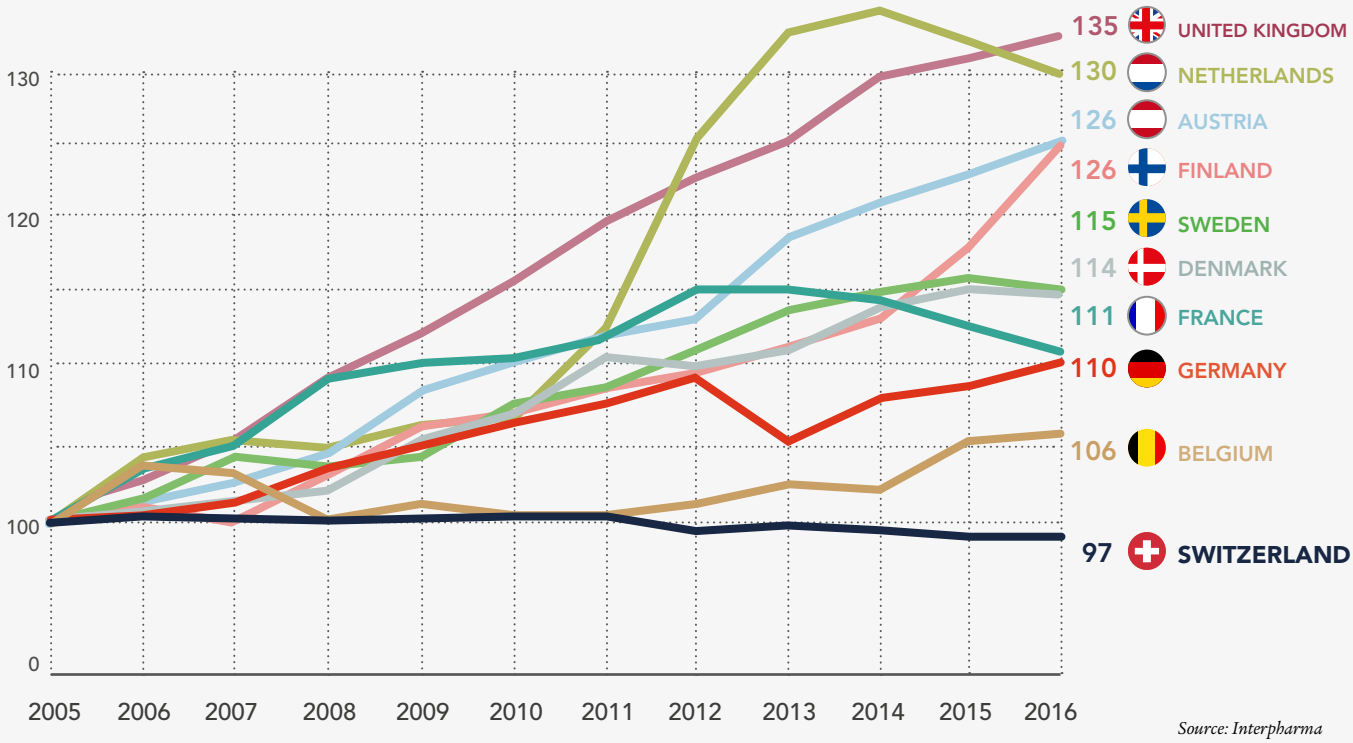
HEALTHCARE SPENDING AS A PROPORTION OF GDP (%)



Source: Interpharma

PRICES INDICES OF THE HEALTH SYSTEM COMPARED WITH OTHER COUNTRIES

HARMONIZED INDEX OF CONSUMER PRICES, SUBINDEX OF HEALTH (INDEX: 2005 = 100)



Source: Interpharma

A REGULATOR OF INTERNATIONAL RENOWN

Petra Doerr, head of sector communication & networking as well as deputy executive director of Swissmedic, the Swiss surveillance authority for medicines and medical devices, discusses changes to the Swiss regulatory system and harmonizing the organization with its global counterparts.

PETRA DOERR HEAD OF SECTOR COMMUNICATION & NETWORKING, SWISSMEDIC

HCLS: Swissmedic has embarked upon a comprehensive overhaul of its regulations in response to changes to the Therapeutic Products Act that were finalized last year. This has included reviewing drug ordinances to simplify pathways to market. What progress has been made thus far?

PETRA DOERR (PD): This is a two-step process, the first stage of which was completed in March 2016 when the federal parliament signed off the revised version of the Therapeutic Products Act. Following amendments to this legislation we are now revising the ordinances so that they correspond to the new provisions of the Act. More than 10 ordinances have to be changed and the timeline for implementation has been set for the beginning of 2019. The main revisions relate to facilitating market access and introduce fresh procedures for products that have been authorized at the EU and EEA levels. They also strive to bring the Swiss regulatory framework up to date with and in closer alignment to the traditional use system of provision already in effect across the EU. Essentially, what we are expecting is a facilitated market access route for OTC products and generics.

One significant element with major internal consequences in the way that we carry out our business is the adaptation of our system for variations to the one of the EU. This is not dealt with specifically in the revised Therapeutic Products Act, but was subject to additional parliamentary interventions. It has been agreed that we should align our system of classification and requirements for variations to that of the Europe Union. Now that we have made the categories the same, we can look closer at revisiting the timelines of approval, which is of course the aspect that will be most interesting to the pharmaceuticals industry and also patients.

HCLS: Do you believe that there is sufficient harmonization between the Swiss regulatory framework and the rest of Europe? Some industry actors have pointed out that it is unnecessarily inefficient and burdensome to maintain two distinct systems, especially when the Swiss market remains comparatively small.

PD: We are already closely aligned with the EU regulatory system because we base our requirements on the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines. The reason for retaining a distinct and separate system is simply that Switzerland is not an EU member state and therefore needs its own national regulatory regime, which is naturally well adapted to the local contextual environment. A distinct regulatory system also allows for the legislator to impose specific regulations in order to promote certain drugs by granting incentives that go beyond foreign regulatory systems (e.g. extended data protection periods for orphan drugs or pediatric drugs).

I would also point out that there are areas that are covered by the Bilateral Agreements between Switzerland and the EU and based on mutual recognition agreements. The medical device sector is a case in point. There is a free market whereby devices that are certified by a notified body here can freely circulate across the EU and vice versa. Unfortunately,

we do not yet have any such comparable treaty governing market access for medicinal products.

That said, if you scrutinize our regular marketing authorization procedure, you will discover that it emulates the model of the centralized procedure of the EU. You start off with an initial phase of assessment with a list of questions followed by submission of answers to questions in the second stage of review and subsequently an approvable/non-approvable letter with a legal option of appeal. What we obviously don't have is the Commission phase because this is very much a national authorization as opposed to a regional one. We additionally incorporate the option of considering the scientific assessments of competent, well-recognized regulatory authorities around the world. EU assessments very much fall into this category.

HCLS: Regulatory convergence and reliance seem to very much be the name of the game these days. How would you describe Swissmedic's international cooperation strategy?

PD: I think that is absolutely right.

Over and above adhering to a baseline of harmonized requirements, Swissmedic is very attentive to identifying projects and initiatives for reliance and work sharing. Many national regulatory bodies are just now getting to grips with tools for reliance initiatives whereas I am proud to say that Swissmedic has had a legal basis for reliance on scientific assessments since as far back as 2002.

> **"MANY NATIONAL REGULATORY BODIES ARE JUST NOW GETTING TO GRIPS WITH TOOLS FOR RELIANCE INITIATIVES WHEREAS I AM PROUD TO SAY THAT SWISSMEDIC HAS HAD A LEGAL BASIS FOR RELIANCE ON SCIENTIFIC ASSESSMENTS SINCE AS FAR BACK AS 2002.**
>
> **PETRA DOERR** SWISSMEDIC

We also apply the concept to GMP inspections. Obviously, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) have been around for quite some time now as international instruments help to synergize and unify different countries' pharmaceutical inspection authorities in the sense of promoting a commonly adhered to set of Good Manufacturing Practices, but we are also seeing a much greater level of inter-regulatory cooperation these days.

Swissmedic does not really have the depth of capabilities and workforce to be conducting GMP inspections abroad, so we leverage the capacities of other regulatory authorities that are PIC/S members and obviously our mutual recognition agreement (MRA) partners. Because we consider those entities to be broadly equivalent to our own standards we would not repeat an inspection undertaken by any of them. For example, if there is a manufacturer in China that has been inspected by the US FDA or EMA, then we will consider their inspection report as the basis to establish GMP conformity. This sort of phenomenon is going to become more and more common across the world as different regulatory regimes converge and become more streamlined. Personally, I believe this is a very positive development that injects efficiency into the regulatory process.

HCLS: We hear that Swiss drug and API manufacturers will also soon be able to allow foreign regulators to inspect their facilities without needing to seek special SECO approval.

PD: That is correct. Hitherto, quirks in our penal code meant that foreign officials were forbidden from conducting inspections within Swiss territory. In the pharmaceuticals sphere, outside regulators wishing to do inspections therefore had to secure a special waiver from the State Secretariat for Economic Affairs (SECO), the federal government structure for all core issues relating to economic policy. As of January 2018, this will no longer be the case. This is when the recent introduction of article 64a of the Therapeutic Products Act will come into force, which means that this layer of bureaucracy will be cut out.

In the future, foreign regulatory authorities will instead only need to notify Swissmedic and gain the consent of the manufacturer about to be inspected. There are some other provisions as well such as the fact that they are obliged to send us, Swissmedic, a report of their inspection findings no later than 20 days after the event. Again, this development fits very well with an increased emphasis on international cooperation and harmonization.

FOCUS: SWISSMEDIC 2016

SWISSMEDIC APPROVED A TOTAL OF 40 NEW ACTIVE SUBSTANCES (NAS) IN 2016, WITH A MEDIAN APPROVAL TIME OF 481 DAYS

APPROVAL AT SWISSMEDIC 2016

19 BIOLOGIC NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF **460 DAYS**

21 CHEMICAL NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF **521 DAYS**

8 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF **438 DAYS**

32 NASs IN OTHER THERAPY AREAS APPROVED IN 2016, WITH A MEDIAN APPROVAL TIME OF **506 DAYS**

TYPE OF MEDICINE

DESIGNATION AND REVIEW TYPE

7 EXPEDITED* NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF **272 DAYS**; THIS IS A MEDIAN **241 DAYS FASTER** THAN THE **33 STANDARD NAS APPROVALS IN 2016**

16 ORPHAN NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF **441 DAYS;** THIS IS A MEDIAN **74 DAYS FASTER** THAN THE **24 NON-ORPHAN NAS APPROVALS IN 2016**

AVAILABILITY IN SWISSMEDIC

5% OF THE NASs APPROVED IN 2016 BY SWISSMEDIC WERE APPROVED BY SWISSMEDIC **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT FDA (USA), EMA (EU), PMDA (JAPAN), HEALTH CANADA, OR TGA (AUSTRALIA)**

7 EXPEDITED* NAS APPROVALS IN 2016, WITH A MEDIAN APPROVAL TIME OF **272 DAYS**; THIS IS A MEDIAN **241 DAYS FASTER** THAN THE **33 STANDARD NAS APPROVALS IN 2016**

THE MEDIAN **SUBMISSION GAP**** TO SWISSMEDIC FOR THESE NASs WAS **274 DAYS**

*Expected review refers to EMA 'Accelerated Assessment and FDA/PMDA/Health Canada/Swissmedic 'Priority Review'
**Date of submission at the first regulatory agency to the date of regulatory submission to the target agency

Source: CIRS

VENDOR CONSOLIDATION ALL THE RAGE IN THE CRO SPACE

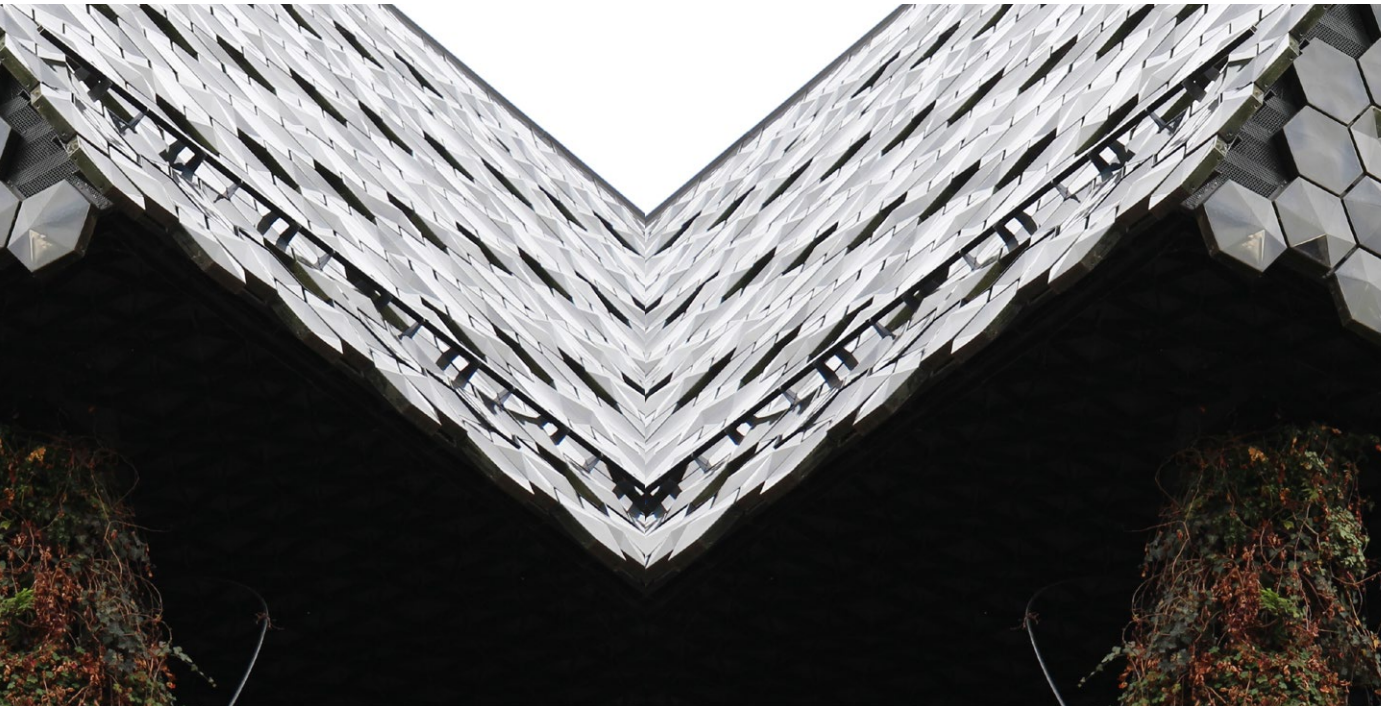
With big pharma reducing fixed assets and calling upon service providers to step up to the plate as mutually invested partners in the drug discovery and development process, a wave of vendor consolidation has been occurring across the contract research segment. Indeed, within the past few years, contract research organizations (CROs), the science-for-hire firms that handle clinical trials and medical-lab testing for drug developers, have been engaging in dizzying array of novel hook-ups previously deemed unthinkable.

