

2019 OUTLOOK
TOP TRENDS TO WATCH

DIGITAL PIVOT
DATA SCIENCE AS PARTNER

BRAND ENGAGEMENT
ESCAPE THE UNCANNY VALLEY

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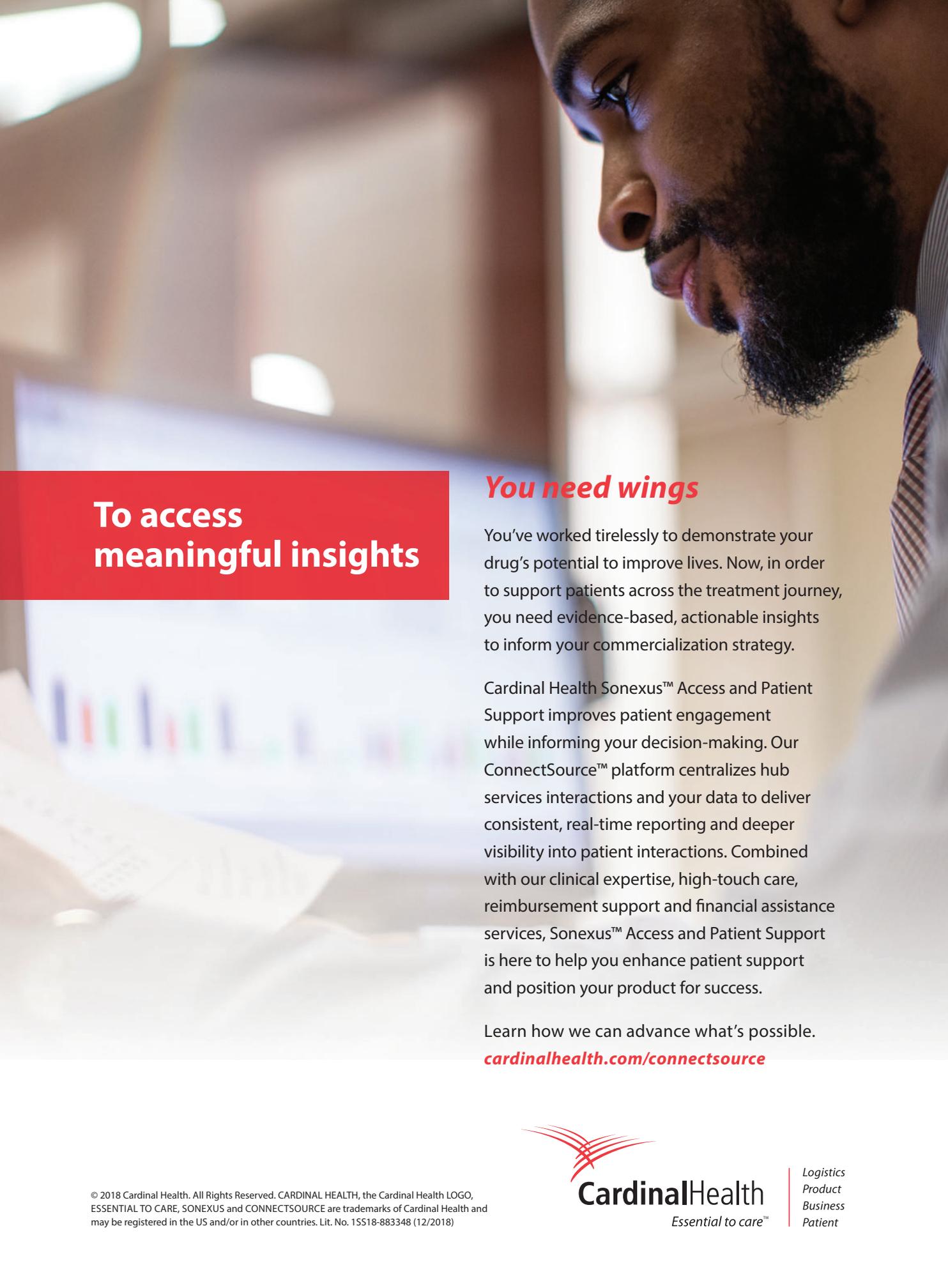
COMMERCIAL INSIGHTS FOR THE C-SUITE

VOLUME 39, NUMBER 1

TASKED TO TRANSFORM

David Meek
CEO, Ipsen





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Don't Ignore These Trend 'Leftovers'

THIS MONTH WE FEATURE OUR ANNUAL INDUSTRY OUTLOOK, culled by discussions with our illustrious Editorial Advisory Board experts. We had a long, long list of topics, but cut it down to the eight you can read starting on page 14. But what about those trends that didn't make the cut? Are they just not hot? Not the case. What makes the cut is when we think the trend is going to have significant impact this year. As an example, let's look at the list we projected for 2018: Patient vs. Consumer, Pricing, FDA Commissioner, Emerging Markets, EMA on Move, Biosimilars, Diagnostics, and eEnablement. Clearly, Commissioner Scott Gottlieb is still a force to reckon with at the FDA, but last year we weren't sure where he was coming from or what he intended to do, so his appointment was very important to last year. EMA moving because of Brexit definitely had impact last year and continues into 2019 (Brexit does make this year's list). Patient vs. consumer was very much a hot topic last year, and to a degree, certain influencers still press pharma to "get with the consumer times," but the newness of that term and urgency is gone. Let's look at the trends that did not make our list this year.

In late January 2018, Amazon, Berkshire Hathaway, and JPMorgan Chase & Co. announced a partnership on ways to address healthcare for their US employees, with the aim of improving employee satisfaction and reducing costs. Since that time, little headway had been disclosed until late in November, when the partners named insurance executive Dana Gelb Safran, senior vice president of enterprise analytics at Blue Cross Blue Shield of Massachusetts, as head of measurement for the initiative. Our EAB said, ultimately, since there is no movement by any of the players for the immediate future, it was being tabled until more progress is made.

The Institute for Clinical and Economic Review (ICER) was founded in 2006 as an independent and non-partisan research organization that evaluates the clinical and economic value of prescription drugs, medical tests, and other healthcare and healthcare delivery innovations. In the intervening 13 years, the institute has gained in exposure and influence, and this past August, CVS announced it would allow health plans and insurers using Caremark to refuse to cover drugs that didn't pass ICER review. The resulting response was that ICER was trying to be the "NICE" of the US, but there aren't more recent news reports about ICER. The EAB ultimately decided that ICER is but one of many influencers on pricing and market access that pharma executives need to be aware of and it didn't merit its own separate category.

There is a widening gap of what regulatory approval looks like and what payers will pay for. This speaks to the trend where regulatory authorities are asking for and providing pathways of approval for more innovative and patient-centric therapies. But that these same

therapies, in the end, may not be supported by payers or governments. Ultimately, this was decided to be an ongoing tension among the stakeholders and will likely not be any more impactful in 2019 than it will be in 2021.

And our final example is the bifurcation of the pharmaceutical industry. On one hand, there is the trend that pharma targets therapies that are very personalized and tailored, usually feature a population with unmet needs or caused by a gene variant, are delivered in a complex way, and have high prices. This group of biopharma doesn't need extensive launch strategies because they are targeting very small populations. They don't need a wealth of added wearables or IoT technology because the therapy itself is the patient engagement tool.

The other side of the divide relies more on prevention and large population healthcare issues, for example, diabetes. These therapies feature extensive launches with direct-to-consumer advertising; they rely on digital therapeutics to engage patients in their care, including their drugs and adherence; and they also feature extensive patient education and patient access programs. Much of the new developments around technology and services are geared more specifically to these larger population therapies. The EAB decided that this bifurcation is only beginning, and the subsequent changes to third-party providers who serve both markets will become more fine-tuned and not imply that all technologies and services are the same for all manufacturers.

Send us an email or tweet at @PharmExec and let us know what you think of this year's Industry Outlook. All of us here at *Pharmaceutical Executive* wish you the best for a very Happy 2019!



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Ipsen's David Meek: Tasked to Transform

By PharmaBoardroom

Pharm Exec partner PharmaBoardroom speaks with American-born David Meek, today CEO of Paris-based multinational Ipsen. Meek takes stock of his two-plus years at the helm of the specialty-driven drugmaker—where through revamped leadership, fostering a biotech mindset, and promoting external innovation, he has helped Ipsen grow in the US and China markets, while looking for ways to boost France's profile on the life sciences world stage.

8

2019 Industry Forecast

8 Tipping Points for Pharma

Pharm Exec's annual look at what lies ahead for the biopharma industry in the coming months examines eight key trends, chosen with input from our Editorial Advisory Board, that are seemingly at tipping points in their evolution and poised to shape the life sciences landscape in 2019.



Data and AI 14

Vertical Integration 16

Emerging Biopharma 18

Payment Models 19

Fight for Pharmacy 20

Lifecycle Management 21

Brexit 23

Digital Therapeutics 24

Guest Column: Finding the Right Digital Health Partner 26

By Paul Upham

NEWS & ANALYSIS

Washington Report

7 Research and Review Issues on Radar at FDA

Jill Wechsler, Washington Correspondent

STRATEGY & TACTICS

Q&A

27 Building a Medicines and Data Science Company

Julian Upton, European and Online Editor

INSIGHTS

From the Editor

3 Don't Ignore These Trend 'Leftovers'

Lisa Henderson, Editor-in-Chief

Back Page

47 Ascending the Uncanny Valley in Healthcare

By Julia Stern

Country Report: Turkey

30 Go Beyond

Focus Reports, Sponsored Supplement



Despite market access hurdles, Turkey's pharmaceutical market holds tremendous growth potential—in both value and volume. But will the country be able to take that final step in creating a regulatory and economic environment that is conducive to further upward development?



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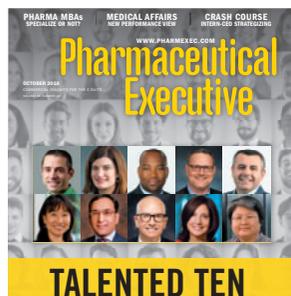
Top Stories Online

**Pharm Exec's 2019 Pipeline Report**

November issue online
Joseph Constance
bit.ly/2P6FOKh

2018 Pharm Exec 50

June issue online
Michael Christel
bit.ly/2yOuP5q

**TALENTED TEN****2018 Emerging Pharma Leaders**

October issue online
Pharm Exec staff
bit.ly/2PB6mba

Securing a Winning Strategy for RWE

December issue online
Julian Upton
bit.ly/2LJGe9m

Integrating Pricing & Market Access Risk

December issue online
Jonathan Chee, Betty Pio, Julia Ehrhardt, Evelyn Siu
bit.ly/2F13sXo

Pharm Exec Podcasts

Episode 22: Virtual Reality and Marketing

Nicola Kayel, VP of marketing at Salix Pharmaceuticals, speaks with *Pharm Exec* editors about the company's recent plunge into virtual and augmented reality and the role these technologies will play in the future for healthcare professionals.
bit.ly/2LMdIJH

Episode 21: Southeast Biotech

In a conversation with *Pharm Exec* editors Christen Harm and Michelle Maskaly, Jack Bailey, president of US pharmaceuticals for GlaxoSmithKline, shares insights on the biopharma landscape in the southeastern region of the US, as part of *Pharm Exec's* ongoing series that looks at growing biotech innovation hubs across the country.
bit.ly/2Q1GdDc

Episode 20: Pipeline Peek

Pharm Exec editors provide a glimpse into the magazine's 15th Annual Pipeline Report, published in the November issue. Topics include cannabis, CAR-T therapy, opioids, biosimilars, and Alzheimer's.
bit.ly/2B6tNkd

Episode 19: The CEO Career Pivot

Pharm Exec speaks with Mei Mei Hu, CEO of United Neuroscience, about how being open to pivoting from your original plan can create a number of opportunities for an executive and their company.
bit.ly/2JqWJGk

Episode 18: Getting 'Real' on Data

Pharm Exec editors sit down with one of 2018's Emerging Pharma Leaders, Christopher Boone, the head of real-world data and analytics at Pfizer.
bit.ly/2Q7JzAz

Episode 17: Commercializing Research

Martin Low and Philip Low, CEO and co-founder, respectively, of On Target Laboratories, talk with *Pharm Exec* about the ups and downs of research that has been previously shelved—and share their strategy in approaching a potential partner to license their technology. bit.ly/2ImLIW5



Pharm Exec Webcasts

On-Demand**Patient Assistance Centers of Excellence: The Next Generation of Brand Support**

bit.ly/2RmUGq0

Contextual Information: Bringing Intelligence to Drug Discovery

bit.ly/2Q5C909

Seizing Pharma Market Opportunities in Japan

bit.ly/2BI2XiP

Reader Feedback

■ I appreciated this quote from Ms. Van Baelen:

"Taking ownership for actions as it relates to individual task flow allows for a productive and efficient workplace and overall team success." She's right, of course. I'd also recommend employing a workflow automation framework to ensure all individual tasks are tracked and accounted for. There's nothing more powerful than providing a complete audit trail to regulatory agencies when questions arise.

Anonymous

"5 Ways to Shape a Regulatory Affairs Workforce for the Future"
bit.ly/2CJH1nU

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**China 2.0**

Pharm Exec examines specific regulatory, R&D, and commercial changes in China's growing biopharma market that are continuing to influence the global life sciences ecosystem.

It will be a challenge for FDA to match or exceed its success this past year in approving record numbers of innovative and generic drugs. These achievements reflect the ability of biopharma companies to capitalize on important advances in science, as well as strong support from the regulators in clarifying requirements and R&D policies. While FDA's Center for Drug Evaluation and Research (CDER) will strive to further enhance its operations, it also will support initiatives to ensure that all medicines are safe, effective, and of high quality.

Amidst these advances, CDER Director Janet Woodcock cites the importance of addressing the nation's deadly opioid epidemic as FDA's top priority for the coming year. The immediate need is to reduce the over 200 million outpatient prescriptions for these drugs each year. Recently enacted legislation instructs FDA to develop evidence-based prescribing guidelines and to explore how manufacturers can provide pain medicines in more secure packaging, Woodcock pointed out at the FDA/CMS Summit in December. At the same time, FDA will develop guidelines on developing non-opioid medicines for acute and chronic pain to improve treatment for patients.

Ensuring quality

Woodcock also aims to advance the safety and quality of medicines. CDER has launched a two-year program to improve oversight of drug safety, featuring new methods to evaluate the more than two million adverse event reports received this year on marketed drugs. The agency is pressing drug companies to

Drug Research and Review Issues on Radar at FDA

CDER priorities for 2019: Opioids, quality, safety, and innovation

comply more fully with good manufacturing practices (GMPs) through more targeted inspections and recalls for those failing to meet standards.

Drug compounding pharmacies and outsourcing facilities will remain in the spotlight, as FDA inspectors continue to find violations at these operations. A related initiative is to continue to implement requirements for tracking drugs through the supply chain to detect unauthorized medicines, an effort designed to have "a big impact on the gray market," Woodcock commented. CDER's Office of Pharmaceutical Quality (OPQ) will continue to seek more timely inspections of manufacturing facilities, a process that should be facilitated by a new inspection protocol for drugs, beginning with sterile drug manufacturing facilities.

These efforts may be enhanced by visible progress in industry implementing advanced manufacturing systems. Woodcock noted at the Summit that five firms have filed applications with continuous manufacturing components, and that generic drugmakers are moving in this direction. Other federal agencies support such efforts as a way to enhance surge capacity when additional treatments are needed to manage infectious disease outbreaks or bioterrorism attacks.

OPQ also aims to launch a structured approach to the manufacturing supplement review

process to better manage product changes through the drug lifecycle.

Accelerating approvals

An important goal for Woodcock is to complete the overhaul of the new drug review process to better manage CDER's growing volume of applications. She recently named Peter Stein director of the Office of New Drugs (OND), and long-time CDER guru Bob Temple will become OND senior advisor, positioned to address the more controversial and difficult drug development and review issues. Woodcock hopes to finalize the OND reorganization by next summer, but it has been delayed by difficulties in gaining Congressional approval of a new user-fee program for improving the regulation of over-the-counter drugs.

Modernizing the review process will involve implementing new automation tools for managing drug applications, study data, and review documents under a "multi-disciplinary, issue-based review document" system. CDER also will continue to carry out provisions of the 21st Century Cures Act and reauthorized user-fee programs to further advance patient-focused drug development, expanded use of real-world evidence, novel clinical trial design, and added authorities to hire more experts needed to carry out these multiple drug regulatory programs. **PE**



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The French Connection

American-born David Meek, today CEO of Paris-based multinational Ipsen, takes stock of his two-plus years at the helm of the specialty-driven drugmaker—where through revamped leadership, fostering a biotech mindset, and promoting external innovation, he has helped Ipsen grow in the US and China markets, while looking for ways to boost France’s profile on the life sciences world stage



David Meek, CEO, Ipsen

Pharm Exec partner PharmaBoardroom, whose “Country Report” series is regularly featured in these pages, spoke recently with David Meek, CEO of Paris-based Ipsen, where they discussed the pharmaceutical ecosystem in France, Ipsen’s bold global expansion and R&D transformation, open innovation as a cultural driver, and digital health, among other topics.

A New England native, Meek was appointed CEO of Ipsen in July 2016, relocating to the company’s headquarters in Boulogne-Billancourt, a Paris suburb. Meek came over from Baxalta, where he was executive vice president and president of its oncology division. Meek began his biopharma career at Johnson & Johnson and Janssen Pharmaceutica and also spent seven years with Novartis. He is a former officer in the US Army, and a graduate of the University of Cincinnati.

PB: *You were brought to Ipsen with two specific tasks: transforming the company’s R&D activity and establishing a presence in new, high-growth markets like the US and China. What is your assessment of the progress made on these two fronts?*

MEEK: We have blossomed from our base as a French company into a growing international player within the areas of oncology, neuroscience, and rare disease. At the outset, we were very clear in our minds that we needed to unleash a profound and ambitious transformation right at the heart of the company that would equip Ipsen to face the future with zeal and confidence. This entailed reconfiguring the leadership team, instilling a biotech mindset, and nurturing a culture of external innovation with a view to driving our research, development, and commercialization.

So far our efforts have met with success. Not only have we proved able to build a global organization and international presence across three hubs (France, the US, and the UK), we have also achieved

therapeutic leadership in our target areas. Over the past two years, Ipsen and its partners have received six FDA approvals, four European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) positive opinions, six EMA validations/European Commission (EC) approvals, and one Medicines and Healthcare products Regulatory Agency (MHRA) approval. Moreover, we rank as one of the industry's fastest-moving players. You will struggle to identify many other drug developers with over \$2 billion in revenue that are expanding at a pace of over 20% per annum.

We are very pleased with this growth profile, especially in the way that we are broadening our reach globally: the US market now makes up 25% of our overall business and our Chinese affiliate is also thriving. Our growth figures were over 21% in the first half of 2018, with over 40% growth in the US.

We have simultaneously made strides in optimizing our portfolio, having successfully launched two oncology indications within the past two years, with our third potential EC approval imminent. Even our established products, like Dysport®, which is the number two neurotoxin on the market, and Decapeptyl®, which was launched 30 years ago for prostate cancer, are bringing significant patient benefit and registering very healthy sales growth.

PB: *How easy has it been to reorganize your top team?*

MEEK: Overall, I consider the biggest transformation within Ipsen has been the people and the culture. A pharmaceutical company's fortunes are often deter-

mined by three core variables: people, products, and pipeline. When you have the right people and the right leaders, positive transformation can occur. What we have been able to do is reconfigure the leadership team, which we knew needed to happen if we were going to strengthen our R&D programs and pivot toward assuming leadership in our targeted therapeutic areas, notably specified areas of oncology with high unmet need. These new leaders, both within our executive committee and our broader global teams, have made sure that our strategy gets executed.

We were very clear in our minds that we needed to unleash a profound and ambitious transformation right at the heart of the company

PB: *Presumably, the dynamism and ambition that Ipsen is currently exhibiting is helpful when trying to attract top talent?*

MEEK: That is precisely what is so exciting about working for Ipsen. Leaders gain the chance to come, drive progress, and bring game-changing medicines to patients. One of my first actions as CEO was to increase our ambition in terms of R&D productivity, raising the bar; so we are now shooting for one new NDA (new drug application) or meaningful

new indication every year. That has given our team a sense of purpose in bringing drugs to patients and treating some of the world's most serious diseases.

Meanwhile, we increased the number of oncology experts across the R&D value chain; and also brought oncology expertise onto our radiopharmaceutical franchise, alongside nuclear medicine expertise. In the neurotoxin business, we've also been having great success in attracting world-class experts to work on our programs at Milton Park in Oxford (England), a site which has positioned itself right at the vanguard of designing next-generation recombinant toxins.

PB: *Practically, how have you gone about the arduous task of engineering a change in company mindset?*

MEEK: It really all begins with the company ethos and collective sense of mission. We have a very clear vision—Ipsen is a global biopharmaceutical company focused on innovation and specialty care. This vision inspires the leaders and the leaders inspire the change. Ipsen has been a great company for many years, but our recent success can be largely attributed to our newfound resolve and sense of purpose. When you commit your company to being a global leader in biopharma, especially innovative care, the entire workplace really takes it to heart and they enact the change.

We distinguish ourselves by placing the patient front and center. It can be difficult, from the standpoint of a pharma company's headquarters, to flip the triangle upside down to where the patient is at the top and the corporation is on the bottom.

We need to start every day with the patients' best interests

in mind. With this kind of mindset, the “walls” that could be preventing corporate cohesion start to come down and we get what I call “a one Ipsen” in which we all work for the patients. Yes, we need each department to be functional, but working cross functionally, both internally and externally—with academic centers, other companies, etc.—toward what is in the best interest of the asset and the company. With that in mind, people collaborate more.

In an era of globalized drug development, the “one Ipsen” mindset is essential, ensuring a spirit of solidarity and joined-up action takes precedence; this has been one of my priorities.

PB: *One of the elements of Ipsen’s R&D transformation has been the pivot toward “open innovation.” How has this come about?*

MEEK: We are built around a culture of open innovation. This approach is making us a partner of choice from early stage development and academic partnerships, through to late stage and product commercialization. Our external innovation strategy that we started to roll out a few years ago explicitly targets the volume of global partnerships that we seek to enter into. While we want to develop our own pipeline, we also strive to supplement it with external assets. At the same time, we are keen to help others bring drugs to the market. In particular, we are ready and able to assist companies that may not have the capacity to manufacture or commercialize their own new products.

So far, we have placed dedicated teams in three innovation hotspots—Boston, the UK, and Paris—and equipped them with

“search and evaluate” capabilities for scouting out new partnership possibilities with biotechs and academia. By ramping up our hiring of physicians and PhDs, we are now able to deepen our interactions with these types of communities.

Ipsen is completely agnostic as to where the innovation comes from. There will be instances when we realize that somebody outside the company has developed something better: a therapy that can be properly termed “best in class.” In such circumstances, we need to be comfortable and at ease with halting our own proprietary program and, instead, going after the best one because we realize that the patients, payers, and we, ourselves, demand the best.

Working with external partners helps keep us sharp. It renders us aware of all the great science that is going on out there, not just within small biotech companies, but within the large pharma companies, too. My belief is that the industry needs to reach a point in which you can walk into a room and you don’t really know where anyone works—and, moreover, you don’t care! Everybody is just trying to do what’s right for the patient. I think that if patients saw that, they’d be highly impressed.

After all, patients don’t look at a label of a drug and ask, “where is this made?” They just care if it does what it says on the tin. The country of origin or the manufacturer is an irrelevance to them.

PB: *How about your commitment to digital innovation and your partnering with actors like IBM Watson?*

MEEK: We are increasingly witnessing the incursion into the biopharma space of tech giants and software and gamification com-

panies, as well as the increased role of AI as a disruptive technological force in drug discovery. There is a change of paradigm whereby one no longer needs to necessarily test a new treatment to produce data. We can start with data through automated biometric processes.

Ipsen’s digital transformation has accelerated since 2014, and the company intends to stand among the leading companies in this area, implementing three significant changes: speeding up drug discovery, improving patients’ and HCPs’ user experience, and inspiring a culture of digital innovation.

The new digital odyssey begins, for us, in drug discovery, where we are harnessing digital means to identify the best drug targets. Our researchers look at data collected from various sources—for instance, real-world data collected from providers such as Flatiron Health—and identify what molecules or treatments will have the highest impact. We can also rely on data to answer some scientific questions, which in the past could be answered only by key opinion leaders (KOLs) and health specialists.

We are simultaneously deploying AI and machine learning in drug development and clinical trials. AI can be a true game-changer not only in helping developers generate a targeted therapy, but also in forecasting drug failure.

I am convinced that by embracing digital disruption, we can massively upgrade and optimize our *modus operandi* for drug development, diagnosis, prescribing, and care delivery.