Back in 2015, clinical research giant Covance was snapped up by diagnostics specialist, LabCorp, further consolidating it as one of the largest CROs in the industry. Then came IMS Health's eyebrow raising purchase of Quintiles in 2016 to form a hybrid entity IQVIA expanding well beyond the standard CRO model to encompass a broad range of data services. Meanwhile INC Research Holdings Inc.'s acquisition of InVentiv Health has highlighted the growing role of private equity firms in the blossoming market.

"All parts of the market are getting more competitive, and these deals – what we can call the real strategic consolidation – are being sparked by the competition," confides Tim Evans, an industry analyst at Wells Fargo & Co. "If a big pharma company is going to select you as a preferred vendor in their list of three or four providers, then they are going to want to be confident that you possess a full suite of offerings… Outsourcing firms are now going head to head to secure the contracts for functions that big pharma players would previously have conducted inhouse and that means they have to demonstrate their competencies not just in running trials, but in managing data, providing consultancy to sales people and in assessing how to make treatments cost-effective."

> **"WE HAVE WITNESSED ALL SORTS OF UNPRECEDENTED M&A ACTIVITY IN THE CRO SEGMENT. WE HAVE SEEN COMPETITORS TEAMING UP WITH DATA AND TECHNOLOGY FIRMS, SWEEPING CONSOLIDATIONS AND VENTURE CAPITALIST VEHICLES GETTING INVOLVED AS WELL.**
>
> **JONATHAN KOCH** COVANCE

Many industry leaders agree that a new trend is now in full swing. "In recent years, we have witnessed all sorts of unprecedented M&A activity in the CRO segment. We have seen competitors teaming up with data and technology firms, sweeping consolidations



and venture capitalist vehicles getting involved as well. The basic driver of this activity has been the opportunities inherent in the late drug development phase and the healthcare space. LabCorp was actually one of the early movers and was quite visionary in identifying and responding to these megatrends," reflects Jonathan Koch, Covance's group president for R&D laboratories.

"Covance and LabCorp together changed the broader environment of how customers view their service providers and there have been a lot of other moves taking places across the CRO segment subsequently. I think what you've been seeing within the last 12-18 months is that drug development has been becoming considerably more complex. As a result, if you ask clients to name the service providers they've had to engage with to get their body of work done from pre-clinical work through registration, then dozens of service providers would be involved to cover those additional complexities," he explains.

Indeed Koch believes that it reached a point where service providers started seeing the sense in bringing a lot of those capabilities either into their own organization or vesting them in a fully integrated "one stop shop" provider. "Clients are attracted to an organization that can simplify drug development and reduce the sheer proliferation of partners that they have to engage with. Simplification is logically preferable because it allows you to condense timeframes, reduce costs and accelerate the speed with which you can bring your product to market. Right now, CROs are pursing all sorts of different combinations and consolidations to reply to this demand," he reasons.

How did the Covance-LabCorp tie up respond to these needs? "I would say there are three main areas where this collaboration has already delivered considerable extra value to our clients. Firstly, by pooling our data we can provide much more integrated solutions along the drug development continuum. Secondly, as a combined company, we can now offer a companion diagnostics service alongside the classic CRO functions. In short, we can offer a very efficient pathway to develop a novel therapy along with its associated companion diagnostic and we can do that from an early development services, non-clinical setting all the way through clinical phases and approval. Thirdly, our coming together has also served to reveal additional aspects of value in real-world evidence. For example, we have been partnering with a customer interested in biomarkers related to the use or non-use of a commercially available product. Through the collaboration we were able to bring a solution that we could never have been able to implement independently," says Koch.

FROM GLEEVEC TO CAR-T

The former head of Novartis Oncology talks tradition, new launches, pricing and value - and what he believes is the start of a golden age of innovation in cancer science.

Please note that this interview was conducted in October 2017. Bruno Strigini has subsequently announced that he will retire from Novartis Oncology in early 2018.

HCLS: Novartis is notable for being the first of the big pharma firms to assemble a global business unit dedicated solely to developing and launching innovative oncology medicines. Why was it deemed necessary to adopt this sort of corporate structure of a 'firm within a firm'? What advantages does it bring?

BRUNO STRIGINI (BS): Novartis' first great foray into oncology dates back to 2001 with the launch of Glivec which was a truly revolutionary cancer drug and formed part of a pioneering group of targeted treatments designed to attack a specific cancer-causing genetic mutation. With the advent of Glivec, the outlook for CML patients changed dramatically, and it is great to hear from patients who have the prospect of a normal life 15 years after starting the treatment.

Another critical juncture came in 2015 when we acquired GSK's oncology business, comprising important products such as Revolade, Votrient, Tafinlar and Mekinist, as part of a broader portfolio swap between the two companies.

Our organizational structure, which right from the beginning was set up as a dedicated Business Unit focused on treatments for cancer, was key to our success. This organizational set-up underscores Novartis' unwavering commitment to pioneering new generations of oncology therapies, and it also provides a real sense of purpose and focus. The overarching idea was to create a nimble outfit, with speedy decision-making power to accelerate the development and commercialization of our products. One of the aspects that has impressed me the most since I joined Novartis, has been the sense of purpose of our associates and I believe that arises partly from having an organization fully focused on Oncology. This is a modus operandi that works, and that's why we're now seeing our competitors trying to emulate us in this respect.

> **"THE OVERARCHING IDEA WAS TO CREATE A NIMBLE OUTFIT, WITH SPEEDY DECISION-MAKING POWER TO ACCELERATE THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS.**

Looking at our productivity in 2017 alone, which includes three new therapy approvals, it is clear that the model we established makes good sense. We launched Rydapt in the US and Europe, for two rare, life-threatening indications, including a mutated form of acute myeloid leukaemia, Also this, year we achieved both US and European approval of Kisqali for treatment of postmenopausal women with locally advanced or metastatic breast cancer. Finally, in late summer we were the first company to receive approval for our breakthrough CAR-T cell therapy Kymriah.

BRUNO STRIGINI CEO, NOVARTIS ONCOLOGY

HCLS: How, then, is the unit structured? What are the key functions and areas of priority?

BS: Novartis Oncology is as a global leader in the oncology, haematology and rare cancer segment with an unmatched portfolio of products including more than 20 approved medicines. We also have one of the broadest pipelines in the industry with over 40 or so new molecular entities in development including targeted and immuno-oncology compounds.

Our research is driven by a distinctive scientific and clinical strategy, focusing on unmet medical needs. Having initially established ourselves as one of the foremost companies in the development of small molecules against cancer, we have now additionally assembled one of the largest pipelines in immunotherapy with 18 different compounds. In addition we are pioneers in Chimeric Antigen Receptor (CAR) T cell therapies, a new class of immunocellular therapies.

Strategically, we have prioritized five therapeutic areas: breast, blood and lung cancer as well as melanoma and renal cell carcinoma. This does not mean we are not doing anything in other areas, for example our R&D groups are active in colon and bladder cancer, but it does help us retain focus in areas where we have depth and breadth of experience. In a highly competitive environment where 40 percent of the industry's investment is in oncology drug development, we must keep to our core strengths.

In terms of our scope and reach, there are more than 10,000 associates fully dedicated to Oncology spread across 85 countries including eight R&D centers. With this level of experience, knowledge and investment behind us, we find ourselves equipped and ready to transform cancer care by bringing more breakthrough products to patients and society.

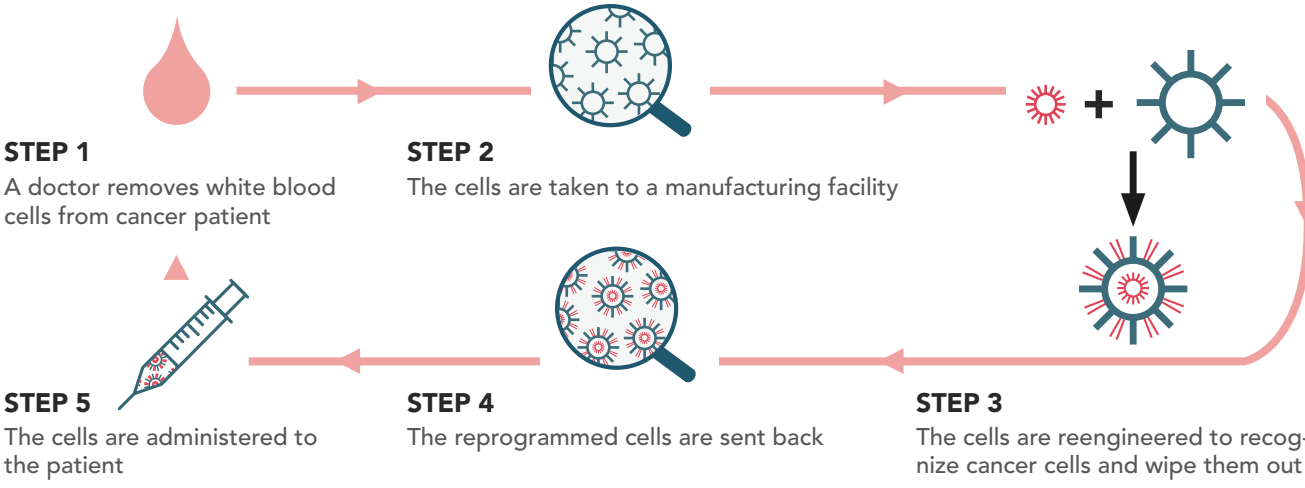
HCLS: This year new ground was also broken when Novartis received the first ever FDA approval for a CAR-T cell therapy, Kymriah. Tell us about the significance of this milestone and how it relates to the positioning of Novartis' oncology business today?

BS: We were very proud indeed to see Kymriah, the first immunocellular therapy, approved in the United States for the treatment of children and young adults up to 25 years of age with B-cell precursor acute lymphoblastic leukaemia that is refractory or in second or later relapse. This is a truly game-changing and revolutionary product that responds to an unmet need that is clearly established. Trial results have demonstrated a high level overall remission rate in this patient population with limited treatment options and historically poor outcomes.

The CAR-T journey started five years ago when we began collaborating with the University of Pennsylvania and invested in bringing – what we believed would be – a paradigm-changing therapy to cancer patients in dire need. Basically, it is a highly personalised therapy in which T cells are drawn from a patient's blood and reprogrammed in our cell processing facility. These genetically coded T cells are infused back into the patient to potentially 'hunt' the patient's cancer cells. This represents an entirely new approach for treatment. Our hope is now to be able to

HOW CAR-T THERAPY WORKS

Source: Novartis; Business Insider




Aerial view of Novartis's Basel HQ, Switzerland

progress this 'new wave' of CAR-T therapies in a host of hematologic and potentially other cancer types.

Overall, our R&D portfolio is made up of two core segments: 'targeted therapy' including our small molecule technology and monoclonal antibodies, and 'immunotherapy' comprising our immuno-oncology pipeline. As CAR-T is an immunocellular therapy it fits perfectly into our overall strategy to attack cancer in a modality-agnostic way.

HCLS: Kisqali was approved in Europe one week prior to Kymriah. What were the comparative experiences of the market access teams for both the EU and US with regards to these two scientific advances in oncology?

BS: The strategies for getting these two different therapies to market had to be thoroughly different. Kymriah needs to be administered in specialized treatment centers and is an individualized approach to modifying a patient's own cells to fight cancer that brings all sorts of additional complexities in terms of manufacturing, handling and logistics. To address the unique aspects of the therapy, we had to go and develop custom-made patient access programs to support safe and timely delivery. Kisqali, on the other hand is about a classic small molecule, and our focus was and is to differentiate our offering from competition.

The dynamics of the two markets are also very different. In the US, the market is a mix of private insurance providers, Medicare and Medicaid. In Europe, you are largely talking about healthcare systems with universal coverage, and country-by-country access and pricing negotiations. Our approach in all instances, however, is consistent and that is to emphasize the principles of value and outcome of our medicines.

Kymriah comes in at a hefty price tag at US$ 475,000 putting it as one of the most expensive drugs of all time. How did Novartis come to this figure and go about its pricing strategy especially considering the current cost-cutting climate and potential political and reputational ramifications?

We put a great deal of thought into how to price Kymriah. We conducted our own detailed health economics analysis, looked into standard-of-care pricing such as bone marrow transplant and took into account independent evaluations such as those of NICE, which estimated a cost effective price of between US$ 600,000 and 700,000.

Let's not forget either, that Kymriah is delivered to each patient just once because this is intended to be a one-time, highly effective treatment. When considering this altogether, the value of what we are proposing becomes more readily apparent.