PB: *Furthering “patient centricity” has become a key tenet of Ipsen’s new vision. What does this buzz-*

word actually mean to you? And how do you measure your performance on this issue?

MEEK: There really isn't a quantitative way to measure our success with the patient, *per se*. The closest you get to such a thing is surveying advocacy groups. What Ipsen has done, though, is to appoint a chief patient officer, explicitly dedicated to ensuring the primacy of the patient and that the patient is positioned right at the forefront of all of our activities. In new drug development, for example, we are attentive to incorporating patient feedback loops early on in the process, with a view to rendering the delivery mechanisms as user-friendly as possible.

As a company with a strong footprint in specialty care, we are compelled to establish strong relationships with our advocacy groups. Meanwhile, we have been working in conjunction with a coalition of advocacy groups, key centers, and regulators in trying to establish an infrastructure to support personalized precision medicine whereby treatments can be tailor-made to each patient's genetic makeup.

PB: *You have been in your current role for over two years now. How would you describe your first impressions of the French market?*

MEEK: My overall impression is that all of the prerequisite ingredients for a great recipe are at hand. France demonstrates great potential for innovation thanks to the country's excellent academic centers and hospitals, an educated workforce, a solid economy, and a strategic geographic location for business. This is a market that enjoys outstanding underlying fundamentals and, as such, France remains

an attractive location for the entire industry from big pharma to small, innovative biotechs and startups.

That said, those very same ingredients can also be found in some other places. The big question for France going forward is how the country can leverage these qualities to the maximum and deliver upon its full potential. Quite frankly, there are alternative ecosystems out there at the moment that are managing to achieve more with a comparable resource base and where the pace of advancement has been astonishingly rapid. At the end of the day, investment flows will always gravitate toward the markets offering the optimal

ble readiness to effect change very rapidly.

Frankly speaking, contemporary drug development is a tremendously hard task. It is a highly risky endeavor and the failure rate can be extreme. We, as an industry, cannot develop innovation on our own in a vacuum anymore. In the old days, a basic research laboratory and bench scientist could identify a molecule and commercialize it all within one company. That way of operating has categorically gone with the advent of cutting-edge, sophisticated biologics. Innovation now comes from all directions, and companies have to prove open to ideas from anywhere across the globe. Furthermore, collabora-

Contemporary drug development is a tremendously hard task. ...We, as an industry, cannot develop innovation on our own in a vacuum anymore

value proposition, so there is no room for complacency if France, or indeed any country, seeks to remain in the game.

PB: *What steps, then, should France take to properly deliver upon its true potential in life sciences?*

MEEK: There is no single, simple way to optimize the system. There is no magic fix or silver bullet. There are many different types of stakeholders in the mix and genuine collaboration will admittedly be tough to engineer. However, if we do not improve, others will continue to pass France by. As we sit, ponder, and deliberate, the world is not waiting for France. Believe me, I [recently] came back from a trip to China and they are not waiting for anybody. On the contrary, the Chinese demonstrate a formida-

tion between industry, patients, researchers, payers, and other actors across the care continuum is ever more critical as health systems battle financial constraints that can only be remedied by acting in concert.

What we need is for the major stakeholders to band together and lay out a comprehensive vision for what the French life sciences community wants to become. What I, and many of my in-country peers, have in mind is for France to assume its place as an innovative center of excellence on a global standard where we develop drugs that benefit the entire world. I think that I can speak for many of my colleagues in the industry when I say that we are super motivated to bring this about. We want the other stakeholders to be equally motivated

What we need is for the major stakeholders to band together and lay out a comprehensive vision for what the French life sciences community wants to become

and energetic. We are going to need a serious private-public partnership to attain these goals.

PB: *What was your feeling about the vibe at the Strategic Council of Health Industries (CSIS) in July, and French Prime Minister Edouard Philippe's speech on the Macron administration's agenda for the life sciences industry?*

MEEK: For me, it's not about one speech, but the subsequent actions that ensue. If we follow through on the plans that we make, then we begin to establish credibility. Predictability has all too often been absent from the French ecosystem. There have been many false dawns. Having a clear sense of the future operating environment is not just a precondition for an enterprise to be able to formulate business plans and place big-ticket investments, but also for the researchers, the academic institutions, and the rest of the life sciences community to perform their tasks competently. If one part of the value chain says one thing, but then does something completely different a few months later, it compromises everyone's productivity.

I think that what was said this summer at the CSIS was certainly encouraging and the posture of the new administration is rather more collaborative and pro-innovation than its predecessor. We're looking forward to seeing this

positive mindset in the social security budget bill for 2019 and the forthcoming decisions on government health policy.

As an industry, we strive to be constructive and are committed to helping to shape the future, but as commercial entities, we also have to be mindful of our capital allocation and take actions that we believe will help us bring great products to patients around the world as fast as possible. I would describe the present mood as hopeful and there is a general appreciation that we have entered a golden window of opportunity in which different stakeholders' objectives are increasingly aligned.

PB: *It is rather rare to find an American leading a French pharma company like Ipsen. How have you dealt with being in this situation?*

MEEK: It certainly has placed me in a unique position. I actually hold the distinction of being the only American CEO in the entire SBF 120 (*Société des Bourses Françaises 120 Index*), the stock index provided by the Paris Bourse. Nonetheless, given my global experience with large multinationals and biotechs, as well as living and working in Italy, Switzerland, France, and Canada, and my familiarity with the mindsets and internal dynamics of these markets, I am pretty comfortable in such an international environment.

I am always keen to stress to people that Ipsen is a global company that happens to have a French headquarters and heritage. We are very proud of our 90-year history in France, but we have, over time, established ourselves as a multinational entity fit for taking on the challenges of contemporary drug development, which is an increasingly globalized endeavor.

The domestic market, though important, is only one component of our overall business. We have strategically established global hubs in Paris, the UK, and the US, and we are continuing to expand across high-growth markets in Asia. Meanwhile, part of my brief is actually to leverage my experience on both sides of the Atlantic to propel the company to the next level by deepening our presence in the US.

PB: *What are your main priorities, hopes, and aspirations looking ahead?*

MEEK: We remain at a critical juncture in our company's life cycle. Understanding that our future strength is in drug development, we have set about trying to put in place a "light" research organization that recognizes that research can be done externally. We are changing the way that new treatments are researched, developed, and brought to market—pushing an open innovation approach, promoting partnerships, and involving patients every step of the way.

Right now, we are firmly on track to meet our 2020 objective for group sales of over €2.5 billion, equating to over 30% growth over the next two and a half years. Our intention is to sustain this momentum by bolstering the internal pipeline and through the acquisition of therapeutic assets that fit with our strategy.

Our future is bright. Our leadership and culture are strong. Our specialized portfolio of innovative and differentiated assets—combined with our strong clinical and regulatory skillset, will allow us to continue to expand indications across existing therapies and to bring new treatments to market. **PE**

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8 Tipping Points for Pharma

Pharm Exec's 2019 Industry Forecast

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Welcome once again to *Pharm Exec's* annual look at what's ahead for the biopharma industry, where we hope the eight trends singled out for this year capture the pulse of change and opportunity impacting leaders and decision-makers in the life sciences the most. From technology and digital health (see accompanying guest column on page 26), to integration of healthcare delivery, to new—and big—competitors at the pharmacy level, to the tenuous countdown and aftermath of Brexit, these topics, chosen with input from our Editorial Advisory Board, all represent key tipping points of sorts for the industry in the coming year. And with some, such as “emerging” biopharma, perhaps already tilted toward definitive change. Whatever the case may be, watching these areas unfold should be an interesting ride in 2019.

OUR TRENDS FOR '19

- Data and AI
- Vertical Integration
- Emerging Biopharma
- Payment Models
- Fight for Pharmacy
- Lifecycle Management
- Brexit
- Digital Therapeutics

A Deep Learning Curve

Keeping pace with data and AI

Broadly, industry's uptake and optimization of artificial intelligence (AI) technologies and data analytics has failed to match the hype that has surrounded the topic. While a September 2018 Frost & Sullivan report predicts that AI and cognitive computing will generate savings of over \$150 billion for the healthcare industry by 2025, it also noted that uptake in healthcare IT has been slow due to strategic and technological challenges. So far, the report said, “only 15%–20% of end users have been actively using AI to drive real

change in the way healthcare is delivered” (bit.ly/2DasYKn).

With the industry moving tentatively into AI, *Pharm Exec* tapped into expert opinion that suggests company activities in this space over the next couple of years could be crucial in forging their path ahead. Those who are embracing and seeking to understand the true potential of AI and data may see their efforts begin to pay off. Others may find themselves facing that ominous decision: “Adapt or die.”

Making sense of data

Mark Lambrecht, director of the health and life sciences global practice at SAS, told *Pharm Exec* that he sees “a lot more realism coming along” from companies that began establishing in-house capabilities and data warehouses a couple of years ago, with company efforts now “maturing to the point where organizations understand what techniques they want to use,” with different architectures and technologies in place for different purposes. “They are following where the data is coming from and how it can help them move forward with clinical development or gain an understanding of what value their therapy brings to the market,” he adds.

Smaller biotech and pharma companies continue to be more innovative, however. For companies with smaller budgets, “automation is definitely a big driver in making the best use of the data and AI—whether that’s natural language processing or image analysis or newer techniques.” Small companies “don’t have armies of people to manually filter out the meaningful signals,” says Lambrecht, “so they want to deploy AI techniques on those big data sets. That leads to more efficient ways of looking at information and helps ensure that their scientists are looking at high-priority problems.”

While the absence of mature healthcare standards and the global variations in how data is structured and used remain “big problems” for pharma, there is positive news in that globalizing policies are driving harmonization, adds Lambrecht. “One example is the EU’s GDPR (General Data Protection Regulation), which is having an effect globally in the way that the people are thinking about patient privacy. One of the downstream effects will be data harmonization and standardization. Another example is that the FAIR (Findability, Accessibility, Interoperability, and Reusability) data principles, initiated in academia, are also becoming more important in the industry.”

AI in clinical development

Looking at the short-term future of clinical development, Lambrecht predicts that n-of-1 trials, or single-patient trials—randomized controlled crossover trials in a single patient—will come further to the fore from a data and AI perspective. N-of-1 trials investigate the efficacy or side-effect profiles of different interventions, with the goal of determining the optimal or best intervention for an individual patient using objective data-driven criteria.

The hope is that every patient can have a specific therapy geared toward their genetic background and their disease, and patients can be matched with the right trial and the right therapies. “These n-of-1 trials offer the opportunity to gather a lot of data—genomics data, proteomics data—and do a lot of real-time analytics,” says Lambrecht.

Indeed, he adds, we are reaching a point when no clinical trial will be run without first consulting real-world data. “It will be part of the whole clinical development effort, from modeling and simulation and predicting where you need to go with your trial, in terms of geography and therapeutic area, to really understanding what the medicine under investigation does for patients.” Using real-world data generated from an abundance of sources—such as video data, demographic data, claims data, financial data—“will help companies understand more about the average patient and create therapies that improve patient outcomes and are impactful for society,” says Lambrecht.

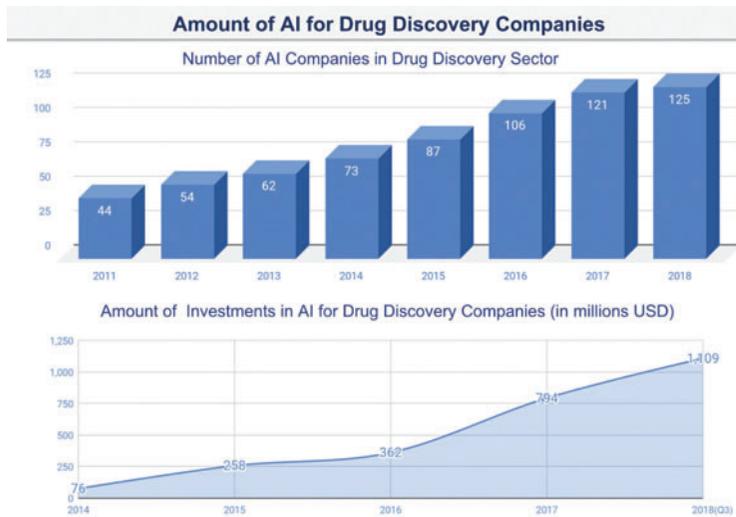
Video data, particularly, will bring more analytics activity, with “streaming analytics becoming more pervasive.” Lambrecht explains: “Take a hospital that is using a robot for a surgical procedure; a lot of video data comes from that. Streaming analytics can be applied to that video data to help support the physician as he or she performs the surgery. In a similar manner, streaming analytics can be used for clinical development. It will help companies to trim down and keep just the data and information that is relevant.”