Importantly, we have also announced a collaboration with the United States Centers for Medicare and Medicaid Services (CMS), which represents a first-of-a kind arrangement in the US. This includes an outcome-based approach and indication-based pricing.

HCLS: How do you reply to those who argue that the extent of current public expenditure on oncology drugs is disproportionately high and does not necessarily represent optimum value for money spent vis-à-vis competing claims (such as for antibiotics)?

BS: Cancer is clearly on the rise. Right now, cancer causes 1 in 8 deaths globally and, in Europe, it is even outpacing cardiovascular disease in terms of prevalence. The World Health Organization (WHO) is now estimating that global cancer rates will be close to 22 million new cases per annum by 2030.

A recent study involving the EU's 5 biggest markets demonstrated that cancer affects mostly people in their prime in terms of ability to be productive. The societal cost to those five countries was estimated at EUR 50 billion just in terms of lost productivity.

At the same time, science and medicine are progressing very rapidly, and cancer treatments are becoming more effective. This allows for the right drug to be employed at the right time for the right patient.

Clearly, industry and the rest of the life sciences community have to work alongside healthcare providers, payers and policy makers in rendering cutting-edge oncology drugs accessible and affordable to all patients. We believe an outcomes and value-based approach will help in achieving this objective.

HCLS: What steps, then, are you taking to make pioneering oncology drugs more accessible to patients in lower-income countries?

BS: We have different programs to facilitate access to our cancer drugs. One that I would like to highlight is our collaboration with the Max Foundation, a global, patient-focused, non-governmental organization. This September, Novartis announced a new collaboration with The Max Foundation to support continued access to treatment at no cost for nearly 34,000 current patients with chronic myeloid leukaemia, gastrointestinal tumours and other rare cancers. We have been long-time collaborators in providing access to care for patients in lower-income countries through the Glivec International Patient Assistance Program (GIPAP), one of the most innovative patient assistance programs ever implemented on a global scale. The new collaboration, called CML Path to Care is an evolution from GIPAP. Under the new initiative, the Max Foundation will assume from Novartis the responsibility for delivering our CML treatments to these patients, including supply chain management and Novartis will provide the funding and drug donation support.

HCLS: Novartis has formulated its very own definition of value. Tell us more about this.

BS. For us, the value of our products includes four components. First, there is clinical value. Second, there is value to the patient in terms of quality of life. Third, impact on the total healthcare budget, for example if a new drug avoids expensive hospitalization, then the cost saving being generated needs to be taken into account. Finally, there is the societal value of getting the patient back to being a productive member of the economy.

In short, we look at value holistically. The comparative value of a drug should be calculated against how well it performs with respect to each of these four criteria.

HCLS: Do you see the concept of value-based pricing gaining traction with governments?

BS: Yes. The arrangement that we struck with CMS in the USA demonstrates that healthcare systems are seeing the potential benefits and are prepared to engage. In Europe, we also witness progress being made on health technology assessment and willingness to start the dialogue on outcome based approaches.

HCLS: Where do you see the emerging trends right now?

BS: There is a huge amount of innovation in the science of cancer. Digital disruption is also shifting the paradigm; this is clearly the case at Novartis. Big data, predictive modelling and advanced analytics are changing the way we work in all aspects of our business: research, development and commercialization. For example in research, it is helping us to shorten the time between finding a target and proof of concept. Also, the use of real world evidence could transform the way we approach the development and regulatory processes for a drug. In short, a golden age of innovation is upon us and convergence is occurring across different areas of science, technology, biology and IT. The onus is on the pharma industry to embrace this change and leverage it. These are all highly positive steps that bring stakeholders together to the benefit of the patient.

> **"CONVERGENCE IS OCCURRING ACROSS DIFFERENT AREAS OF SCIENCE, TECHNOLOGY, BIOLOGY AND IT. THE ONUS IS ON THE PHARMA INDUSTRY TO EMBRACE THIS CHANGE AND LEVERAGE IT.**

HCLS: Do you have few words to conclude on Switzerland and its role in life sciences?

BS: Switzerland is the home of two of the top global pharmaceuticals players. It possesses a vibrant and flourishing life sciences industry and is also notable for having one of the best functioning health care systems. Part of this no doubt derives from a historical tradition of innovation and engineering, and I believe the country's openness and collaborative spirit contributes greatly to this success.

BRINGING RESPONSIBLE ACCESS GLOBAL

With two billion people globally - predominantly in low and middle-income countries - having little or no access to medicine, a select group of service providers have emerged to try and further dialogue between pharmaceutical companies, regulators, healthcare professionals and patients on the issue of expanding access to medicines. At the forefront of this group is the Swiss-based FarmaMondo, which draws on over 100 years of history to help provide access to medicines to patients with unmet medical needs around the world.

A UNIQUE BUSINESS MODEL

FarmaMondo was set up in 1915 in the Italian-speaking Swiss canton of Ticino - where the company remains based today – initially as a small community pharmacy. Over the last 100 years, and especially during the last decade, FarmaMondo has grown to become a service provider to various international stakeholders in the niche of unmet patient needs. Jaron Spigel, FarmaMondo's French-born CEO notes, "The whole world is moving toward patient-centricity and our efforts to facilitate patient access to medicines are at the core of this." FarmaMondo operates through two distinct lines of business: Global Early Access, helping provide fast-tracked access to unlicensed medicine in over 65 countries worldwide across all continents and Named Patient programs, whereby certain patients can access products prior to their approval. The company is continuously developing its methodologies for patient access to medicine specific to each country or region in which it operates, with activities in the established markets, such as the EU, as well as new frontiers in Asia, Russia / CIS countries and Latin America as key markets.

A key tenet of FarmaMondo's business model is that the access to medicine that it helps facilitate must be 'Responsible' and 'Ethical.' The 2013 case of Josh Hardy in the USA - where social and traditional media launched a campaign to pressure Chimerix to allow access to a novel, yet unapproved therapy, despite the patient not fitting the drug maker's access requirements - further highlighted the need for more 'Responsible' and 'Ethical' access. Manufacturers, biotech companies, regulators and healthcare professionals alike called for more stringent guidelines for providing access in a responsible manner, separate from societal or media pressure; an area in which FarmaMondo specializes.

SWISS SPECIFICITIES

In terms of the advantages of being based in Switzerland, Spigel highlights that "Providing responsible access to medicine is a concept that indisputably fits the Swiss DNA – a combination of being compassionate towards other people, exporting products and services, strict regulatory compliance and international scope." Furthermore, given its unique business model, "FarmaMondo could only have developed in a country like Switzerland; a regulated, innovation-driven, well-established market where quality infrastructure for distribution, imports and exports is in place to an extremely high standard," Spigel notes.

Spigel also highlights the fact that SMEs in Switzerland are able to go global without the need to become significantly bigger. He posits that "Thanks to the same great business infrastructure that larger companies enjoy, a privately-owned SME business in Switzerland can enjoy the possibility of looking at world markets and considering them as opportunities that are within reach. Our size also brings operational

JARON SPIGEL
FarmaMondo

agility, enabling us to more fully take advantage of this infrastructure." Additionally, Swiss pharmaceutical MNCs such as Novartis and Roche are appreciative of the quality of smaller Swiss-based service providers; "they remain Swiss even though they are global giants" he opines.

Close working relationships with the major Swiss companies are, however, just one part of FarmaMondo's international success story and of Swiss solutions to patient access issues across the world. Swissmedic, the Swiss pharmaceutical regulator, is also of key importance in this effort. Spigel points out that "Swiss innovators are becoming major powers in the effort to provide early access to medicines to address unmet patient need through FarmaMondo, utilizing the unique regulatory frameworks that exist globally. In parallel, Swissmedic is providing precious guidance to allow us, as a Swiss-licensed service provider, to navigate through the jungle of regulations that are in place intentionally governing access to unlicensed medicines." He concludes, "We are playing a key role in the industry's effort to expand access to medicines to wherever unmet patient need exists ... This is a global task, but Switzerland is at the forefront."

A CLASS APART

Despite occupying a very specific niche – as evinced by the fact that its genuine global competitors can be counted on one hand - FarmaMondo's service offering places it at the crux of several of the core challenges facing the modern healthcare industry. Spigel elaborates these challenges as "the need to expand access to medicine, the fight against the substandard distribution of drugs, the influence of social media on pharmaceutical companies' decisions, and the need to navigate through multiple regulatory landscapes." Moreover, he highlights that FarmaMondo's business model puts the company firmly in line with the three major trends of the modern industry; namely "Patient-centric initiatives, enhanced access to medicine early in the product life cycle, and innovative regulatory mechanisms that are flexible enough to accommodate individual patient needs."

Novartis Oncology

Changing the practice of medicine

At Novartis, we harness the innovation power of science to address some of society's most challenging healthcare issues. Our researchers work to push the boundaries of science, broaden our understanding of diseases and develop novel products in areas of great unmet medical need. We are passionate about discovering new ways to extend and improve people's lives.

NOVARTIS

SWITZERLAND

The Great Pioneer

Three momentous events defined the Swiss pharmaceuticals and life sciences industry in 2017. Firstly, the emerging field of modifying and deploying a patient's own cells to fight cancer received a massive boost when Novartis secured FDA approval for the first-ever chimeric antigen receptor T cell (CAR-T) cancer therapy. Secondly, the highly acclaimed Swiss biotech, Actelion, was acquired in an unprecedented USD 30 billion all-cash deal. Thirdly, Swiss pharma exports surpassed a value of CHF 80 billion (USD 80.9 billion) bringing a net trade balance in at around CHF 47.9 billion (USD 48.5 billion), by far the highest of any country in the world. Each of these developments, in their own way, point to the growing relevance and influence of Swiss pharma and life sciences on the world stage. What is less publicized is the highly innovative and inspirational role that Swiss firms are also currently playing in reshaping the pharma value chain and contemporary paradigm of healthcare provision.

PETRA DOERR

head of sector Communication & Networking, deputy executive director, Swissmedic

BRUNO STRIGINI

CEO, Novartis Oncology*

JEAN-PAUL CLOZEL

CEO, Idorsia

FRESH TACTICS FOR THE WAR ON CANCER

With cancer now causing one in eight deaths globally and, in Europe, even outpacing serious cardiovascular conditions in terms of prevalence, Switzerland has long positioned itself firmly at the vanguard of countering a disease which the World Health Organization (WHO) predicts will reach an incidence rate of 22 million new cases per annum by 2030. Pertinently though, Switzerland's trailblazing spirit in facing down this major public health threat never ceases to impress.

First came Novartis' unprecedented decision to assemble a global business unit (or 'firm within a firm') dedicated solely to developing and launching innovative oncology medicines, thus enabling the company to deploy a nimble outfit, with speedy decision-making power especially suited to accelerating the development and commercialization of new generations of cutting edge cancer therapies.

Then, this year heralded the Swiss giant's unveiling, to great fanfare, of 'Kymriah,' the first CAR-T immunocellular therapy, approved in the United States for the treatment of individuals with B-cell precursor acute lymphoblastic leukaemia. "Basically, this constitutes a highly personalized and game-changing therapy in which T-cells are drawn from a patient's blood and reprogrammed in our cell processing facility. These genetically coded T-cells are subsequently infused back into the patient to potentially hunt down the patient's cancer cells," describes Bruno Strigini, now former CEO of Novartis Oncology.

For many analysts, though, this represents merely the tip of the iceberg and an entire multitude of Swiss life science firms are furiously busy behind the scenes reconsidering how to go about treating and managing a disease that is no longer necessarily a death sentence. "There is a whole new market segment materializing that pertains to cancer supportive care," points out Saad Harti, president and founder of Legacy Healthcare. "If you think about it, cancer can increasingly be regarded as a chronic illness because many people are today surviving the acute stage of the disease, but ending up with a substantially reduced quality of life following the affliction," he reasons.

"Because cancer hits you everywhere, synthetic chemical medicines with onerous side effects often have to be utilized to counter the initial impact, but it makes little sense, however, to be prescribing additional drugs carrying yet more side-effects. Far better, wherever possible, to instead resort to reaction-free botanicals at this particular stage when the patient is already highly medicated," he argues. Legacy's lead candidate, CG428, a botanical hair lotion geared towards helping re-establish the natural balance of the hair cycle when disturbed by chemotherapy and hormonal cancer treatments, strives to do exactly that.

> **"A WHOLE NEW MARKET SEGMENT IS MATERIALIZING PERTAINING TO CANCER SUPPORTIVE CARE…CANCER CAN INCREASINGLY BE REGARDED AS A CHRONIC ILLNESS BECAUSE MANY PATIENTS ARE SURVIVING THE ACUTE STAGE**
>
> **SAAD HARTI,** LEGACY HEALTHCARE.

Nor is this an isolated example. Other local entities like the medical device firm, Stratpharma, have been arriving at much the same conclusions. "Right now, we are entering the therapeutic area of supportive cancer care, specifically radiation oncology. One of our main products, StrataXRT, is for the prevention and treatment of radiation dermatitis. Basically, we take the management and treatment of radiation dermatitis and do it in a completely different way. So we're rethinking the manner in which the symptoms are handled," explains CEO and founder, Darren Kerr.

"Eight of the top ten cancer drugs today are biological. You have TK9 inhibitors or EGFR inhibitors, each of which targets cells and molecules, which are also involved in the functioning of the skin, so patients report unpleasant drug rashes and radiosensitive skin. So while we are offering new radiation machines that have skin-sparing

* Please note that the interview with Bruno Strigini from which his quotes are taken was conducted in October 2017. Bruno Strigini has subsequently announced that he will retire from Novartis Oncology in early 2018.

technology, the drugs are running in the opposite direction with greater efficacy, but nasty side effects. Our products work to significantly reduce these drug rashes in a non-chemical way. It's quite simply a fantastic breakthrough well received by the patients themselves," he affirms.

A NEW COHORT OF ADVENTURERS

Switzerland's pioneering contribution to going beyond the boundaries of medicinal science is not confined to the urgent matter of oncology. Even the most cursory glance across the nation's bio-valleys and life sciences hubs uncovers a myriad of SMEs active at the sharp end of new discovery.

Neovii's flagship product, Grafalon for example, has attained great acclaim for its potential to prevent chronic GVHD after stem cell transplantations. "Historically, the product was used to prevent acute rejection of the organ during transplantation. It has been developed into a stem cell transplantation setting; a development that has been well documented in relevant medical journals," recalls CEO, Juergen Pohle.

"We have seen opportunities to develop the product further. For example, we can transfer the product into allogenic paediatric stem cell transplantation and hub flow

DARREN KERR
CEO, Stratpharma

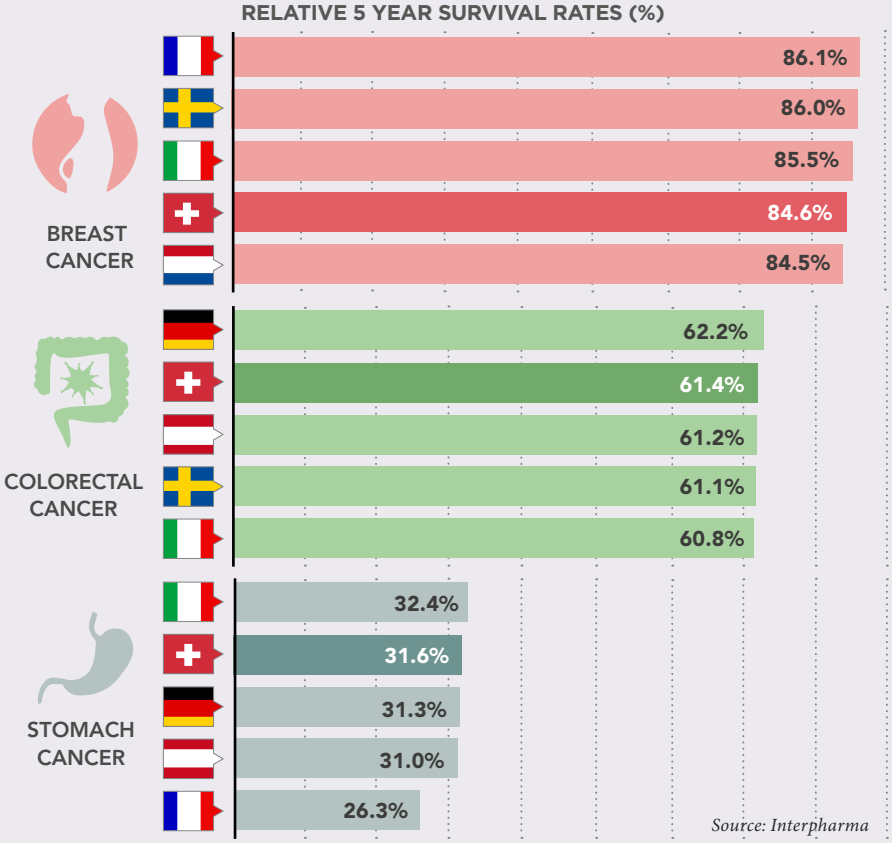
JUERGEN POHLE
CEO, Neovii Pharmaceuticals

haploidentical stem cell transplantation. We are also looking at opportunities to enter autologous stem cell transplantation as well. This aspect of pharmaceutical study has been brought to our attention through recent scientific publications. So essentially, we are looking at expanding Grafalon's value both from a patient's and a physicist's perspective. Specifically, we are interested in cells that are transplanted into the patient. The potential is huge," he assesses.

Another homegrown innovator, Polyphor, has invented an entire new class of antibiotics called Outer Membrane Protein Targeting Antibiotics (OMPTA). "A new class for Gram-negative pathogens of this ilk had not been witnessed for over 40 years. This is an area where there is an increasing and enormous medical need, and Murepavadin, the frontrunner of this new category is looking extremely active against resistant strains, which will be major news if it successfully passes phase III trials," exclaims CEO, Giacomo Di Nepi.

Geistlich, meanwhile, a family firm that dates back to the 1850s, has been innovating bone graft technologies and collagen based-products for regeneration in the dentistry and orthopedic sectors. "We started early on with tissue and bone as a main focus before branching out

COMPARISON OF CANCER SURVIVAL RATES IN EUROPE



Source: Interpharma

PAUL NOTE
CEO, Geistlich

OLIVER RINNER
CEO and founder, Biognosys

into underserved areas where we can make a real difference to patient lives," remarks the company's CEO, Paul Note. "We work hand in hand with universities and some of the best specialists in the field in other institutions worldwide and are incredibly proud to rank as one of only a handful of companies that holds in-house research and development resources in these areas."

Yet others are engaged in defining entirely novel fields of therapeutic enquiry. Biognosys's main focus is the decoding of the proteome, an activity that its founder, Oliver Rinner, claims "will impact the life sciences more than the genome revolution. Proteins constitute the most significant functional elements in the body. The human physiology is almost entirely run by proteins in regards to cellular structure, enzymes, and receptors. The purpose behind the creation of Biognosys has been to better understand the mode of action of various drugs and biological processes by understanding the changes in the protein levels and activation," he proclaims.

What then nourishes this abundance of locally implanted pioneers? Some would say an incredibly supportive ecosystem and a talent catchment pool encompassing some of the sharpest scientific minds. "We are fortunate to be able to bank upon a highly efficient local infrastructure with easy access to exactly the caliber of scientists that we require," laughs Note "The highly-skilled talent available here is immense. The country also has a very positive attitude towards innovation and business as well as a reputation for being extremely stable politically. This backdrop allows independent companies to put reliable long-term plans into action," agrees Pohle.

Another driver could well be the dramatic success story of biotechs like Actelion that stand as role models and reference points. Johnson and Johnson acquired Actelion earlier this year for a mighty USD 30bn. The deal was unique in that nobody was laid off, Actelion's project pipeline was not disrupted, and the development capabilities were spun off to form a new independent entity called Idorsia. "There was no value destruction. We have to be the only start-up that sets out with 650 people! … That pretty much sums it up. I sincerely hope that we can act as a model for others to follow in how to conduct M&As intelligently and non-destructively," urges Jean-Paul Clozel, Actelion's former owner and now CEO of Idorsia.

He does sound a cautionary note for anyone striving to copy his achievements, however. "Past success is the biggest enemy of future success. Just because you have succeeded in the past does not mean you will necessarily succeed in the future. This has been true with the creation of Idorsia … You need to be constantly reinventing yourself. Idorsia's story should be viewed as a reinvention. I do not want Idorsia to turn out as an Actelion clone. If anything,

it has to be an improved Actelion, an 'Actelion-plus' if you like," he counsels.

OUTSOURCED MANUFACTURING: AT THE ELITE END OF THE SPECTRUM

Unknown to some, Switzerland meanwhile remains both influential and relevant in global pharma circles not just for the obvious core activities of research, discovery and marketing, but also for its prowess in outsourced manufacturing. This might seem rather surprising considering the comparatively high cost of Swiss labor relative to the rest of Europe, let alone further afield. "[Switzerland] is not known to be the cheapest destination when it comes to the cost of labor, but when you measure it in terms of quality at source, it comes right at the top of the leader board," counters Marc Funk, COO of Lonza Pharma &

> **"FIRMS ARE INCREASINGLY BRINGING THEIR OUTSOURCED FUNCTIONS BACK TO COUNTRIES THAT ARE 'QUALITY AT SOURCE' FRIENDLY… HAVING LEARNED THE HARD WAY THAT 'WHAT IS CHEAP IS ALWAYS TOO EXPENSIVE!**
>
> **MARC FUNK** LONZA

Still Room for the Family & Friends-style Firm

BENJAMIN ROUSSELOT
—
vice president Strategy & Corporate Development, Laboratoires Diepharmex

Many of Switzerland's most avant-garde, pioneering life sciences outfits constitute family and friends-run small and medium sized businesses. Laboratoires Diepharmex, which two decades ago disrupted the ear-hygiene market with what was then a groundbreaking product to remove earwax, Audispray, serves as a good example. The family-run firm has today lost none of its original pioneering spirit and recently set about launching a brand new high-end OTC product line called "Micro H" for the treatment of haemorrhoids, which notably is presented in a single dose form, in contrast to conventional cream-based therapies.

Benjamin Rousselot, the company's vice-president for strategy and corporate development, believes Laboratoires Diepharmex's nimble organizational setup, family ownership, entrepreneurial mindset and flat reporting structure have all been key ingredients in the sustained success of a firm that today manages to punch far above its weight.

"I think our major strength is our very fast decision-making process. Our management model is collaborative, and it is my duty to make sure that everyone has the opportunity to bring new ideas to the table. Usually, it does not take long for our management team to decide whether to work on a new idea or not. Most of our competitors constitute Big Pharma companies. In France for instance, we go head-to-head with proper heavyweights such as Sanofi, Bayer and Pfizer. Typically, these companies tend to require a rather longer decision-making process. Being a first mover and making the right decisions first time round can be challenging, but we also know that being able to outstep the competition in this way can also deliver a decisive market advantage."

MARINA LUGOVA
—
executive VP for business development, Synbias Pharma

A similar dynamic can be witnessed with some of the more creative service sector firms. Synbias Pharma, a contract manufacturer that produces highly potent APIs used in cancer therapies, started out in 1995 as a small entrepreneurial venture between a doctor, an oncologist and several chemists. The firm subsequently gone on to achieve worldwide renown and success in the niche of anthracycline antibiotics, but still retains the original start-up mindset.

"We place great emphasis on the makeup of our team and make a point of not accepting status-quo people," confides Marina Lugova, executive vice president for business development. "We remain a small company with 80 employees in total spread across Germany, the Czech Republic and Switzerland and firmly believe that being small confers an important advantage… As you know, many Big Pharma companies are suffering from a lack of innovation. Even companies such as Pfizer and GSK are currently spinning off parts of their business into start-up companies, because they emphasize the value of start-up culture. I am immensely proud to be able to say we possess this culture."

Biotech. "Switzerland ranks very highly for doing things right first time and for the established trust between customers. So it's clear that manufacturing where these sorts of attributes are highly valued, has a key role to play in the Swiss economy. This is something that our partners understand well," he continues.

Indeed, those seeking to manufacture high grade, complex pharmaceuticals are increasingly drawn to reliable, high performance and efficient environments like Switzerland. "You just have to look at the direction of outsourcing trend horizons: how many companies relocated to places with a low cost of labor and have, in time, reverted back to countries that are quality at source friendly? There is a lot of truth to the saying, 'What is cheap is always too expensive!'" laughs Funk.

The same rings true for active pharmaceutical ingredient (API) producers. Synbias Pharma, which took a strategic decision to relocate to Switzerland back in 2011, is a case in point. "We secured our first credit line from the European Bank for Reconstruction and Development which was a very important milestone for the company's development because it enabled us to invest in our own fermentation plant and rely on our own raw materials... before long we found ourselves dominating the world market for anthracycline antibiotics," recalls Marina Lugova, executive vice president for business development.

She considers their unique selling points as quality, process innovation and efficiency. "The foremost challenge in our segment constitutes the regulatory requirements, which are becoming ever more stringent, so the most sought-after criteria tend to be quality and safety. Our clients have been working with us for over a decade and will continue to do so because of our track record and

A Novel Format of Partnership

MARC FUNK
—
COO. Lonza Pharma & Biotech

A joint venture between Lonza and Sanofi for a combined facility in the southern Swiss district of Visp has raised eyebrows for disrupting traditional Pharma-CMO dynamics. The initiative, which comes in to the tune of an initial investment of roughly CHF 290 million (USD 294 million) shared equally between both parties, puts Lonza's Ibex™ manufacturing concept to the test, and essentially couples flexibility in facility-build-out with fully tailored business models.

"By joining forces with our partner Sanofi, we can reduce our individual requirement to build assets whilst remaining responsive to future needs and uncertainty in a more efficient and effective manner. When you have a joint plant that can cater to both Sanofi's and Lonza's manufacturing capacities you end up with a very different type of facility than if we had both gone ahead and built our own separate factories. Ultimately, we can better plan capacity usage and anticipate production cycles as well as ensure better usage of the entire possible output," affirms Lonza's Pharma & Biotech COO, Marc Funk.

"Often, when a large pharma player possesses an important commercial molecule, the tendency is to build a large-scale asset that is then not maximally used because the number of units required is not necessarily clear in advance. By making this facility versatile enough to cover the type of loads that we will need to produce alongside those of Sanofi, we can ensure that, at all times, the plant will be operating at maximal capacity irrespective of fluctuations in market demand," he reasons.

dependability on the quality front and the trustful relationships that we have managed to forge. Our most eye-catching feature is the purity of our APIs, and the fact that our products are truly best in class, matching the very highest European and American standards," she affirms.

Lugova also agrees that the sorts of efficiency savings, productivity levels and intelligent processes that they are able to leverage in an advanced ecosystem like Switzerland more than outweigh any labor cost drawbacks. "We are renowned for the extent of our process innovation which is reflected in our portfolio of different patents and our cost structure… Our capabilities started from API production and we integrated backwards into fermentation building new competencies and expertise all the while. Being in Switzerland and utilizing Swiss talent has enabled us both to outsmart some of our competitors and create our own intellectual property," she confides. "Switzerland also provides us with unparalleled opportunities for fundraising so as to further develop the business," she adds.