AI in drug discovery

Margaretta Colangelo, partner at Deep Knowledge Ventures, notes that biopharma companies were skeptical of the disruptive potential of AI in drug discovery (AI in DD), but by 2018 were showing “more interest in the sphere.” However, she says, companies are still moving very slowly in embedding advanced AI technologies into their internal R&D processes.

“The majority of biopharma professionals did not have AI or well-developed IT technologies integrated into their education,” says Colangelo. “Although biopharma companies have sufficient budgets to hire really strong AI specialists to start understanding this field, they are the most resistant to adopt new AI in DD technologies.”

Noting that the industry famously takes a long time to make decisions, and even longer to transform its operating procedures in the face of new



Source: Deep Knowledge Ventures

advancements and technologies, Colangelo adds, “Biopharma giants are just that—slow and lumbering entities, incapable of the kind of agility shown by the smaller and younger companies.” These smaller companies will continue to push advancements in AI in DD. Deep Knowledge Ventures expects, for example, to see 10–20 new AI in DD companies emerging in 2019, with the total number increasing from 125 in 2018 to around 140–150 by the end of 2019.

Colangelo points to generative adversarial networks (GANs) as the most significant AI technique to gain widespread traction in 2018. GANs pit a pair of neural networks with machine intelligence—one generative, the other discriminative—against each other in a “competition,” potentially producing outputs over time that are beyond human capability. While GANs have been used in the generation of

images and music, in 2017, scientists from Mail.Ru Group, Insilico Medicine, and MIPT applied a neural network to create new pharmaceutical medicines with the desired characteristics.

GANs, Colangelo explains, “grew from an extremely new, next-generation technology at the beginning of 2018 to being embraced as the leading frontier of AI and deep learning—and the de-facto standard for modern, advanced AI—by the end of the year.” She predicts that in 2019–2020, GANs will be surpassed by the next generation of novel AI technologies, “resulting in new techniques that are as far advanced in relation to GANs as GANs are currently to normal recombinant neural networks.”

So far, only a “select few” AI in DD companies are applying GANs as a core part of their R&D processes, because the high level of expertise required means hiring very strong AI specialists—“a scarce resource in the industry right now,” says Colangelo. In order to survive in the coming years, the major biopharma companies will need to “reinvent themselves completely,” adopting AI as the core component of their R&D, allocating substantial budgets to hire the best AI specialists and proactively keeping pace with new AI advancements.

While a few existing biopharma corporations will prove capable of surmounting this challenge, “the rest will prove incapable and will be fated to die out as a result,” warns Colangelo. She adds, portentously, “No area of biotech and healthcare will be untouched by AI techniques. They will disrupt all niches entirely.”

— Julian Upton

New Era in Drug Management

Vertical integration of payers, PBMs, and specialty pharma

In early December 2017, CVS Health and Aetna announced their intent to merge in a \$69 billion deal. Soon after, in March 2018, Cigna and Express Scripts announced their vertical integration at a \$52 billion price tag. As of this writing, both mergers have yet to close. CVS Health/Aetna is much closer, having been approved by a number of state regulators and a divestiture of Medicare Part

D prescription drug plan business for individuals required by the US Department of Justice. Cigna/Express Scripts extended its merger deadline from December 9, 2018, to June 8, 2019, but has also gained some state approvals. While the extension now makes the vertical integration of payers, pharmacy benefit managers (PBMs), and specialty pharma too early to call a homerun 2019 trend,

with the forward motion of the merger approvals and already set-in-motion programs by each of these PBMs, the impact of the vertical integrations on pharmaceutical manufacturers is well in sight. Outside of the big two, other integrations include UnitedHealthcare/OptumRx and Blue Cross Blue Shield with Prime Therapeutics. However, because Prime is owned by a number of BCBS plans but not all of them, it is slightly different.

According to Cathy Kelly, who regularly reports on PBMs in her role as senior editor for the *Pink Sheet*, the newest mergers are not likely to result in significantly more members or covered “lives” for any of the players. CVS had already been managing some duties for Aetna’s pharmacy benefit along with its own internal PBM, and Express Scripts had recently lost Anthem as its largest client, so the addition of Cigna members more or less brought them back to equal.

But what the combinations could lead to is a greater allocation of PBMs managing medical benefit drugs, rather than just drugs covered under the pharmacy benefit. Kelly suggests that with their ability to see the claims coming across the insurers database, the PBM insight into how to better manage or control the costs of the more complicated physician-delivered drug landscape, which is usually in the scope of the specialty drugs, is a potential.

On the other hand, one challenge for the PBMs involved in the pending mergers is that the combinations lose clients because of the actual or perceived competition. For example, insurers that don’t want to use Express Scripts as their PBM because of the Cigna relationship.

PBMs and manufacturers are bracing for a major disruption in the current system of drug contracting, with possible regulatory action coming from the Trump administration to restrict the use of rebates. In the meantime, the major PBMs are introducing programs that aim to reduce the reliance on rebates. The most apparent trend emerging that warrants pharmaceutical executive attention are those programs.

As Kelly told *Pharm Exec*, “PBMs have been taking a lot of heat the past couple of years over rebates.” And our own Editorial Advisory Board (EAB) suggested that the increased pressure on the PBM is leading many to challenge or question PBMs’ power in the supply chain. Kelly acknowledged that pressure is due, in large part, to manufacturers’ efforts. “The manufacturers have worked very hard on educating



Cathy Kelly

the public on how the supply chain works, how they have to build money back into their list prices to account for the rebates. They have done a very effective job.”

But PBMs came back swinging at the end of 2018, and seem to be swaying government opinion, if not public opinion. Express Scripts announced that as of Jan. 1, it will offer employers the option of using a formulary that would prefer lower-cost alternatives to expensive brands and would exclude the brands from coverage as a way to effectively lower prices without violating the terms of rebate agreements already in place. A press release stated, “The Express Scripts’ National Preferred Flex Formulary provides a way for plans to cover lower list price products, such as new authorized alternatives that drugmakers are bringing to the market and reduce reliance on rebated brand products.”

The CVS response, announced in early December, is its new approach to pricing, called guaranteed net cost pricing, described in a press release as guaranteeing “the client’s average spend per prescription, after rebates and discounts, across each distribution channel—retail, mail order, and specialty pharmacy...with the guaranteed net cost model, clients continue to have the option to implement point-of-sale rebates to provide plan members visibility into the net costs of their medication.”

As Kelly explains, both the Flex Formulary and the guaranteed net cost pricing are options for employers, so the uptake of the programs may not be known for some time. “PBMs are usually not forthcoming about clients, but these are high-profile programs, so they may want to put that information out there.” However, the net overall effect of the PBM programs, as well as their mega-mergers, will only start to be realized this year.

Will PBMs be able to improve their overall public perception in 2019? Again, time will tell. As Merck & Co. CEO Kenneth Frazier was quoted in this article, bit.ly/2rXj6Lu, “I mean no disrespect to anyone else in the supply chain, but I know how hard it is to make my 50 cents on the dollar. I have to invent something that’s never existed in the history of the world. And I have to ask my shareholders to be patient with their capital. I think that the system has got to change.”

— Lisa Henderson

Past the Tipping Point

Playing field for smaller biopharma has emerged

The FDA is now approving more drugs and biologics coming from companies that have never had an FDA approval before. *Pharm Exec* Editorial Advisory Board (EAB) member Kenneth Kaitin, director and professor, Center for the Study of Drug Development (CSDD) at Tufts University, says, “The landscape is shifting now beyond the tipping point and what that means to the traditional drug development ecosystem. How do these smaller companies get feedback on development and on launch?”

As has been widely noted in *Pharm Exec*, the FDA is also approving more new molecular entities (NMEs) that serve the orphan or unmet disease space, much of which is dominated by the biotech and smaller or emerging biopharma (EBP) market.

Tufts’ November/December 2018 CSDD Impact Report, bit.ly/2EUN3nW, tackled this topic, outlining the following facts:

- » Since 2002, pharma partnerships have been the largest funding source for biotech development, providing 44% of all biotech financing last year.
- » Biotech products most recently accounted for 41% of annual revenue for the top 20 pharma companies. Author of the report, Ronald Evens, PharmD, adjunct research professor at Tufts CSDD, noted: “The biotech-pharma relationship is likely to grow, as the demand for innovative treatments to address a host of unmet medical needs expands.”

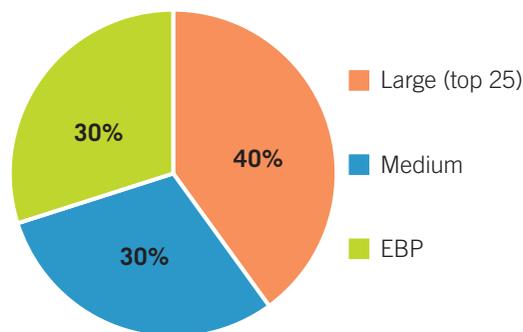
- » Biotech products now account for more than 30% of all new US drug and biologic approvals.
- » From 2007 through 2017, biotech sales as a share of all company sales have almost doubled, from 23% to 41% among the top 20 pharma.
- » As of August, Phase III clinical trials were underway on 532 biotech products spanning 264 indications.
- » Biotech products accounted for 31% of the 457 drugs with orphan designations that have won US marketing approval since 1983, a share that is expected to grow in the medium to long term.

With the increase in smaller biopharma launches and targeted therapies, the logical progression would be a lessened need for big pharma’s sales-force. However, the Tufts numbers don’t back that up. Sanjiv Sharma, vice president, North America Commercial Operations for HLS Therapeutics, and also an EAB member, says that big pharma will not lose its role, in that “they have the ability to break through the noise and if they need a Phase IV, where large pharma dominates in the KOLs (key opinion leaders), then that will still work. As a buyer or partner, large pharma still has the upper hand.”

While the traditional pharma market has covered its own bases with licensing, sales, partnerships, and the like with biotech and EBPs, where do the third-party providers meet the needs of the small achievers? Some speculate that because of smaller patient pools and more complex drug delivery requirements, these EBPs don’t require the level of scale that traditional contract manufacturing organizations (CMOs), contract research organizations (CROs), or market access offer.

CROs are facing a similar criticism that they have faced all along when contracting with smaller pharma, and that is the lack of attention if the company’s product portfolio is not large. Big pharma equals big CRO is the mantra, and the outcome of the preferred provider contracting relationships. This whole new world of biotech and EBPs that need CROs’ help for drug development is causing some concerns among their C-suites. As noted in this article, bit.ly/2SmqH1N, based on a roundtable from CBI’s Finance and Accounting for Bioscience Companies conference held in Boston in late September, CFOs have common concerns of being billed for patient tests not even within their proto-

Number of Launches by Commercializing Company 2007–2016



605 launches from 2007–2016

Source: IQVIA National Sales Perspectives (NSP) and Launch Excellence Archetype database. Note: Hepatitis C virus launches not included.

col or compounds relevance; not delivering on time or on budget; and requiring a lot more oversight than originally thought or planned for. CBI is hosting a conference specific to EBPs and CROs oversight in Boston in early March (bit.ly/2Rf3fq4).

With all the forward motion with biotechs and EBPs and the clear positive performance with FDA approvals, the only challenge is in the markets. Les

Funtleyder, portfolio manager for Esquared Asset Management, and EAB member, says, “The last two years have had record capital-raising for the biotech/emerging biopharma. If there is any volatility, or capital sources dry up, the ultimate downstream effect on large pharma would change.”

— Lisa Henderson

Curative Care Upending System

Gene therapies change pricing and payment model dynamics

The continued advancement of curative cell and gene therapies onto the market stage is clearly challenging traditional pharmaceutical payment and reimbursement structures, driving new strategies, and ultimately moving this topic well beyond simply the initial price—or wholesale acquisition cost (WAC)—of a treatment.

While there remains many publicized developments focused purely on pricing, including the return this month of price hikes by several big pharma companies after holding the line on increases for a period last year amid pressure from the Trump administration; Medicare Part B drug reform, where the Centers for Medicare & Medicaid Services (CMS) is considering a new reference/“International Pricing Index” (IPI) payment model that would link reimbursement to the average price paid in foreign industrial nations; and more state laws passed seeking greater pricing transparency, at the heart of this issue is the emergence in recent years of novel and expensive treatments with potential one-time administration and lifelong benefits. CAR-T drugs for cancer, other immuno-oncology and immunotherapy agents, gene therapy, and vaccines—many addressing orphan and ultra-rare diseases—have changed the paradigm of how the current healthcare payment/reimbursement system operates, one built on high-volume transactions. Curative-type products approved so far typically have front-loaded or high upfront pricing.

“[These drugs] are pushing the issue to, ‘how do I, as a payer, know that I’m actually going to get the value that you’re asking me to pay for this?’” Debbie Warner, vice president, commercial consulting, Kantar Health, told *Pharm Exec*.

In 2019, the Institute for Clinical and Economic

Review (ICER), which provides clinical and cost-effectiveness analyses of treatments and other medical services, will be examining that same question more closely as it applies to curative-intended therapies and whether it needs to adjust its value assessment framework accordingly. For example, should more latitude be allowed for the cost per quality-adjusted life year in certain cases?

Ron Philip, chief commercial officer for Spark Therapeutics, which, in late 2017, won approval for Luxturna, the first-ever targeted gene therapy approved in the US, says new modalities such as gene therapy—in Luxturna’s case, a one-time treatment for inherited retinal blindness for patients with the rare RPE65 gene mutation—are disrupting the current healthcare ecosystem, where the tendency for most stakeholders is to get stuck on the upfront pricing element.

“When you think about the lifetime costs of that patient on therapy and compare it to a one-time treatment that [a company] gets a certain amount of money for upfront, the savings to the healthcare system could be tremendous,” Philip told *Pharm Exec*. “We’re advocating for the changes that we think are needed in order to make these one-time therapies progress in a more viable healthcare system.”

The former Pfizer executive, who joined Spark in 2017, says the biotech is championing for changes in Medicaid best price and US price-reporting regulations, addressing aspects such as portability, which is when patients move from one health plan to another. Treatment durability—and restrictions on how many years out companies will want to structure durability reads—is also a concern when assessing one-time therapies.

Last January, Spark announced a list price for Luxturna of \$850,000 per one-off treatment, or \$425,000 per eye. To ease costs for patients and payers, Spark has a rebate deal in place with Harvard Pilgrim, which ties Luxturna's cost to clinical outcome. Specifically, it will pay back 20% of the price in the form of a rebate if visual improvement objectives are not reached within two and a half years. Spark has also created what it calls Path, a flexible contracting arrangement between payers and treatment centers, where they can bypass the traditional buy-and-bill process, which can sometimes be taken advantage of in the form of price markups. In addition, Spark has submitted a proposal to CMS to allow Luxturna payments to be spread out over time.

Some believe Spark's value framework for Luxturna, which was approved in November in Europe (Novartis will commercialize the product in that region), can serve as a model or blueprint for innovative pricing plans for curative-intended therapies.

In general, outcomes- or value-based contracting arrangements between payers and drug manufacturers, an area we've covered extensively in *Pharm Exec* (see bit.ly/2Av68JH), continue to build steam with various pilot programs initiated, particularly in the diabetes and cardiovascular disease space. Overall, however, these deals remain relatively in the infancy stages, experts say. Depending on the disease targeted, a wide range of variables are still at play, such as access to patient records in some cases, as well as practical questions around how both sides can agree on what kinds of outcomes to measure. "The devil is in the details with regard to getting the data and being able to tease apart whether there are confounding factors," says Warner, who before joining Kantar spent 13 years at AstraZeneca. "The more subjective the evaluation is or the more patient variability there is, the more difficult it's going to be to do anything at a standard level in terms of an outcomes-based contract."

— Michael Christel

Fight for the Pharmacy

Gauging Amazon and Google's immediate impact

It seems like almost every day, there is a strongly worded headline declaring an Amazon or Google-type company's foray into the healthcare industry. Or an article that touts a new partnership geared toward competing with these organizations for a share of the consumer marketplace.

Examples include Amazon's acquisition of Pill-Pack, a full-service pharmacy that sorts and delivers medication right to a person's door, and CVS's late 2018 announcement that it was testing CarePass—a membership in the Boston area that costs \$5-a-month, or \$48 annually, and includes free delivery on most online purchases and prescriptions, access to a pharmacist helpline, a 20% discount on all CVS-branded products, and a monthly \$10 coupon.

Another example is grocery store chain Kroger's exploratory pilot partnership with Walgreens, in which they plan to collaborate "on a new format and concept that combines Kroger's role as America's grocer and food authority with Walgreens global expertise in pharmacy, health, and beauty," according to a press release last fall.

All these cases seem to mention the pharmaceutical industry in some way, but the partnerships don't go as far as creating a major distribution or therapeutic disruption. So, should pharma C-suite executives be concerned about these moves, because they are impacting the ultimate product end user—the patient? The answer is: yes, and no.

Experts who spoke with *Pharm Exec* suggest that drug manufacturers need to keep a close eye on what is happening, but should not immediately feel threatened by the presence of Amazon, Google, or the like compared to other players in the healthcare space—despite the likelihood that the fight for the patient from a supply chain perspective will continue to garner attention throughout 2019.

While none of these high-tech giants are creating a commercial therapeutic, there could be an impact down the road for life sciences companies when it comes to pricing, as well as how their product gets to the patient.

"It's very important to recognize that Amazon, etc. are going first for the pharmacy, not the pharmaceutical companies," says Pratap Khedkar, man-

aging principal at ZS Associates. “That’s distribution vs. manufacturing—a huge difference in investment/risk/margins/ROE/business models. Just because Walmart decided to sell light bulbs, it did not nullify GE’s ability to invent and make them. There will, of course, be a strong price pressure from this, but it will be felt mostly by the generics now, not the brands—unless Amazon enters payer-style rebate negotiation, which has not happened yet.”

However, that doesn’t mean pharma manufacturers should be complacent. “They now have to recognize the potential power of these players when it comes to pharmacy,” says Ashraf Shehata, advisory principal at KPMG. “Some of these tech players may have assets that can be deployed when it comes to patient education, medication adherence, or improving patient engagement.”

Shehata, who works with healthcare and payer organizations, explained that Amazon and Google are both well capitalized, don’t have the legacy assets that retail chains have, and understand customers very well. They also have the means to invest in technology and people to create opportunities to reach patients. Amazon also has leading-edge technology to manage a supply chain.

“This can be very disruptive to retail pharmacies and we’ve seen a great deal of merger activity in the healthcare sector to better position themselves to

“The business model that empowers the consumer will be the most sustainable.”

counter new entrants into healthcare,” says Shehata.

What drugmakers do need to pay close attention to is the influence Amazon and Google and these non-traditional partnerships will have on the industry as a whole—the shift to understanding the patient from a consumer perspective.

“Consumers of pharmacy benefits are facing a rapid evolution of the supply chain,” says Albert Thigpen, vice president, president and chief operating officer of the pharmacy benefit management (PBM) division of Diplomat Pharmacy. “Potential pharmacy alternatives like Amazon, vertically integrated health plan models (UnitedHealthcare, CVS/Aetna, ESI/Cigna), and an ever-increasing use of high deductible health plans where consumers pay the majority of the cost are making the choice of pharmacy more of a consumer-based model. Key stakeholders such as pharma should pay close attention to these changes. The business model that provides actionable information and empowers the consumer to make those changes will be the most sustainable model. Amazon has proven this in the retail segment already.”

— Michelle Maskaly



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From Zero to Life

Lifecycle management strategies evolve

Calculated attempts to extend a drug’s lifecycle, and defend its patent is nothing new to the pharmaceutical industry. It has been practiced for years through the legal system, Phase IV clinical trials, and generating evidence for new indications, among other avenues.

But experts say the number of companies taking advantage of this has increased significantly, which has more people talking about it publicly, and looking for new strategies in lifecycle management.

“The rationale is the relative cost of spending \$2.6 billion to create a new drug with all the uncertainty of approval vs. the few tens of millions to extend life by a few years or even months without

approval uncertainty; plus it is a way to help short-term revenues,” says Pratap Khedkar, managing



principal at ZS Associates. “It takes 8.5 years to get a new drug to market on average from the NCE (new chemical entity) stage and even in oncology, the odds of approval from Phase II/III is only 8%-10%.”

The tools available to help facilitate product lifecycle have also expanded. Most notable, and what makes it something to watch evolve in 2019, is that as the lines blur between technology and pharma, new ways of delivering a therapy are being developed to extend the lifecycle.

“We’re seeing effective strategies that focus on patient engagement and creating more value for consumers,” says Jodi Reynolds, principal, life sciences and healthcare, Deloitte Consulting. “For example, companies that have drugs that have a device element, like an inhaler or an injectable, are advancing those devices to make them smart and linked to an app. That creates an ecosystem that provides further value to the consumer just by taking the drug. It also protects the brand—brand affinity is key to extending the life of a patented drug and things that add value for consumers provide a level of comfort.”

One example of how technology has extended the lifecycle of a therapy is Bayer’s autoinjector for its multiple sclerosis (MS) drug, Betaseron, which was approved by FDA in 1993, and went off patent in 2016. A year earlier, Bayer announced that it won FDA premarket approval for its Betaconnect electronic autoinjector. At the time, the company was also facing competition from new oral treatments such as Biogen’s Tecfidera.

In May 2017, FDA approved a supplemental biologics license application for Bayer’s myBETAapp and the BETACONNECT Navigator. According to a company press release, with this software in relapsing-remitting MS, people using the electronic Betaconnect autoinjector to administer Betaseron can use Bluetooth technology to connect their current autoinjector to the myBETAapp on their mobile device or computer.

Last April, Bayer executives were featured speakers at the Asembia Specialty Pharmacy Summit, where they spoke about the technology and how it added a new lifecycle to a 20-something-year-old drug.

Generic competition

To protect their patents, some companies are also creating branded generics, which, experts say, can be a double-edged sword.

“One of the biggest positives is leveraging the consumer’s comfort and familiarity with the brand, so when there’s competition, it still stands out,” says Faith Glazier, principal, generics segment leader, Deloitte Consulting. “Consumer perception adds a level of trust and familiarity.”

But the down side is that it will cannibalize the brand itself.

“Any thought of maintaining the uniqueness of the brand is sacrificed,” says Glazier. “It could be a useful strategy at times, however. When companies want to be able to lower a price point without showing dramatic price drop on the branded product, for example, they can do it for one dose or dose size of the generic and leave the branded product alone.”

Speaking of generics, manufacturers of these drugs are also looking for ways to extend the lifecycle of their products.

“The generic market is deflationary,” says Edward Allera, co-chair of Buchanan Ingersoll & Rooney PC’s FDA practice group and a former associate chief counsel at FDA. “Companies in that space are looking for new opportunities. The logical step is to move into the 505(b)(2) space, which is analogous to the product lifecycle extension space.”

Allera explained that the normal first step is extended-release versions of oral tablets. Then companies look for other new dosage forms that make the active ingredient safer, such as improving the bioavailability or the solubility.

“Then they look for new indications that require clinical trials and can use different salts or esters, so that they can get additional market exclusivity and perhaps pediatric exclusivity,” says Allera. “Also, they may seek a new indication for an old product that can be genetically modified to produce an orphan-drug approval. Numerous combinations and permutations of technology and drugs are available. The space is wide open.”

Interesting approaches

There have been some untraditional approaches that innovator companies have taken to protect themselves against generic competition. Chip Davis, CEO of the Association for Accessible Medicines, which represents generic drug manufacturers across the globe, says the most egregious example of anti-competitive behavior may be Allergan’s recent ploy to thwart a challenge to a patent for its blockbuster drug, Restasis, by transferring the product’s intellec-

tual property to the Saint Regis Mohawk Tribe in order to “rent” the tribe’s sovereign immunity from legal proceedings.

Davis wasn’t the only harsh critic of the move. Allergan received backlash from not only government leaders, but also US agencies and court systems that oversee these matters. In May of 2018,

retail pharmacies legally challenged the company, alleging anti-trust violations.

While the decision to do this caused great controversy, experts say the industry should expect to see more out-of-the-box moves in this space.

— Michelle Maskaly

Withdrawal Symptoms

Facing the realities of a ‘no-deal’ Brexit

Given the Brexit turmoil that has consumed the UK for the last two-and-a-half years, it seemed optimistic, ambitious even, to predict in *Pharm Exec*’s last Industry Outlook that the country would be much closer to agreeing on a withdrawal strategy by the end of 2018. But as that date passed, and with just three months to go before the UK leaves the European Union (at 11 p.m. GMT, March 29, 2019), one might have expected at least some further clarity around the withdrawal deal.