Naturally Swiss API providers tend to concentrate on the most sophisticated categories where the value additions are most pronounced. "We hone in on the more complex molecules that would be most difficult to emulate," says Peter Kaufmann, CEO of Selectchemie. Their flagship product, Caspofungin takes a time-consuming 34 fermentation steps for the API to take form. Consequently, few companies around the world possess the necessary capabilities to fabricate it. "Caspofungin must be stored at minus 70 degrees Celsius, shipped at minus 20 degrees and is kept in a vial form. Initially we had expected clients to buy the dossiers through a down payment and a finished dosage form, but interestingly, this was not the case. The process is actually so complicated that buyers would prefer to purchase the finished product than look to assemble it themselves, so we now have to oversee that step as well," he admits.

PETER KAUFMANN
CEO, Selectchemie

STEFAN FREFEL
CEO, Bilfinger Industrial Services

ADVENT OF THE FLEXIBLE SERVICE PROVIDER (FSP)

With both the pharmaceutical and biotech industries increasingly looking to outsource critical functions from manufacturing to clinical research, Swiss service companies and multinationals operating locally have been quick of the mark to embrace fresh business models more aligned with evolving needs. "One trend that we perceive is that the nature of our interactions with our clients is undergoing a profound shift and we now find ourselves serving a whole range of different types of actors often displaying distinctive requirements," reflects Lonza's Marc Funk.

"If we look back, the mainstay of our work in the past used to be about supplying manufacturing batches and

JONATHAN KOCH
group president R&D Laboratories, Covance

conducting development work across modalities for both small molecules and biologics. We, of course, continue to perform all of these functions, but that offering alone is not sufficient for the present context. The number and type of actors populating the biopharma landscape today is very different from in the past. The category of therapies being developed is also very different and nowadays comprises many sensitive matters when handling biologics and thus a great deal more risk and uncertainty," he notes.

The ramifications of all of this have been a surge in demand for bespoke, custom-made solutions rather than one-size-fits all, cookie-cutter services. "Our clients also require more flexibility in terms of how to address future volumes and commitment to reserving manufacturing capacity in the light of the uncertainty and unknowns inherent in the clinical trials process. There is also a real desire on the part of our clients to reduce the costs and increase the efficiency of the manufacturing part of the value chain." he reveals.

VICKY LEVY
head of life sciences and healthcare, Deloitte

Switzerland's contract manufacturers have therefore been responding by repositioning themselves as 'flexible service providers.' Thomas Huber, CEO of Skan Group gives an example from his niche segment of pharmaceutical conditioning. "Quite frankly the new world of medicinal science has been revolutionizing the filling manufacturing business. Small batches and personalized medicines are now very much the name of the game… Today, customers require the production of as many as four different products on the same machine in the same shift. The challenge is thus

not so much the filling process itself anymore, but rather how to clean the machinery between batches to ensure there is no cross-contaminations between products," he explains.

German entity, Bilfinger Industrial Services, which undertakes not just pharma manufacturing but a suite of industrial service solutions including assembly, maintenance and process technologies, equally finds itself being compelled to be more versatile. "We've noticed quite a lot of unpredictability even from our big client accounts. One year, they could have full production, the next they could have low production, and we have to adapt smoothly and seamlessly to this fluctuation," recounts Stefan Frefel, the company's CEO for Switzerland.

The business logic underlying the contract manufacturing process has therefore matured to better reflect the trajectory of demand. "A decade ago, everybody was talking about scaling up. The aim was basically to acquire a small production line and then, providing everything went well, to purchase a large one so as to mass-produce products for the global market. Today we are instead speaking about scaling out. You buy one small line, then a second, a third and so on. Rather than having one mega line housed in a single production center in a choice country, you'd nowadays prefer to have four small lines distributed around the world and be able to produce much more locally," elaborates Huber.

THIERRY MAUVERNAY

president and delegate of the board, Debiopharm

Service firms also need to be much more internally agile so as to be able to simultaneously cater to the demands of differentiated client groups. "Lonza has many Big Pharma customers on its books that already possess in-house capabilities. The nature of our relationship with them is very much one of true partnership. They require a partner to manage their overall

KAREN HUEBSCHER
CEO, Solvias

manufacturing strategy and we view ourselves, in many respects, almost as an extension of their assets. The style of relationship we have with them is much more entwined than that of a traditional outsourcing service provider," explains Funk.

When it comes to servicing biotechs, however, the nature of the relationship is rather different. "Generally, they do not possess in-house capabilities or any kind of know-how about the manufacturing process. In many cases, they are seeking not just the use of our facilities, but also the expertise on identifying optimum manufacturing and development solutions for molecules where the destiny of the end product is often still fraught with uncertainty. In this case we serve as a one-stop-shop CDMO and partner of choice that can fulfill their full range of needs, whilst helping them buffer volatility," he says.

A very similar pattern of disruption can be perceived in the clinical research domain, where the leading CROs have been jockeying to inject more flexibility into their service offering, mindful of the changing dynamics of medicinal discovery and drug making. "There are many more types of organizations participating in pharmaceutical development today, from small biotechs to mid-size biopharma, to large multinationals … These clients have a wide range of different needs and as a top-tier CRO you have to be versatile and flexible enough to respond to these forces. The one-size-fits-all template of yesterday is no longer fit for purpose," concurs Jonathan Koch, group president for R&D Laboratories at Covance, a leading US clinical research specialist whose state-of-the-art Global Central Lab in Meyrin, in the canton of Geneva, stands as the largest of its kind in Europe.

"Some clients come looking for a partner that can be highly and truly full-service in nature. Others may be conducting the trial predominantly in-house, but nonetheless require an element of support maybe in the data resources or monitoring or programming or oversight. Flexible service providers are agile enough to conform functionally to whatever is required at a particular moment and that is precisely why we have been making some strategic acquisitions that can bolster our capabilities and help us deliver the precise breadth and depth of service that each and every one of our clients are seeking. Our recent purchase of Chiltern, for instance, allowed us to round out those FSP solutions by bringing us added strength in areas such as clinical analytics," he recounts.

Karen Huebscher CEO of Solvias, a world leader in contract research, development and manufacturing (CRO/CDMO) very much mirrors these assertions. "The

API Trading: Finding the Right Groove

API trading, commonly associated with slender profit margins and bulk sales, is not the sort of activity one would ordinarily imagine sophisticated Swiss companies to be performing, but even here, certain companies have proved creative in carving out a niche. "Considering the global context nowadays, if you wish to trade commodity APIs it is very tough to be competitive unless you work with a massive volume of drugs and operate vast economies of scale. We know this first hand from experience because 20 years ago we traded ascorbic acid in the hundreds of tons from Asia to Europe and beyond," reflects Selectchemie CEO, Peter Kaufmann.

Conscious that the role of middleman is no longer as relevant in a globalized world where many API manufacturers can easily go direct to market, he has therefore been concentrating on other elements of the process where genuine value additions can be wielded. "Our expertise has always centered around our high caliber multi-talented workforce based out of Switzerland. Our differentiator is that we properly understand the regulatory frameworks across multiple jurisdictions and can offer our clients reliability, reassurance and peace of mind that these aspects will be properly taken care of. The need to invest in proper regulatory adherence and the paperwork that comes with it is all too often overlooked, and although companies can make a short-term fast profit trading by cutting corners, the long-term loss is harmful to all parties," he surmises.

Just how much of an asset is it to possess a Swiss brand when matters of trust and reliability are involved? "In the beginning, the Swiss badge of trust was very important, but carries rather less weight today. If you rewind a few decades, the mark of Swiss-ness was deemed prestigious, but now there is plenty of credible competition at the high-end … Selectchemie is indeed synonymous with quality and trustworthiness worldwide, but that is as much to do with our exemplary track record and an attentively cultivated brand image that has been some 50 years in the making," he muses.

complexity of drug development today is driving a tendency towards outsourcing to the point where the pharma companies of the future might well be holding the platform, with significant activities actually in the hands of third parties. Meanwhile, the service industry is transitioning from a pure transactional model towards much more of a partnering, full project scope interaction," she observes.

"As a Swiss entity with a staunchly scientific, perfectionist, precision technology mindset, we have to show ourselves flexible enough to adapt to customers' real needs… sometimes they will require speed and functionality, rather than the gold-plated, luxury version and we have to be versatile enough to deliver that. If what a client really needs is a Citroën 2CV, then we can't be insisting that they take a Ferrari," she warns. "Developing a drug is a massive undertaking and our mission at the end of the day is to understand our customers and help them bring products to the market faster, efficiently and more cost effectively."

The nature of the work conducted has also been changing. "We've overseen a re-balancing of our service portfolio over the last four years between small and large molecule development. Our business line dedicated to large molecule development has been registering strong growth of in excess of 20 percent and biologics are constituting an ever-greater share of our workload," she concedes.

> **"GOLD PLATING HAS ITS LIMITS… IF WHAT A CLIENT REALLY NEEDS IS A CITROËN 2CV, THEN WE CAN'T BE INSISTING THAT THEY TAKE A FERRARI**
>
> **KAREN HUEBSCHER** SOLVIAS

ACTIVELY SHAPING THE FUTURE OF PUBLIC HEALTHCARE

It is not merely in client relations that locally implanted firms have been reconsidering their way of doing things, but also in their engagement with payers, healthcare providers and the public health system. "While US companies are innovating through partnerships with biotechs and health technology specialists and can often claim to be at the forefront of a lot of the scientific advancement, I see the European companies, generally speaking and especially the Swiss, leading the charge in endeavoring to tackle the main challenge associated with contemporary healthcare: how to manage the health of populations that are getting older and sicker and in need of affordable treatments, but simultaneously innovative ones that can counter the disease profile of today," analyses Vicky Levy, head of life sciences and healthcare at Deloitte.

She perceives many Swiss pharma companies "reaching out to health systems and paving the way for new financial arrangements that reduce costs to the health systems, whilst still rewarding the industry for the patient outcomes they achieve with their medicines."

First among them is probably Novartis, which has shown itself open

to negotiating entirely new performance-related payment mechanisms for some of their latest-generation therapies. "We put a great deal of thought into how to price Kymriah, which is delivered to each patient just once because this is intended to be a one-time, highly effective treatment. Our approach was to collaborate with the United States Centers for Medicare and Medicaid Services (CMS) and come up with an outcome-centered arrangement whereby they only pay if the patient proves responsive to the therapy and also indication-based pricing, which together represent a first-of-a kind arrangement for the United States," details Bruno Strigini.

When pressed on how his company believes value should be determined and calculated, his response is comprehensively thorough. "First, there is clinical value. Second, there is value to the patient in terms of quality of life. Third, impact on the total healthcare budget, for example if a new drug avoids expensive hospitalization, then the cost saving being generated needs to be taken into account. Finally, there is the societal value of getting the patient back to being a productive member of the economy … In short, we are calling on healthcare authorities to look at value holistically and calculate the comparative value of each drug against how well it performs with respect to each of these four criteria," he asserts.

Debiopharm's president Thierry Mauvernay meanwhile is appealing to health authorities to rethink the pricing of antibiotics especially given that recent KPMG studies demonstrate that this important category of medicines adds, on average, some ten to 15 years to human life expectancy, compared to only five or fewer for many oncology products.

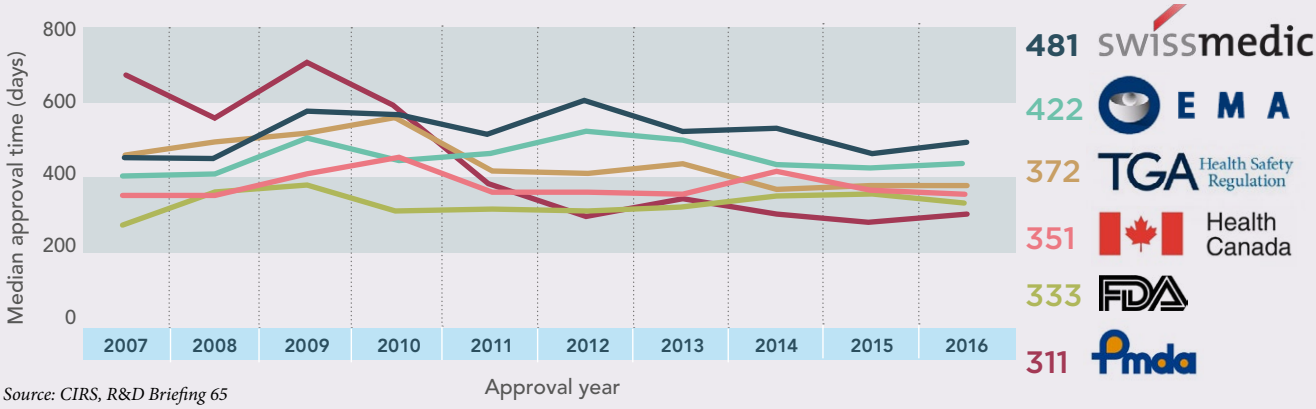
"In our view, the prices of many antibiotics are set far too low and not sufficiently appealing enough for industry because it's difficult to cover the costs of developing new antibiotic compounds. Changing the business model is therefore an urgent necessity. Considering that new targeted compounds are only being deployed by physicians when absolutely necessary so as to minimize the spread of antibiotic resistance, we believe a smarter way of doing things would be to have antibiotic price policy mirroring that of the insurance industry," he advocates. "For instance, for a hospital with 100 beds, you could end up paying a fee each year for the right to use a targeted antibiotic. With 200 beds the amount would be doubled regardless of whether they actually end up being filled or not," he elaborates.

SHIFTING REGULATORY GEARS

Interestingly, the Swiss authorities themselves recognize the importance of proactively working hand in hand with the industry to lower the costs of drug development so that innovative therapies can become more affordable again. "Switzerland's uniquely consensus-driven culture where industry is warmly welcomed to participate in the broader healthcare dialogue reflects the underlying fabric of our society and a federalist governance system geared towards mutual benefit and solidarity," conjectures Pascal Strupler, director general of the Federal Office of Public Health (FOPH).