That faint hope, however, seemed to evaporate when Prime Minister Theresa May postponed a Dec. 11 crunch vote to get her controversially compromised version of the deal through the House of Commons. May was not expected to get the backing the government needed—hence her decision to buy more time—but the postponement created further chaos, with the PM forced to delay her plea-bargaining tour of Europe while she fought to retain the leadership of her party in a confidence vote. May went on to win the backing of most of her MPs, but this did little to quell the sense of disorder. While she gave an assurance that the Commons vote would take place no later than Jan. 21, she was accused of “running down the clock,” and, in the words of one of her government’s rebels, effectively “giving the country [and] Parliament no choice at all—except between her deal and no deal at all.”

At the time of going to press, the prospect of a “no deal” between the UK and the EU looks like a real possibility. As such, pharma, like other industries with “skin in the game,” is “upping its contingency planning—and hoping,” says *Pharm Exec*’s Brussels correspondent, Reflector. “Every

month, around 45 million packs of medicines leave the UK destined for patients in Europe, with 37 million packs heading the opposite way. In total, that is around 1 billion packs of medicine crossing the border between the UK and the EU each year,” he explains.

That sort of traffic will be desperately vulnerable to the new border checks that a no-deal scenario would impose. This is not just an economic issue for manufacturers and customers; for the healthcare sector, the primary concerns are patient safety and public health, he adds. “The industry



has invested in fall-back positions—but this is not enough. The authorities have to act, too,” says Reflector.

To counter the risk of customs and other checks at ports and borders causing delays—together with the possible suspension of air flights and, thus, the delivery of medicines and time-critical clinical trial materials to patients—Reflector points to a series of industry demands to “mitigate the damage that will arise from a disorderly UK

“The industry has invested in fall-back positions—but this is not enough. The authorities have to act, too.”

disengagement from Europe.” Among them is the call for ports to provide fast-track lanes or priority routes for medicines; the temporary exemption of medicines and clinical trial materials from any new customs and borders checks; the need for the European Air Safety Authority to recognize certificates issued in the UK to ensure that planes can continue to fly; and for the EU to continue to recognize UK-based testing—at least for the time being—as not all companies will manage to relocate batch-release testing to the EU by March 30. As for the protection of public health, there are calls for ongoing cooperation between current EU–UK systems, for example, the European Center for Disease Prevention and Control’s infectious diseases warnings.

Parastoo Karoon, principal consultant, regulatory, with the contract research organization Parxel, told *Pharm Exec* that, in preparing for a no-deal scenario, businesses “must establish an EU/EEA (European Economic Area) legal entity (to transfer UK licenses to); establish a qualified person (QP) release site and testing facilities in EU/EEA locations; and obtain new CE marking from an EU-registered body for their existing devices.” He adds that companies “would do well to stockpile commercial and clinical trial supply in both regions, as well as establish a QP responsible for pharmacovigilance (QPPV) and transfer pharmacovigilance system master files to an EU/EEA location, while making substantial amendments to

clinical trial applications for change-of-sponsor legal entity.”

Stockpiling is also being advocated by the UK government. In December, the government asked pharma companies to increase their rolling six-week stockpile of medicines to a six-month stockpile in the event of no deal. Following the announcement of May’s postponement of the Commons vote, Mike Thompson, chief executive of the Association of the British Pharmaceutical Industry (ABPI), gave an assurance that the industry’s focus “is on making sure that medicines and vaccines get to patients whatever the Brexit outcome” and that it is “working as closely as possible with government on ‘no-deal’ planning.”

Despite these contingency plans, however, the industry remains overwhelmingly opposed to a “no deal.” ABPI’s Thompson also emphasized that a no-deal Brexit would present serious challenges that “must be avoided.” He commented: “Politicians need to find a way through the current impasse and reassure patients that medicines will not be delayed or disrupted come March 2019.”

His comments were echoed by Nathalie Moll, director general of the European Federation of Pharmaceutical Industries and Associations (EFPIA), in her end-of-year blog on Dec. 13. Calling on the UK and EU to push for a deal that allows for “immediate and intense focus” on the regulation and supply of medicines in the post-Brexit relationship, Moll asserted that “explicit commitment to securing long-term, extensive cooperation around the regulation of medicines and medical technologies is in the best interests of patients and public health.” She added: “This has to be priority in 2019.”

—Julian Upton

Pharma’s Digital Dive

Wading the digital therapeutic waters

Will 2019 be the year that the pharmaceutical industry figures out how digital health fits into its business—and makes a giant leap into the space? It’s uncertain, but, whatever the result, it likely won’t be from a lack of trying to navigate the shifting terrain.

In fact, experts who spoke with *Pharm Exec* said that digital health has become such a top priority in their organizations that some planned to split their time between the J.P. Morgan Healthcare Conference in San Francisco and the Digital Health Conference at the Consumer Electronics Show (CES) in

Las Vegas, both of which took place the same week in early January. The experts said they are using the time at CES to not only meet with digital leaders who excel in consumer healthcare, but also to learn more about how consumers, or patients, are using digital products.

During a number of roundtable discussions at CBI's Digital Therapeutics Conference in New York City last month, executives agreed that digital health strategies at pharma companies are often still dictated by specific goals set by C-suite leaders. And just because they may declare digital health is a priority for their organization, it could mean anything from digitally updating the supply chain, to actually creating a digital therapeutic; the definitions and expectations of digital health vary greatly.

Defining the terms

As David Amor, vice president, quality and regulatory affairs at Pear Therapeutics, asked at the start of his presentation during the CBI conference, "what the hell is a digital therapeutic?" Although it may seem like a simple question, the fact of the matter is that it can be more complicated than one might think.

According to the Digital Therapeutics Alliance (DTA), a non-profit trade association founded in 2017, digital therapeutics are defined as delivering evidence-based therapeutic interventions to patients that are driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.

It's clear that this definition is not the same as the product a traditional pharma company is used to making. In fact, as Amor explained, in many cases, according to government regulations, these treatments fall into the medical device category. "Digital therapeutics, for the most part, are treated as medical devices," he said. "What does that mean? Is there a chemical reaction? No. So, that's why it's stated as a medical device."

In other words, drugmakers who are looking to create, purchase, or partner with a company around a digital therapy, are now entering an area, including the related FDA regulations, that they may not be traditionally familiar with: medical devices.

Determining the outcomes

Stepping into this new space, experts say, means that pharma companies will need talent with a dif-

ferent skills set than they would normally be looking for when recruiting new hires.

As a result, the industry, experts believe, will start to see more forward-thinking pharma manufacturers bringing in employees who have medical device experience as well as programmers from top tech companies to join their ranks. But speakers at the CBI conference said that someday in the near future, they hope to see college graduates who would typically head to the Silicon Valley, instead choose the pharma corridor.

"Digital therapeutics as a sector will become sexy enough that they will want to work in digital

"There is a misperception that an app can pivot on a dime, and we are going to get FDA clearance—it's not that simple."

therapeutics, and not wonder why they would want to work for a drug company," said David Keene, chief technology officer at Dthera Sciences, during a panel discussion.

Challenges ahead

In addition to the hurdles mentioned, one of the main challenges—and perhaps biggest—facing pharma companies in the coming year around digital therapeutics is revenue. As David Klein, co-founder, chairman, and CEO of Click Therapeutics, pointed out at the conference, despite there being hundreds of thousands of digital health apps available, with more being added everyday, no one is "deriving significant revenue in that space."

"If you need FDA clearance, the bar is set pretty high," said Klein. "There is a misperception that an app can pivot on a dime, and we are going to get FDA clearance—it's not that simple."

Despite the fact no one has solved the "business-model" problem when it comes to digital therapeutics or digital health apps, it doesn't mean companies aren't going to keep trying. In fact, Klein said that over the next six months, expect to see some "significant transactions that will serve as catalysts," as the industry gains more startups and investments in the digital therapeutics space.

"We have just seen the tip of the iceberg," he said. "Expect to see a significant shift in capital, partnerships, and reimbursements."

— Michelle Maskaly

Finding the Right Digital Health Partner

Pharma manufacturers are expanding their portfolios into digital health solutions. To find the right partners, there are a number of key considerations that inform their evaluation and selection.

Structure and approach

Depending on the key business drivers for a given digital health project (e.g., digital therapeutics, digital endpoints/biomarkers, remote monitoring, etc.), there is a typical structure and approach to take from project initiation to final selection of a partner. First, define the business need. This may be driven by a franchise team, a therapeutic area, or even an individual molecule or brand team and should include a preliminary view on the target geographies for launch. From there, establish an evaluation lead and form a cross-functional team. Typically, the leads are from the corporate business development function, but may also involve a procurement organization. To select the members of the cross-functional team, consider the nature of the business need to determine the mix of representation from: commercial, clinical, technical, legal, regulatory, and IT. This team is then accountable for any due diligence and evaluation activities.

Once the team is formed, define the solution's target product profile. This is especially critical for digital therapeutics where there is a clinical endpoint. For non-therapeutic digital solutions, this may simply be a requirements document. Once there is some product definition, perform a landscape assessment to look for any possible existing solutions, companies, or products that may be worth considering. Finally, establish the evaluation criteria and weighting, meet with the companies as a team, evaluate them against the criteria, and make a final recommendation.

Key areas for evaluation

As part of the commercial strategy, define the business need and provide commercial input to the target product profile. Further, the commercial strategy should include a preliminary launch strategy that includes target markets and launch sequencing, and business models (e.g., standalone reimbursable solutions vs. brand-supportive solutions), to help guide other team members in their evaluation. Alignment with regional affiliates and their preliminary reimbursement strategies is critical at this point.

For the clinical development aspects, evaluate potential solutions against the molecule/brand portfolio requirements and define the target indication for use and patient population. Establish the efficacy success criteria against a standard of care in the selected therapeutic area. Then, focus on assessing the clinical viability of potential

solutions. This is critical when evaluating licensing or acquisition of existing solutions. Define a preliminary clinical strategy that describes the likely efficacy-directed and registration-directed clinical studies, and health authority registrations.

The technical development team should evaluate the potential partner's development organization, structure and development approach, as well as seeking evidence of their capability to comply with health authority and other standards and regulations (e.g., IEC 62304, ISO 13485, IEC 62366, ISO 14971, GDPR, HIPAA, HITRUST, etc.). Further, this team should evaluate the partner's quality systems, design controls, risk management, and other lifecycle management processes and procedures. Key to digital projects is assessing the partner's support of mobile OSs, handsets, browsers, etc. for clinical and launch platform support.

The legal team typically focused on contracts and intellectual property at this stage. They define the licensing/purchasing strategy and evaluate the partner's existing agreements and encumbrances. Define the preliminary IP strategy (e.g., patenting approach, trade secret expectations, etc.), perform a preliminary IP landscape evaluation based on the target product profile, and assess the relevant patents held by potential partners.

The IT cybersecurity/data privacy team develops a preliminary solution architecture in order to understand the roles and responsibilities of each party and any data interfaces between the partner and the pharma company. This team should also evaluate the partner's existing IT infrastructure to understand their organization, technical design, outcome of recent evaluations or audits, and generate a preliminary gap analysis against the pharma company's corporate/global standards.

Due to the novelty of some of these digital health solutions, there is often a lack of regulatory clarity in many markets. The regulatory team should develop a preliminary strategy based on the target product profile to establish: is the solution regulated as a medical device; the registration strategy (e.g., 510(k), CE Marks, *de novo*, etc.) A thorough evaluation of the partner's regulatory capabilities and capacity is critical to determine how much of the regulatory work the pharma team must own.

As digital health solutions proliferate, pharma is taking an increased interest in partnering or acquiring technologies that are synergistic with their portfolios. As such, it is critical for pharma to define the business need and strategic approach in order to guide a cross-functional team in the evaluation and selection of technology providers and solutions.

— Paul Upham, Director, Smart Device Technology Center, Roche/Genentech

Future Pharma: Data Science as a Strategic Partner

Leaders at Novartis share how the big pharma is laying the foundations for a potential new operating model as a ‘medicines and data science company’

By Julian Upton

At the beginning of 2018, Novartis CEO Vas Narasimhan spoke of reimagining Novartis as a medicines and data science company. The drugmaker was sitting on a “goldmine” of vast datasets, “built from having conducted countless studies in thousands of diseases.” Taking advantage of this “wealth of clean, curated, longitudinal, and interventional data,” Narasimhan explained, “has the potential to completely transform the way we develop medicines.”

Novartis had already begun signaling its commitment to the plan with a series of high-profile appointments of data science experts from outside the industry. In August 2017, the company hired Bertrand Bodson to the new role of chief digital officer. Bodson had no pharma background; he had previously served as chief digital and marketing officer for the UK retailer Sainsbury’s Argos, where he played a pivotal role in guiding the company’s digital transformation from a catalogue business “into a multichannel online powerhouse with more than a billion visits online annually.” Earlier, he had spent three years as Amazon’s senior group product manager. “The pharma space in particular is ripe for disruption,” Bodson commented in October. “Looking forward, data science will drive more of our decisions and more of our programs—including our medicines—will be digital.”

Following more appointments of data experts from outside the industry in 2018, *Pharm Exec* talked to two key players in Novartis’s push for digital transformation—Mimi Huizinga, vice president of strategic data and digital, and Miriam Donaldson, head of HR Digital—about how this influx of new talent is fueling a cultural change that is set to define the future of the drugmaker’s data science activities.

PE: Can you outline Novartis’s mission to transform itself into a medicines and data science company?

MIMI HUIZINGA: Novartis associates are learning to be data curious and more agile in how they approach their work. We are seeking ways to use



Mimi Huizinga, MD



Miriam Donaldson

data and digital to support every aspect of the company—drug discovery, trial planning, manufacturing, commercial operations, talent management, and many more. It is truly a transformative time.

MIRIAM DONALDSON: Through our digital transformation, we aim to be the leading medicine company powered by data and digital. If you look at external research about what leads to successful digital transformations, a common theme is capability building. This is a priority for us as well. We are looking at capabilities across three different populations at Novartis: all associates, our leaders, and our digital practitioners. We are building different capability solutions for each, as they have different needs from general awareness and understanding of the potential of digital to leading teams who feel empowered to experiment, to having world-class data and digital expertise.

Importantly, we want to encourage all of our associates to be curious, and feel comfortable around data and digital, and help us to see how these things can work better for us. We need to set them up for success to be part of that journey, so investing in their digital awareness and capabilities is really critical.

PE: What are the challenges in achieving this transformation? And what advantages do you have?

HUIZINGA: We want data and insights to drive our digital solutions, but healthcare data is difficult—the data is siloed with no single source of a complete, longitudinal record. This means that we have to deeply understand the data and its limitations to

ensure we use the right dataset for the question at hand—and that our analytics help to minimize the risk of false conclusions from the inherent biases in the data. We are not able to understand patient barriers in the care journey as rapidly as we would like and that slows our development of potential digital solutions.

DONALDSON: To lead a digital transformation, you have to be comfortable with failure. You

and former epidemiologist, I joined Novartis because of the core focus on patients. That focus really clarifies how we make decisions and set priorities. There is a fantastic set of data, analytics, and digital experts within Novartis. We are working now to create more connectivity across the company. Finally, having leaders that understand the importance of data, analytics, and digital makes a tremendous difference.

son team. Through his work there, he experienced many of the use cases we are looking to address and has learned what works and what doesn't. We believe that pairing that experience with our incredible in-house team of healthcare experts is going to be a powerful combination. Possibly most important with both of these leaders is that they have leadership styles consistent with the culture we aspire to and which we feel will engage our teams to work together in new ways to innovate in data and data science in close partnership with the business.

With the new talent we're acquiring, especially in the data science area, the questions we ask ourselves when they come into the company are: How do we set them up for success? How do we help them to understand our organization while also asking them to help evolve it? We're not trying to build a separate digital business, we want to transform our business using data and digital, which means integrating and influencing both what we are doing and how we do it. Specifically, we're focusing now on how we elevate data science at Novartis, which in the past has maybe been viewed more as a supporting function to our clinicians, and other types of scientists and reposition the organization as a true strategic partner to the business.

PE: *What specific initiatives and policies are you implementing to drive technological and cultural change?*

HUIZINGA: Broadly speaking, our activities fall into three buckets: data, analytics, and impact. For data, we are seeking to optimize the use of internal and external data while looking for new types of data that might provide value. We are working to

We're moving from rewarding individual heroes to teams that systemically solve problems and design innovations that scale

have to be excited to experiment, learn from what works and what doesn't and then act on it. You have to do it quickly and build solutions that you can scale. But that's not the culture we're starting from at Novartis. We have to help shape an environment where curiosity can really thrive and we have leaders who support their teams, not by telling them what to do but by creating a space where they can experiment and learn and not be frustrated if things don't work the first time. Novartis is also transforming from being a collection of seven interdependent companies into one integrated company. This idea of building solutions that scale across Novartis is new for us. There's a cultural aspect to this as well, we're moving from rewarding individual heroes to teams that systemically solve problems and design innovations that scale.

HUIZINGA: Novartis does have many advantages—our mission, our people, and our commitment to data and digital. As an MD

PE: *You've made key new hires from companies such as Google and Amazon. Can you talk about the importance of hiring from other industries?*

DONALDSON: We approached this as choosing people with the portfolio of skills and experiences that will be important for the transformation. It started with the hiring of Bertrand Bodson as our first chief digital officer, who came from Amazon and retail, and had no experience in pharma prior to joining Novartis. For other key roles, such as our head of data strategy and head of data science, it was important to us that the folks we hired at this level had experience leading transformations.

That's what led us to Raj and Shahram. Raj, for example, worked in the financial industry, which is also highly regulated and has some of the same challenges. He had successfully built data strategies in several banks and also worked at Google. Shahram helped to build the IBM Watson Health organization, a 4,000-per-

organize the data and enable access to all appropriate employees while keeping data privacy top of mind. In the analytics bucket, we are automating our core analytics so that we can free up our analysts to think about the business issues and more complex analysis. We are also using artificial intelligence and learning how to industrialize AI models in our daily work. In order to see impact, we use design thinking concepts to ensure that results are meaningful and that visualization tools are intuitive. We also look to see how we can automate pull-through and build digital solutions that fit within an associate's workflow and support the patient journey.

I am working to promote a data curious culture in our US Oncology group. I work in all of the areas—data, analytics, and impact. I love seeing the “ah-ha” moments and hearing about how we helped someone think differently about a potential opportunity. My job is to ensure that when we build the data infrastructure or the analytics framework, that it will be able to meet our evolving needs three to five years from now. To do that, I have to understand our business strategy and be able to translate the commercial and medical leaders' needs to our IT and analytics colleagues. On any given day, I may have conversations about our metadata management plan, detailed review of a Markov model we are bringing into production, brand level launch strategy, real-world evidence needs for a cost-effectiveness model, clinical trial feasibility, ideas for our next visualization product, and our website content management strategy. All of this makes my job challenging but very fun.

DONALDSON: One of the things we're doing in our capability-building is around teaching our leaders how to help teams who need to work differently, such as agile working, which has been really important in software development in other tech companies. It's a completely different way of organizing teams and pursuing the work that needs to be done. This

I love seeing the “ah-ha” moments and hearing how we helped someone think differently

is one of the ways that we're trying to get teams more comfortable with the rapid innovation cycles, customer-centric solutions, and building solutions we can scale.

For things this agile to work at Novartis, our leaders need to lead differently. We're building a program that we call Digital Immersion for Leaders, which is a three to four-hour experience for teams. It's kind of a “choose your own adventure,” where we build cases around different scenarios at Novartis. We show leaders how digital is already changing the work we are doing and provide them with some leadership challenges, so that they see the impact that they have on teams who are trying to innovate, and work in the way that we aspire to—and all while seeing how these solutions address their real business challenges. We launched a beta version of this program to our top 300 leaders back in September, and we will be rolling it out to the larger company over the next several months.

PE *How will the next couple of years play out in terms of the transformation?*

DONALDSON: Now that we have our heads of data strategy and

data science onboard, we are ramping things up quickly. So, I expect in 2019 that we're going to be making a lot of hires in that space. And as our associates, leaders, and practitioners benefit from our investments in their capabilities and our culture and ways of working evolve, we think it will feel really exciting to work at Novartis. Almost every ele-

ment of our business can be touched by this transformation, so that we can make smarter decisions based on data that help us bring meaningful medicines to patients faster.

HUIZINGA: I have been amazed at how much we have accomplished since I joined in August 2017, but that work was largely foundational. We have really gained momentum over the last three months. We have a few tools deployed to the business and great engagement of our leaders. We are planning to launch an internal visualization tool [this month] that will provide deep insights to our commercial leaders. Our goal is that these tools will help the leaders ask better questions faster.

We have industrialized one AI model and over the first half of 2019, we will be testing the limits of that model to understand when we need to refresh and rebuild. We will also place the outputs of a second AI model into pilot mode during that time.

By mid-2020, our goal is that everyone in US Oncology will have a unique visualization product that supports their work and that stems from a common set of data and analytics. 

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TURKEY

GO BEYOND

Turkey stands out as one of the world's most interesting healthcare and pharmaceuticals markets in 2019. It is a country that occupies the grey area between being a developed and an emerging market – it, at once, displays the traits of an “emerged economy,” with a mature universal healthcare and reimbursement system, as well as traits of a developing country, with capricious currency fluctuations, political tensions and untenable trade deficits denominated in foreign currencies.

So, what is the international pharma community to make of this country of over 80 million people? There are several key trends and characteristics of the Turkish healthcare and life sciences ecosystem that are not often publicized in the international press – first among them being the country's remarkable, rapid Health Transformation Program (HTP) that has elevated the nation's health system to an advanced level in the matter of a decade. The second is the highly nuanced debate over the Turkish government's reimbursement policy, wherein a fixed exchange rate and discount requirement, which, especially given the current economic climate, poses a variety of problems for both Turkish and international firms. Thirdly, the country has recently embarked upon an ambitious localization campaign, a move that, depending on its execution, could either turn Turkey into a health-independent exporter or a country populated by simple generics manufacturers, bereft of R&D activity.

“Despite persistent market access hurdles, there is no doubt that Turkey's pharmaceutical market holds tremendous growth potential both in terms of value and volume,” summarizes Gilles Renacco, general manager of Servier Turkey. Furthermore “there is skilled, energetic, and driven talent here, dedicated to moving the country forward,” highlights Dr Fabrizio Guidi country chair & general manager Rx at Sanofi Turkey between January 2015 and November 2018 and Sanofi's general manager primary care GBU Germany, Switzerland and Austria and country chair Germany since January 2019.

What remains to be seen is how the country is able to take that final step in creating a regulatory and economic environment that is conducive to further growth – very few, though, would deny that all of the pieces are in place for Turkey to indeed go beyond.

HEALTHCARE: RAPID DEVELOPMENT AND ECONOMIC UNCERTAINTY

The Turkish government has, for the past 15 years, understood very well that establishing a strong healthcare apparatus is crucial to attaining broader economic development. “Despite possessing a relatively medium-sized population in comparison to some emerging countries, Turkey is notable for its universal health scenario, whereby over 99 percent of the population is covered by a nationwide social security system,” explains Hakan Yurdakul, head of economy monitoring and coordination at the Presidency Office of the Republic of Turkey.

The Turkish government’s success in ramping up the healthcare apparatus has indeed been “eye-catching.” But how exactly did the country manage to establish such an advanced universal healthcare system in the matter of a decade and a half?

“When the AK Party entered government in 2003 after a steep economic crisis, Recep Tayyip Erdoğan [who was serving as Prime Minister at the time – Ed.] established the comprehensive overhaul of health as a priority. This vision translated into the HTP,” explains Prof. Dr Sabahattin Aydın, rector of Medipol University, chairman of the Executive Council of TUSAP Healthcare Platform, former executive board member of the World Health Organization (WHO) and former deputy undersecretary (2003-2010) at the Turkish Ministry of Health.

Aydın credits a few key measures that the government implemented to ensure the HTP was effective. “A first success factor I would highlight is that we aimed from day one to harmonize health benefits for the entire population, and not only for the people that had existing health coverage,” he says. “Political stability also emerged as a crucial enabler of health reforms: for example, when we started designing the HTP, we found out that its full benefits would materialize in the 2030s! In this context, one easily understands why it is typically hard for politicians to invest political capital into bold, health-related programs, whose results will not appear before the next election cycle. Turkey’s political stability since 2003 has provided us with the time, continuity, and consistency to successfully implement the HTP.”

Moreover, “one of the priorities in the Turkish government’s ongoing ‘Vision 2023’ has been to further refine the Turkish healthcare infrastructure and underlying technologies; and the method of achieving this has been to deploy private-public partnerships (PPPs) to establish so-called ‘city hospitals’ which strive to provide high quality healthcare services at an immense scale,” recalls GE Healthcare’s general manager, Yelda Ulu Colin. “For instance, Ankara Bilkent Hospital will be the biggest hospital in the entirety of Europe when it finally opens its doors in Q1 2019 and there are no less than 29 PPP health campus projects already planned in Turkey, of which eight are already operational,” she elaborates.