Certainly, the regulator appears attuned to industry concerns and proposals. "It is undeniable that the regulatory burden today is more onerous that in the past and therefore we are sympathetic to the [drug companies'] predicament and the effect that this has on end pricing. I would point out, though, that a more stringent regulatory regime is the natural consequence of enhanced patient safety. The

NEW ACTIVE SUBSTANCE (NAS) MEDIAN APPROVAL TIME FOR SIX REGULATORY AUTHORITIES IN 2007-2016



Source: CIRS, R&D Briefing 65

solution is to work together to optimize the regulatory process without any reduction in standards. I think that a more pragmatic flexible approach to clinical trial design is the direction in which we are all headed. Already you see the FDA taking a lead in rethinking and reevaluating the parts of the clinical trial process to make it more fit for purpose under certain specific circumstances. Swissmedic can be expected to follow suit," declares Swissmedic executive vice president, Petra Doerr

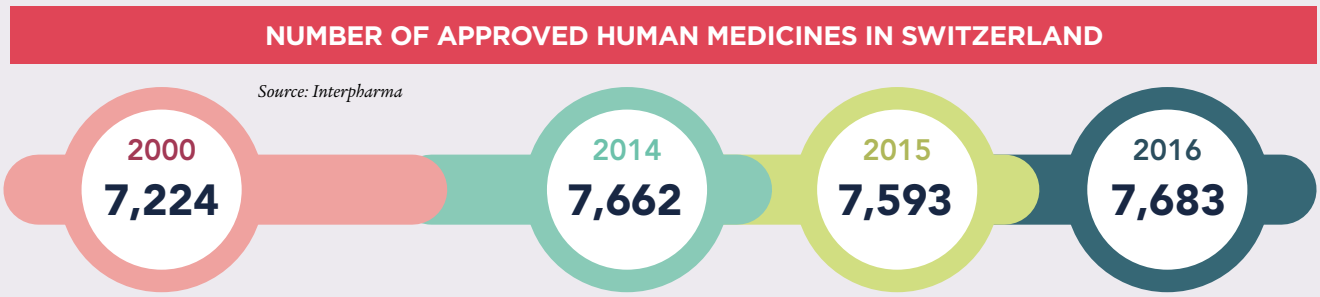
She notices a rising tension between a demand for faster access to innovation from patients on the one side, and a call for enhanced regulatory stringency and oversight on the other, but is confident that competing interests of safety and innovation, flexibility and regulation, and price can be balanced through deep collaboration involving all stakeholders. "We have established a working group with representatives from different patient consumer organizations that meets four or five times a year to discuss precisely this sort of conundrum. Right now, we are at the stage of exchanging insights and information so that all stakeholders around the table understand each other and the different motivations in play. There are ways to square the circle, but the starting point has to be common understanding. Pharma companies obviously seek faster approval timelines and payers demand affordability, but this cannot come at the expense of safety and no one really wants us to degenerate into a soft-touch regulator," she explains.

Equally forward-looking on the part of the Swiss regulator is their overt acknowledgement that, in an era of upheaval in drug development characterized by post-market access clinical studies, predictive modeling and the fast emergence of personalized therapies for which the genetic variances make clinical evidence impossible, the regulatory framework itself is in need of modification so as to adapt to the times. "The way that drugs are being developed is being rethought as new technologies become available and scientific awareness in areas like genetics increases. We do therefore feel a need to update and mature some of our legacy processes to make them more fit for purpose and aligned with the current environment. To ensure that we are proactive in doing this we have implemented a system for horizon scanning that seeks to identify trends and developments likely to affect us in the future. It is clear that we have to move with science and be flexible and versatile enough to react in time to unfolding developments," admits Doerr.

AGENTS OF DIGITAL DISRUPTION

Yet another way in which the Swiss are managing to shift the paradigm across drug discovery, targeted medicine and healthcare provision is in facilitating the big data revolution. "[The incorporation of disruptive technologies in the medical world] is definitely ten years late, not due to a lack of interest, but because of regulatory difficulties" opines Debiotech's CEO, Laurent-Dominique Piveteau. "The political environment of Switzerland is crucial for this type of development."

He continues, "Switzerland boasts a strong image for respecting privacy of data thanks to its heritage stemming from the banking sector. Despite the current negative connotations surrounding the financial sector, it must be outlined that from a personal data and legal perspective,



alongside a stable political context, Switzerland ranks highly. If you have a private, semi-public or public institution keeping your data, you want to make sure as a patient that over time this will remain the same and that things won't change. You don't want a change in the political environment tomorrow which will make digital data available to everyone. That is why stability is a crucial aspect."

Already, locally active firms have been quick in mastering the arts of secure life science data. For instance, INSIGHT Health, which acts as a data provider and consultancy, is proud of the scope of its capabilities. "We have assembled an experienced team of 25 professionals dedicated to taking care of data quality processes and so forth. This way we can minimize the risk of mistakes and have full control over the data. Our secure solutions begin with the data we receive: it is already anonymized. Not even a malevolent person could retrieve personal information from our data," enthuses Petra Exner, regional director for Germany, Austria and Switzerland.

"Moreover, if we zoom into micro regions, we never look at a single data source like an individual pharmacy. We combine several pharmacies in one 'brick.' Our bricks never fail to contain more single sources than the data protection law requires. This way we can work with very detailed data but simultaneously can ensure the highest level of confidentiality. We therefore demonstrate that market transparency and data security are both simultaneously possible," adds Tobias Haber, the company's managing director for Switzerland.

PETRA EXNER
regional director for the DACH countries, INSIGHT Health

Nor should the extent of these achievements be underestimated. "With fast and transparent supply of data analyses we can create value additions for the pharmaceutical developers, health insurance, scientific institutions as well as decision makers in healthcare provision," claims Exner.

"Today we see ourselves as a solution provider for the entire marketplace supporting our customers individually and efficiently in all manner of ways – from product launches and optimization of sales force to portfolio management and patient-know how – while at the same time affording them access to a DACH-wide database that provides an overview on the performance of brands and products across Germany, Austria and Switzerland simultaneously.

Another entity, AppRiver, which is regionally headquartered in Switzerland has been making headway in securing medical records so that they can be digitally handled by the appropriate practitioners and patients. "All our services

TOBIAS HABER

managing director for Switzerland, INSIGHT Health

are cloud-based; therefore, our customers' mission-critical information never leaves Switzerland. In the healthcare industry, email encryption has been an extremely strong area for us. For example, when a doctor sends an x-ray file to a patient via email, it is like sending a postcard at the post office. The perception is that nobody can view this information, but the reality is that administrators can see this confidential file at any time. Therefore, we have developed an end-to-end encrypted technology, so the file can be sent privately by the doctor and the patient can encrypt the message," expounds Rocco Donnino, executive vice president of corporate development.

Tellingly, moves are already afoot within Switzerland to incentivize life sciences-related start-ups to get on the bandwagon and start furthering the digital revolution. Debiopharm, for example, has set up a special

The Botanical Pathway to Patient-Centricity

SAAD HARTI
—
president and founder, Legacy Healthcare

Today, the vast majority of medicines that patients ingest in mature markets tend to be chemically synthesized, potent compounds with unique mechanisms of action, often carrying adverse side-effects, untested long-term toxicities and unknown drug-drug interactions. Saad Harti, of Legacy Healthcare, believes that such a treatment paradigm is "far from desirable in a world in which fewer people are dying from acute illnesses, but more patients find themselves needing to live with and manage prolonged chronic disorders that are non-life threatening, but still, requiring day-to-day treatment."

Pointing to FDA studies that suggest that adverse drug reaction have become the fourth biggest cause of mortality in the United States and spending on unhelpful drug combinations is an unnecessary and counterproductive drag on health expenditure, he is advocating the widespread use of botanical therapies to manage the symptoms of chronic disease. "Current treatment pathways, in many cases, no longer fit with what patients truly expect from a treatment for their chronic disorders: improve quality of life, without triggering other issues so we are suggesting the use of botanics as a complementary therapy to address these shortcomings," he posits.

Legacy Healthcare, therefore takes botanical ingredients that people consume on a regular basis and turns them into drugs. "Our drugs exhibit fewer, and considerably less severe side-effects than synthetic drugs. They inherently register much better tolerance profiles because rather than extracting a single molecule, we take everything so what is being consumed is as close as possible to what people would be ingesting naturally on a regular basis. Incidentally this also means that we can collect data from the public domain, which you obviously cannot do with a brand new, untested chemical entity, so there is even an acknowledgement of a priori safety," he maintains.

Raising the necessary capital to bring a rich pipeline through to fruition is complicated, however, with many venture capitalist funds wary of gambling on such a young and fresh sectoral niche. "It's only a matter of time before we reach a tipping point, though, where botanics go mainstream as an important part of the therapeutic mix… Legacy Healthcare views itself very much as one of the first movers that will trigger this effect," he confidently predicts.

Fast-Track Assessment (As Long As You Can Pay!)

One pioneering and tangible outcome of Swissmedic's engagement with industry has been the opening up of a premium, fast-track approval channel. "This came about as a direct result of our discussions and negotiations. They were asking us to shorten our approval timeframes and we were explaining to them that this would only be possible if we could increase our capacity and have more resources at our disposal. As a result, we agreed to offer them a shortened procedure under a "pay for performance" rationale. Essentially, we offered an additional procedure for products not qualifying for fast-track, whereby they would nonetheless still be dealt with quickly, but for double the fee. Whereas the regular fee sets a company back some CHF 70,000 (USD 70,500), this premium service would cost CHF 140,000 (USD 141,000)," reveals the agency's Petra Doerr.

Initially, for the first two years of operation, firms were slow to take up the scheme. "There was a certain reticence, in some quarters, about paying more. Lately, though, we have noticed a surge in applications as companies begin to properly appreciate the full benefit of being in the market two to three months earlier than their competitors," she reports.

'Innovation Fund' that invests in smart data companies to acquire know-how. "Our industry badly needs strong data management competencies to progress … we look for companies developing solutions in precision medicine – digital therapeutics, digital markers, clinical decision support systems, patient monitoring tools and smart drug discovery and development tools – areas where utilization of big data and AI can create tremendous improvements for patient care. The goal of this CHF 150 million (USD 151 million) fund is to build a portfolio of smart data companies and build the future together," envisions Mauvernay.

This is vitally important because often life sciences entities are ill-equipped to fully utilize and exploit the data that they are collecting. "A crucial aspect is the relationship between data generation and data interpretation. The latest technological developments have enabled the acquisition of huge data sets but ultimately researchers want to test their hypotheses and answer their research questions. Converting data into knowledge is often the hardest step in this process as few biologists come from a statistical or data analysis focused background," observes Biognosys founder, Oliver Rinner. "Moving forward, I think data interpretation can become a main value driver. By using reference data sets, for instance, we can offer contextualized information that has been built up over many years," he points out.

Already some prominent actors along the pharma value chain have been making headway. Novartis has been astute in leveraging Big Data, predictive modeling

First Impressions and Immediate Priorities

JEFF DUFOUR
—
country manager, Pfizer

Having previously focused his career on the US market and with a stellar reputation at Pfizer HQ in New York - including in his most recent role as vice president global marketing Inflammation & Immunology - Jeff Dufour took on his first country manager position at Pfizer Switzerland in July 2017.

In terms of first impressions, Dufour feels that Switzerland "is a country that punches well above its weight class and has a level of sophistication that is genuinely surprising for a country of only eight million people. Almost everything about Switzerland is incredibly advanced and the country is at the cutting-edge in a number of different aspects." Swiss healthcare also stands out to Dufour as "particularly interesting from an American perspective because if you take the logical conclusion of President Obama's healthcare reforms in the US; it's Switzerland… When you look at that level of sophistication here, it shows that the dream of Obamacare can work!"

During his first half year in the role as head of an already successful affiliate, Dufour has prioritized bringing more clinical trials to Switzerland, noting that "We do a lot of clinical trials in oncology here, but there is probably room for us to do more in paediatrics and rare diseases for example. Switzerland is an ideal place to do clinical trials for any of the more sophisticated therapeutic areas because the levels of being able to find patients and treat them effectively is very high here." Due to the Swiss healthcare system's similarities with the US, Dufour sees the potential for Pfizer Switzerland to play a bigger role at the cutting-edge of the global organization as something of a test market, noting that "we may be in a place to look at new models for areas such as gene therapy."

Looking towards the future, Dufour foregrounds the importance of increased stakeholder dialogue and closer relationships in Switzerland; foreseeing "a fundamentally different relationship with the insurance providers and the Federal Office of Public Health (FOPH)." In terms of Pfizer Switzerland's role in the global organization, Dufour hopes "that we can establish ourselves as the pilot launch country in Europe."

and advanced analytics to shorten the time between finding a target and proof of concept, leading Bruno Strigini to speak of the "dawning of a golden age of innovation brought by a gathering convergence of the worlds of science, technology, biology and IT."

Covance, for its part, has earned the epithet of 'the Google of Blood' for its amalgamation of LabCorp's proprietary lab data with Covance's operational data to better inform drug discovery. "The skill is to identify which specific disruptive technologies are going to be the most productive and effective tools, because there usually is a lot of attrition involved so you can't pursue them all simultaneously," admits Jonathan Koch.

RESTLESS AMBITION

Marc Funk, COO of Swiss-headquartered product development service specialist, Lonza, discusses the company's remarkable recent fortunes, how it has anticipated emerging trends in its sector, and his key priorities for the future.

Marc Funk
LONZA

HCLS: These are very exciting times for Lonza, with the company entering a growth phase as it attempts to extend out along the healthcare continuum and anticipate emerging megatrends. How would you describe Lonza and its place in the world today?

MARC FUNK (MF): We mustn't fall into the trap of overlooking Lonza's remarkable heritage and established track record, which dates back over a century – in fact this year is our 120th anniversary! It's the achievements attained over this period of time that have made the company what it is today. These cumulative experiences are an important part of our corporate identity and influence the way in which we go about our work.

The task at hand, right now, is to capture these qualities and to project them into the current context of a rapidly evolving drug development environment. In recent years, we have been witnessing changes in our customer's needs and the manner in which we are being called upon to supply both classical and disruptive medicines. In response, we've been striving to get closer to our clients by meeting their needs, right along the biotech and pharma spectrum. With Lonza's support, they in turn can get closer to their patients.

> **IF THERE IS A SINGLE SECRET INGREDIENT TO LONZA'S SUSTAINED LEADERSHIP IN THE CONTRACT-MANUFACTURING SEGMENT, IT'S THAT WE HAVE NEVER BEEN CONTENT TO REST ON OUR LAURELS**
>
> **MARC FUNK** LONZA

If there is a single secret ingredient to Lonza's sustained leadership in the contract-manufacturing segment, it's that we have never been content to rest on our laurels, and have always demonstrated great willingness to move with the times. Our recent acquisitions are very much a strategy to keep in step with the industry-wide changes that we currently perceive, and to anticipate future ones. We're looking to extend out along the healthcare continuum and, as such, we believe we will be well aligned with emerging megatrends.

HCLS: What are your core priorities looking forwards?

MF: We aspire to move the company and the relationship with our customers from being 'a' functional service provider to 'the' strategic partner of choice in supplying the most innovative medicines of the 2020s decade. We seek to be truly transformational during these extremely exciting times that we live in today in which medical science is making huge breakthroughs. We strive to bring blue-sky thinking and genuine innovation to our part of manufacturing, which has for so long been neglected, and that's a really beautiful and interesting challenge to be working on.

BECOMING 'GLOBAL ARCHITECTS'

Vicky Levy
DELOITTE

Vicky Levy, head of life sciences and healthcare at Deloitte Switzerland provides a fascinating insight into the life sciences sector on both sides of the Atlantic Ocean whilst also detailing Deloitte's aspirations and latest innovations in Switzerland.

HCLS: The Swiss life sciences industry employs 356,000 people, exports USD 80 billion, and is now beginning to house a concentration of regional headquarters for major MNCs. With this in mind, what do Switzerland, and specifically Swiss life sciences, mean to Deloitte globally?

VICKY LEVY (VL): In both scale and importance, the life sciences sector is immense. It is one of largest sectors for us globally. Moreover, as one of the key industries of Switzerland's economy, it is one of Deloitte Switzerland's three key industries that we serve.

Given this importance, here in Switzerland, we are well supported by our global network. I work very hard to make sure my team is collaborating with the right companies and bringing the best of the best to our clients in Switzerland. In order to be successful in the life sciences sector locally, you need to be global architects capable of achieving contact with leading executives and engaging them on their global plans. When global companies (Amgen, Biogen, Bayer etc) settle here, they are making multidisciplinary decisions. Therefore, Deloitte needs to reflect these needs in the region and bring global, multidisciplinary, and engaging talent.

HCLS: Deloitte's November 2016 report 'De-Risking Pharma' suggested seven strategies that companies should adopt to de-risk and create values for patients: continuous R&D innovation, collaborative directed research, accelerated access processes, clinical pathway delivery, lifetime patient data management, digital platforms, and new factories. Do these strategies hold true for your clients in Switzerland and the industry generally?

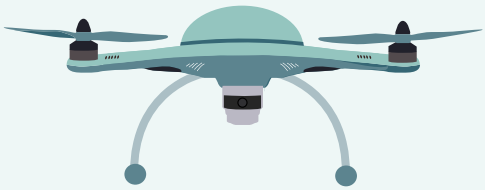
VL: Certainly, the aspect of cost structures proving unsustainable holds true. Whether huge multinationals or regional bases, all companies are looking at the industrialisation of their business models whilst radically determining how they

> **"IN ORDER TO BE SUCCESSFUL IN THE LIFE SCIENCES SECTOR LOCALLY, YOU NEED TO BE GLOBAL ARCHITECTS CAPABLE OF ACHIEVING CONTACT WITH LEADING EXECUTIVES AND ENGAGING THEM ON THEIR GLOBAL PLANS.**
>
> **VICKY LEVY** DELOITTE

can deliver products to their patients in a reasonable and faster ways. That is a universal trend and one that certainly applies to Switzerland. As noted before, we're seeing a rise in demand for digital transformation and automation. Automation is a huge topic in the Swiss market. Whilst it is true that some jobs will disappear, there are so many jobs that will be created due to the constant evolution of the industry, and we do not know what roles will need to be fulfilled in 2037. In the life sciences sector, it is important to equip talent with new skills that can address the needs of tomorrow. I think our Swiss clients will take extra care navigating this trend because of impact on local employment. So essentially the focus is not just on changing the number of people we have here in Switzerland but also on changing the responsibilities and competencies of people here in Switzerland today and into the future.

We have already mentioned Swiss labour and the Swiss mentality regarding innovation but there is also a way of doing R&D in Switzerland that is very apparent. Many of the companies operating here also have development sites either in Basel or Zurich. These companies require innovation to fully utilize their latest technology and analogies. Also, innovation is particularly important when seeking a strong relationship with regulators. These relationships can benefit organizations with their pre-clinical trial studies and ultimately help them to create medicine together in a far more efficient way. The use of data in health systems is another example where Switzerland is looking to de-risk the industry.

ADVENT OF DRONE DELIVERY



As the spotlight turns towards optimising supply and delivery chains in pharma logistics, Swiss Post has distinguished itself as one of the early movers in trialling autonomous drone logistics for commercial purposes. In March 2017, the company and its partner, Matternet, received clearance from the Swiss aviation authority to fly unmanned drones transporting blood between two hospitals in Lugano. Moreover the results from the initial test phase, involving more than 100 autonomous test flights, appeared to validate the value of drone transport in terms of safety, practicality and reliability.

"Drones are playing a role in three different fields," reasons Marc Hasler, Swiss Post's head of product and market development. "The first field is for special value or critical goods. That's where health and pharma come in. The second is special locations that are not on the main delivery axis. For example, currently we drive up to each chalet in the mountains, which takes basically a minimum of 20 minutes up and the same down, maybe just for a single customer. So drone is an interesting option for delivery for theses types of remote locations. The third is emergency deliveries. For example, if someone is in the forest and has a sugar breakdown and is logged with a health diagnostic watch, we can see something is going on and we know his GPS coordinates so we could deliver something to him."

Other logistics specialists are fast coming to the similar conclusions. "We envisage promising uses and a wide array of differentiated applications for drones," confides Jan Denecker, marketing director healthcare at UPS Europe. "Potential functions are manifold. Internally we have been deploying drones inside some of our warehouses to check stock levels or available space and this has resulted in notable efficiency gains. Externally, drones can also be utilised to transport products from one location to another that might be more difficult to reach otherwise," he explains.

Indeed his company is currently conducting a project in Rwanda where they leverage drones to deliver blood products to different transfusion centres across the country, given the sheer logistical challenges of delivering blood products on time and in appropriate condition due to poor and unpredictable infrastructure. "We have 15 drones that are used for postpartum haemorrhaging. In this case, the transfusion centre sends an SMS, and within half an hour they can get the required blood," explains Denecker.

> **"I THINK WE'RE REALLY STARTING TO REASSESS HOW WE DO THINGS AND RECONSIDER THE TRADITIONAL MODUS OPERANDI**
> **MARC HASLER** SWISS POST

In other instances, the objective is more about trigger incremental efficiency improvements. "In the US, we have been trying out drones to deliver packages in very rural settings. We have developed a delivery vehicle combination with a driver and a drone. The vehicle goes to deliver at one location while the drone delivers a package to a different location. This actually increases delivery timeliness," he says.

What is becoming increasingly clear is that the logistics segment is undergoing significant disruption and transformation. "I think we're really starting to reassess how we do things and reconsider the traditional modus operandi," reflects Hasler. "Let's not forget that drone use is just one of a suite of recent technological innovations seeking to utilise autonomous systems whether that be delivery robots or intelligent shuttles."

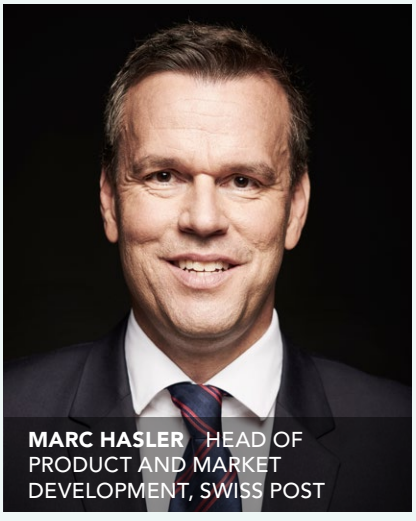
It may be some time, however, before postal drones become the norm because significant obstacles remain to a more widespread adoption of this novel technology. "In many countries drones are prohibited; the lack of a clear legal framework is thus the main challenge," warns Denecker. "And while we see a lot of promise from drones, they can't ever replace our uniformed service providers, who can make thoughtful judgments about whether a package can be left securely, receive a confirmation of delivery signature, move heavy items, or enter a multi-tenant building to leave packages with the mailroom attendant," he admits.

THE MEDICINE SUPPLY CHAIN: BRACED FOR GREAT CHANGES

Marc Hasler, head of product and market development at Swiss Post, speaks out about the strategic significance of the life sciences segment to an iconic national brand, while shedding light on emergent trends in healthcare logistics.

HCLS: What would you say is distinctive about the logistics space in Switzerland?

MARC HASLER (MH): When you consider the contextual environment, Switzerland is situated right at the heart of Europe, but not part of the European Union, which complicates matters for the logistics provider. On the one hand, the Swiss market enjoys its own rules, which have been very supportive of innovation and breakthrough technologies. A good example of this would be the manner in which the authorities at national and cantonal levels have been backing our deployment of autonomous systems such as drones. On the other hand, the fact that, as a nation, we are out of kilter with regard to EU-wide legislation, means Swiss Post has to take on additional responsibilities in assisting its clients, especially SMEs, with the internationalization process.



MARC HASLER HEAD OF PRODUCT AND MARKET DEVELOPMENT, SWISS POST

HCLS: How would you describe the strategic significance of the life sciences logistics business to Swiss Post?

MH: For Post Logistics, the logistics division of Swiss Post, our core branch is, without doubt health and pharma. The total health market, encompassing hospitals, nursing homes and pharma, counts for as much as CHF 70 billion, representing a whopping 15 percent of total Swiss GDP. Servicing this segment is far from a simple undertaking. Firstly, we have to navigate the jurisdictional idiosyncrasies of 26 different cantons. Then we have to engage with some 250 different hospitals, which is a pretty large number for such a tiny nation. On top of that, Switzerland possesses an aging population, which means we have to supply at least 2,700 nursing homes. Together these facts make for an extremely fast-growing and ever-more-complicated market segment.

When we talk about life science clients, we conceptualize three main categories of customer each with its own distinctive set of needs and requirements: firstly, hospitals and nursing homes; then pharma and biotech; thirdly the personalized medicine domain dealing mainly with home deliveries

HCLS: Today, which of these segments contribute most to revenues, and how do foresee market demand evolving over time?

MH: Currently, the mix is evenly balanced between hospitals and the pharma or biotech companies. Diagnostic and medtech clients represent a smaller portion, but the growth there is strong. In the hospital sector, especially, we are witnessing significant transformation. A proliferation of private hospital is redefining the rules, while cantonal or regional hospitals tend to be experiencing extreme cost pressures. Many of these types of hospitals are refocusing on their core competences and looking to outsource their supply chain management. Based on Swiss Post's value and reputation, we are normally the first choice.

HCLS: What are your thoughts on Amazon's announcement that they will enter drug distribution? Does this represent a threat for established players like Swiss Post?

MH: Amazon wants to be a global ecosystem for trade. They start-

ed trading conventional merchandise such as book, and now want to extend into high-value, sensitive goods. The medicines and medtech trade represents a logical next step for them. But, you have to look at the markets Amazon tends to take on. First it is always the domestic US market; then, they penetrate the largest markets in Asia and Europe. Only in a third phase will they go for mid-sized markets such as Switzerland. From a volume and value point of view, Switzerland is not that interesting. Switzerland's real relevance comes from the margins that be made. Hence for now, we are not taking this announcement as an immediate threat.

> **"IN THE FUTURE, "INSTANT PHARMA" WILL VERY MUCH BE THE NAME OF THE GAME.**
>
> **MARC HASLER**
> HEAD OF PRODUCT AND MARKET DEVELOPMENT AT SWISS POST

I do think, however, that Amazon's announcement is emblematic of an emerging trend. In the future, "instant pharma" will very much be the name of the game. More medicines will be administered directly at the home instead of at the clinics and hospitals and that will force us to rethink how we go about delivering medicines. Cutting-edge technologies such as drones and delivery robots may well be the best way forward.

The Art of Frugal Innovation

JAN DENECKER
UPS Europe

At a moment when global supply chains in the life sciences industry are becoming increasingly complicated and costly, many logistics specialists are now starting to embrace the concept of "frugal innovation," the technique of stripping away complexity to generate revenue savings for their clients. "I believe we can learn from the mindset of 'doing more with less' both in healthcare and in the supply chain environment," muses Jan Denecker, marketing director healthcare for UPS Europe.

"If you look at emerging trends in healthcare, both as an industry and as a supply chain, there is immense pressure on all stakeholders to become more efficient and contain costs…If you ask our customers what the number one challenge is in terms of supply chain leadership, more often that not it comes down to balancing supply chain cost with the excellent service that is expected and required when delivering high-value sensitive goods such as medicines."

Sometimes, however, it is the simplest improvised solutions that can best achieve this combination rather than gold-plating services with yet more expensive technologies.

"With frugal innovation, we are encouraging our employees to come up with common-sense, down-to-earth ideas on how we can be more efficient or how we can provide better customer service. At the end of the day, we are a customer service company, and our people are still our most important assets," explains Denecker.

"We have been training our drivers at UPS to save even seconds when they make deliveries. We have over 100,000 delivery vehicles worldwide, so small, incremental improvements, like saving a few seconds for each driver on a delivery, can add up to massive cost savings. How do we do this? These can be little things. For example, when drivers leave the truck, they take out their key and put it on their pinkie finger so they don't have to search for the key. A simple, seemingly insignificant adjustment like that can gain vital seconds, which when replicated across all our operations, generates a big impact."

COUNTERING A SILENT PANDEMIC

Worldwide, severe side effects from classic medicine are becoming a health risk in themselves, often misdiagnosed as symptoms of other problems, resulting in further prescriptions, further side effects and unanticipated drug interactions; the so-called 'prescription cascade'. Saad Harti, founder and CEO of botanical biopharma company Legacy Healthcare, describes this situation as "a silent pandemic" due to the fact that "the full extent of the side effects derived from the repeated taking of many classic drugs over a prolonged period of time to treat the symptoms of chronic disease is still rather poorly understood."

Harti continues: "The FDA estimates that adverse drug reaction has become the fourth biggest cause of mortality in the United States and a full 42 percent of American citizens over the age of 65 are taking a concoction of five drugs or more on a regular basis." In terms of spending, "The cost of adverse drug reactions mortality and morbidity was estimated to be USD 177 billion in 2004 and during the 2004-2014 period, side effects reported to the FDA increase five-fold."

Harti explains that Legacy Healthcare aims to break this cycle of adverse drug reaction, by "betting big on botanical drugs." He posits that "Not all botanicals are safe, but by using extracts from the ones our bodies are used to ingesting, we have the chance to develop very safe drugs with few side effects and long-term toxicity." While Harti does not go so far as to say that botanicals stand to replace classic medicines completely, he does feel that his company offers drugs that are "much more patient-friendly and can serve as a useful complement to classic, synthetic medicines."

In terms of industry skepticism towards bringing innovative botanical products to market, Harti notes that "The first product we developed has been commercialized by Sanofi, Abbott and Galderma-Nestlé Skin Health, all pharmaceutical firms. Provided the science is solid and the proof of efficacy and safety are there, the industry understands the benefit." However, he does point out that "skepticism comes from the venture capital funds, which we need as a drug development company." The embryonic state of the sector is summed up by the fact that "to date, the FDA and EMA have only approved three innovative botanical drugs in total so there is a lot of work to do to get this niche, with its huge potential, flourishing." However, Harti remains optimistic and concludes with an analogy from another industry: "Most people would not have bet a dime on Tesla a decade ago; now the whole automobile industry is shifting to cleaner cars!"

"THE FDA ESTIMATES THAT ADVERSE DRUG REACTION HAS BECOME THE FOURTH BIGGEST CAUSE OF MORTALITY IN THE UNITED STATES

SAAD HARTI LEGACY HEALTHCARE

SWISS BASE, GLOBAL REACH

Cristina Marti's colorful and successful career has taken her across Asia from Spain, before settling in Switzerland with Indukern. In this interview, Marti explores themes of competition in Switzerland, the differences in global markets and why Indukern Switzerland and other API sourcing firms are a reliable route to understanding market dynamics.

Cristina Marti
INDUKERN

HCLS: What are the major developments that have occurred over the past three years for Indukern in Switzerland?

CRISTINA MARTI (CM): After so many years present in China and India, the way that Indukern in Switzerland was working was with strategic suppliers and exclusivity agreements. On top of this, we were doing spot business.

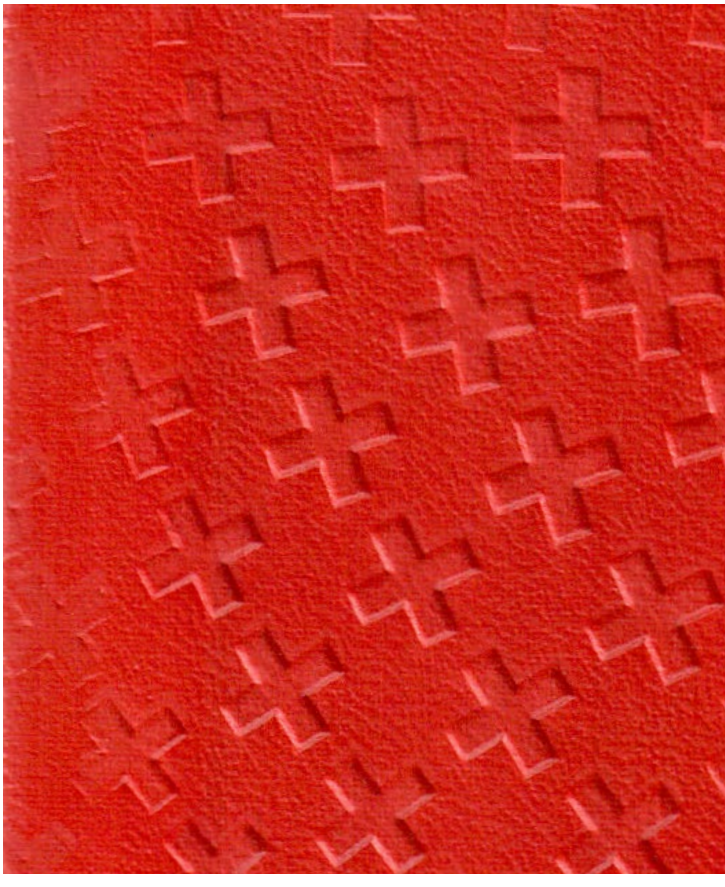
Further improving the strategic alliances with suppliers is advantageous because you develop the market together with the supplier and give them an added value too. Sometimes the suppliers face a cultural gap and the language barrier can be unproductive. It is curious that when I travel to China I often find myself translating English to English given the differences in Chinese mentality and European mentality! After 10 years living in China, I understand perfectly what is meant by the Chinese business peoples' conversation, whereas the European sitting next to me might struggle to understand, and so I relay the information with a European lilt. These cultural observations are things that you pick up when you have been in a country for a long time and understand how they think, and that should not be underestimated.

What we have been doing for the past three years is to identify our main projects, molecules and markets in which we need to focus and to grow from there. Further, with all this movement and convulsion in the Indian and Chinese markets, we seek other options to support both our customers and suppliers to make sure the products are not short

HCLS: Why does it make sense, for a Spanish HQ API supplier to base itself in Switzerland to reach out to the greater European market and more?

CM: The API distribution business in Switzerland developed very fast as a consequence of the importance of pharmaceutical activity in Basel. That was also the case for Indukern.

The office in Spain was historically focused more on LatAm countries due to the accessibility and the cultural proximity, and the regulated markets were taken care of from Switzerland. We have changed this recently and all the business for pharma and veterinary is done from Indukern in Switzerland for all markets except for those where we have an office (Spain, Brazil, Mexico,



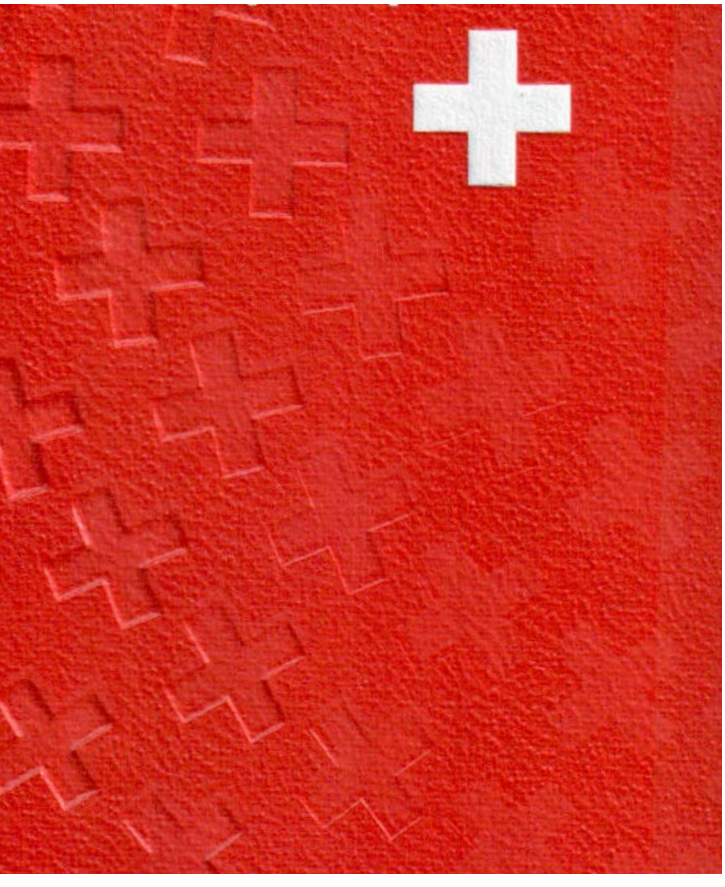
Dominican Republic and Colombia), still with a global strategy coordinated from here.

In our business, the advantages of being in Switzerland outweigh the disadvantages. Switzerland has solid GDP and that is a quality stamp that speaks for itself worldwide. Switzerland is a country that the world trusts which has a positive impact on our customers.

> **SWITZERLAND IS A COUNTRY THAT THE WORLD TRUSTS, WHICH HAS A POSITIVE IMPACT ON OUR CUSTOMERS.**

HCLS: How do you see the role of the Swiss office evolving in the future?

CM: From an API point of view, we are not in a country but a region, so it will gain importance. The regulatory requirements for the entirety of Europe, including Switzerland, are the same, so when we develop a product or project here, we develop it for the whole of Europe. This is of course challenging, but this makes the offices lead the strategy.



Furthermore, we are used to being aware of regulated and non-regulated markets at the same time and inside the same market you always have exceptions. You sell a product to a company in Eastern Europe, that product will be sold in Russia, and it has a registration from a long time ago, so you need a specific regulation for that product that is different from the others.

Whereas if you are the director of the pharma department in Mexico, you only know about the Mexican market, Mexican regulation, Mexican law, etc. Our international build makes Indukern the best insider group to lead the strategy with a wider view.

HCLS: Switzerland is home to several API companies. How do you distinguish yourselves from the competition?

CM: Indukern's global presence is much bigger and we are the leaders in the veterinary API business where they are not strong. Still, with so many molecules launched on the market year on year, and given the shared mutual respect and similar strategies in the industry, there is room for everybody in the business. There can be competition for a specific project, or a specific customer but one company is not necessarily better than the other, it is just better positioned for a certain project. It all boils down to relationships with suppliers, product choice, and knowledge of that specific product.

> **IT ALL BOILS DOWN TO RELATIONSHIPS WITH SUPPLIERS, PRODUCT CHOICE, AND KNOWLEDGE OF THAT SPECIFIC PRODUCT.**

Our Group – Indukern Group – also has a generic pharmaceutical company, Kern Pharma, which is also producing some APIs; and a generic veterinary laboratory, Calier, which is not the case for our competitors in Switzerland. In our internal meetings we are able to ultimate identify the needs of our customers and the trends of the market, allowing us to define our strategy better.

BEYOND GENERICS

Indian generics powerhouse Dr. Reddy's has prioritized biosimilars as a key component of the global organization's ongoing transition into a specialty pharma company. As one of the first companies in the developing world to branch out into this segment - launching four biosimilar products between 2001 and 2011 – Dr. Reddy's now has three biosimilars in R&D and three in Phase III clinical trials for the USA. The company's biosimilars revenues have tripled since first internationalizing in 2011, volume production has increased fivefold, and manufacturing capacities have been expanded and upgraded "to meet both the expected growth of our currently marketed biosimilars as well as support the launch of a significant portfolio of new biosimilar products in the years to come," according to Raymond De Vré, senior vice president Biologics. De Vré outlines the company's vision: "Dr. Reddy's is known the world over as a pioneer and leader in quality generics, but our aspiration is to become very much more than that in the future."

The company has identified a two-pronged strategy for its biosimilars activities, consolidating activities in emerging markets while simultaneously breaking through into tightly-regulated mature ones. As De Vré points out, biosimilars, in addition to being an affordable way to "increase patient access to biotech-based therapies in economies with low purchasing power and limited state financial firepower … are also coming to be highly valued in mature, developed markets as a way of cutting costs and generating savings in line with the prevailing climate of austerity policies." In the latter markets, Dr. Reddy's stands out as "one of only a handful of Indian outfits to have generated the appropriate volumes and quality of evidence to stand a chance of being able to successfully navigate [the regulatory process]".

> **"DR. REDDY'S IS KNOWN THE WORLD OVER AS A PIONEER AND LEADER IN QUALITY GENERICS, BUT OUR ASPIRATION IS TO BECOME VERY MUCH MORE THAN THAT IN THE FUTURE.**

RAYMOND DE VRÉ
DR. REDDY'S

Within this transition to becoming a significant biosimilars player in both emerging and mature markets, Switzerland emerges as a vital piece of the jigsaw. Compared to India, where obstacles abound in international capital flows and onerous bureaucracy, "Switzerland offers a much more favorable jurisdiction while also being strategically located right in the heart of Western Europe," notes De Vré. Building on a long-established legal entity in Switzerland, Dr. Reddy's is now enhancing its Swiss presence by establishing a regional headquarters of 25-30 people. De Vré points out that "Switzerland, and especially Basel, forms the nucleus of an entire life sciences ecosystem where there is ready access to an excellent talent pool. It is also a great meeting place where industry, government and academia closely interact so an excellent location for forging relationships and identifying and initiating new partnerships." He continues, "If you're conducting technology deals with British, German and French companies, it is essential to have a permanent presence in Europe and Switzerland lies in the backyard of all of these significant pharma markets, not to underestimate the importance of Swiss life sciences technology itself."

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