Hakan Yurdakul, head of economy monitoring and coordination, Presidency Office of the Republic of Turkey; Dr. Fahrettin Koca, minister of health; Dr. Hakkı Gürsöz, president, TiTCK



Prof. Dr. Sabahattin Aydın, rector of Medipol University and chairman of the Executive Council of TUSAP Healthcare Platform

GE’s own involvement is perhaps testament to the sophistication of many of these new initiatives. “We provided more than 90 percent of the medical equipment installed in Mersin – Turkey’s one of the very first operational PPP hospitals – introducing and installing top range and technologically advanced solutions from imaging devices to ultrasound to lifecare services,” reveals Yelda Ulu Colin.

Meanwhile the accomplishments of these ongoing efforts are increasingly recognized. “Healthcare accessibility is no longer a main issue for this country...

This is because we have successfully managed to ensure that people can these days seek treatment without having to worry about financial risks,” proudly affirms Dr Fahrettin Koca, Turkey’s Minister of Health. “Primary care services are recognized and have become publically available in the true sense.... Moreover, according to the OECD health data and European Commission reports, Turkey now ranks highly for satisfaction and services as soon as corresponding levels of expenditure are taken into account,” he adds. “Now, the health services in both the public and private sector in Turkey are of the same quality as those in the developed countries of the world,” confirms Mehmet Ali Aydınlar, chairman of the board and CEO Acibadem, a leading Turkey-based healthcare group boasting 22 hospitals and 16 medical centres throughout Macedonia, Bulgaria, the Netherlands and, of course, Turkey.

Further abetted by political support from then-Prime Minister Erdoğan, the HTP has simultaneously played a role in reconfiguring medicine access pathways, notably triggering the creation of a new drug regulatory authority. “The Ministry of Health conducted a comprehensive assessment and came to the conclusion that Turkey should follow the example paved by many developed and developing countries when it comes to handling regulatory and inspections functions. This led to the creation of the Turkish Medicines and Medical Devices Agency (TiTCK) in November 2011,” says Dr Hakkı Gürsöz, president of TiTCK.



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Despite the advances in science, health issues are getting ever more complicated. The number of people who lost their lives in 2015 due to non-communicable diseases reached 40 million.¹ There are more than 7,000 rare diseases in the world and 80% of them are genetic diseases.² Each year, more than 2 million children die because of lack of access to vaccines.³

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SANOFI  *Empowering Life*



Fabrizio Guidi, country chair & general manager Rx, Sanofi (Jan 2015 – Nov 2018); Philipp Haas, chairman and CEO, DEVA; Abidin Gulmus, founder and chairman, Gen Ilaç

The sudden maturity of Turkey’s healthcare and life science landscape leads stakeholders to question whether or not the country can still be considered an emerging market. “When I think of Turkey as a ‘pharmerging’ market, I am of two minds because it has traits of an emerging market, but it is also now rather similar to many other developed countries around the world,” opines Dr Erdal Bozdoğan, general manager of Takeda. “Looking at Turkey from a pharmaceutical and healthcare perspectives, the country immediately stands out for its well-established regulations, which contributed to establishing Turkey as a role model among other emerging countries, alongside South Korea and Taiwan. Turkey’s

well-monitored pricing and reimbursement system is also particularly centralized, which affords a remarkable efficiency in providing access to the entire population.”

While it is advanced in some regards, Turkish pharma nonetheless still possesses many characteristics of an immature market in the eyes of MNCs. “Marketwise, Turkey shares with other pharmaemerging countries the tendency to hold a dense, generic-oriented domestic industry, which has gained a strong presence in the market top 20,” explains Gilles Renacco, general manager of Servier. “Turkey’s remaining market access hurdles throughout drugs approval, pricing, and reimbursement processes are also rather typical of a pharmerging market.”

Thus, Turkey stands at a crossroads – public health enjoys priority status from the government, yet key obstacles within the business operating environment need to be resolved before the pharma and medical device industries start to regard the country as a real ‘power market.’ “The government did well in implementing a reconstructed healthcare system while managing costs,” notes Dr Fabrizio Guidi, country chair and general manager Rx from January 2015 to November 2018 at Sanofi. “However, looking at the total spending, only five percent of Turkey’s GDP is allocated to healthcare, although the level of public coverage is quite impressive despite the relatively conservative expenditure.”

“We have the strength to become a serious global player,” concurs Turgut Tokgöz, secretary general of the Pharmaceutical Manufacturers Association of Turkey (IEIS), “but the current regulatory framework is hindering the industry from realizing that next step.”

PERNICIOUS PRICING POLICY

That established, the primary regulatory challenge facing the Turkish pharma sector today is the government’s pricing policy. “Turkey’s reference pricing system was implemented in 2004.

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Source: IMS Dataview – 05/2018

Emerging Markets Mastery



Gilles Renacco,
general manager,
Servier

In recent years, Servier has built up an extremely strong footprint in emerging markets. China already stands as the company's strongest international affiliate, while its operations in Russia reel in more than USD 250 million in annual revenues. That established, how does Turkey fit in to Servier's global strategy?

"There is no doubt that Turkey constitutes a priority for Servier Group," professes Gilles Renacco, general manager

of Servier Turkey. "The local affiliate is moreover expected to be one of top three fastest growing affiliates of the group (in turnover) in 2018, with a targeted 23 percent growth in

value and a double-digit objective in volume. With regards to volume, Turkey is already the third country within Servier Group, behind Russia and China."

Servier's success in Turkey is largely due to the company's masterful anticipation and adaptation to Turkey's localization policies. "Servier was indeed among the first movers in this regard because my predecessor and our local Turkish team swiftly identified the potential positive outcomes that localization would usher in for the affiliate, the Group at large and Turkish authorities," says Renacco. "Servier's HQ realized that this model would enable to meet our company's quality standards while displaying an improved cost efficiency. Today, 98 percent of Servier products sold in Turkey are locally manufactured."



Turgut Tokgöz,
secretary general,
IEIS

Introduced to contain costs as coverage increased, the system allows prices in Turkey to be determined based on the lowest price amongst France, Spain, Italy, Portugal and Greece. On top of this, Turkey also adds mandatory discounts on both innovative and generic drugs," explains TiTCK's Gürsöz.

However, the aspect of the pricing policy that most binds pharmaceutical companies is not the referencing, but rather the fixed exchange rate for reimbursement – particularly now, as the Turkish lira has fallen more than 30 percent in value since this time last year. "Although this system is particularly satisfactory from a government perspective, we understand that it also entails complications for the industry. Today, TiTCK's fixed exchange rate revolves around EUR 1 being equivalent to TRY 2.69, despite EUR 1 being equivalent to around TRY 6 at current market rates," continues Gürsöz.

This artificially low exchange rate, on top of the already low prices guaranteed by the government's reference system and discount policy, creates a serious profitability problem for pharmaceutical and healthcare companies, primarily those that rely on intermediary products denominated in foreign currency.

"The main problem is the fall of the Turkish Lira, which not only effects the imports and exports deficit, but also TiTCK's price reference system," claims Hakan Koçak, CEO and general manager of Koçak Farma, a leader in the area of oncology in Turkey and producer of half of the oncological products purchased in the country. "Another problem for domestic companies is that we

are importing APIs from abroad in either euros or US dollars, so it is important to bridge this deficit gap. Inflation has increased 13 percent in 2017 and is continuing to increase, which will not help the import and export deficit either."

"It is quite hard for foreign managers to wrap their heads around Turkey," comments Ismail Yormaz, vice president &



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Mehmet Ali Aydinlar, chairman of the board and CEO, Acibadem

regional director southeast at Recordati İlaç. “You have to explain to them the exchange rate policy, the devaluation of the lira, the discount policy, and so on... Turkey is tough to analyze.”

Moreover, as companies cannot reap a profit by registering the most advanced, costly-to-produce products with the social security system, they decide simply not to register; rather, they use the government’s named-patient program that allows them to sell on a per-patient basis in a foreign currency.

“Nobody wants to come and register in Turkey because Turkey’s prices are used as a reference in other countries. Registering here would reduce their returns elsewhere. This is why many companies prefer to sell through the Turkish Pharmacists Association’s special access program, which lets them sell in euros,” notes Dr Orhan Mutlu Topal, general manager of Emre Ecza, an ambitious local vaccine producer.

It is true that investors, particularly internationals, are dissuaded from entering the Turkish market with certain product lines. “The local exchange rate is simply too low,” announces Recordati İlaç’s Yormaz. “Running a pharmaceutical company in Turkey is a bit like building a ship in a bottle – you want to build an extraordinary product, yet the environment prohibits you from doing so, granting you only a small opening from

which to operate. As they continue to narrow the bottleneck, it becomes more difficult for us to build our “ship.”

Other companies are also feeling the constraints. “Industry growth in Turkey essentially comes from mature products; however, innovative companies’ sustainability is sourced from new molecules. In order to reach sustainable progress and promote innovation in the pharmaceutical industry, the prices of the products really have to be reasonable for both parties,” points out Sanofi’s Dr Guidi.

Dr Altan Demirdere, president of Novartis Group Turkey and head of Sandoz Turkey, points out that the government budget is simply too small to respond to national demand. “Local drug consumption per capita is around USD 60-70 per year. The average consumption per capita of the five countries in Europe with the lowest drug prices is around USD 600 per year,” notes Demirdere. “This makes you ask yourself: Are the five cheapest European countries significantly richer than Turkey? Or do they just care more about their pharma industries’ future and the health of their people?”

The pricing pressure additionally exacerbates the already high costs of marketing in Turkey. “The value chain of the industry begins with the pharmaceutical companies then passes through doctors to pharmacies and finally finishes with the patient. The doctor is the king of the prescription – without communication to doctors, a company in Turkey will not succeed,” adds Tahsin Yüksel, general manager of Teva. “Therefore, the promotional expenditure in Turkey is often greater than in other emerging markets.”

Time to Introduce “Command & Control” to City Hospitals?



Yelda Ulu Colin, general manager, GE Healthcare

GE Healthcare is a familiar face within the fabric of Turkey’s national healthcare infrastructure. Indeed, the med-tech integrator has been servicing hospitals and clinics up and down the country for some three decades and now claims an installed base of over 59,000 units of medical equipment spread across more than 3,000 care institutions. With the country having embarked on an ambitious construction spree of PPP-financed healthcare mega-structures, however, the opportunity is now presenting itself to be especially radical.

This is because, globally, GE Healthcare is the proud pioneer of a disruptive new concept of hospital management that borrows mechanisms from other disciplines such as the command systems of air traffic control in the aerospace industry. As healthcare providers seek out ways to boost the efficiency of their operations so they can continue to deliver high quality care as patient volume increases, GE’s algorithm backed ‘Command

Centres’, in essence, strive to harness digital technologies like AI with a view to deftly orchestrating the delivery of care across the hospital structure thus bringing consistency to processes, prioritising actions, eliminating waste and predicting tomorrow’s pressure points.

The question now is whether Turkey is ready for such a radical step. “Honestly, I think that the PPP hospitals in Turkey are perfect candidates to implement GE’s Command Center. This is a service providing high technology, IT and monitoring systems that thoroughly keep track of a hospital’s KPIs. We have already successfully rolled out this concept in the United States’ Johns Hopkins Hospital and Canada’s Humber River Hospital, and it has been proven truly transformational,” enthuses GE Healthcare’s general manager, Yelda Ulu Colin.

“It is worth bearing in mind that this one-of-a-kind solution enables administrators to anticipate logistical overflows in early stages and prevent any bottlenecks, which is an absolute necessity in Turkey’s new PPP hospitals given their considerable size and patient flows, not to mention the complexities of the multi-stakeholder services stipulated the concession agreements,” she contends.

The government has recognized that the industry is feeling the pinch from its pricing policy, though, and diminished the gap between the artificial and market exchange rates – however, some companies feel that this measure is not enough. “Beginning 2018, as a consequence of some economic and fiscal concerns, the exchange rate adjustment that should have been around 23 percent was capped at 15 percent with the introduction of a temporary provision to the related decree,” argues Pfizer country manager, Elif Aral. “Moving forward, the policymakers must consider how they will ensure that Turkey does not become a second rate destination for innovation. It becomes difficult for pharmaceutical companies to invest in Turkey because they cannot afford to sell new, life-changing products at the current price points. Industry concerns must be addressed to maintain access to innovation and the government should be selective to decide where they can allocate a greater budget,” adds Sanofi’s Guidi.

Some local companies in Turkey, however, are using the pricing pressure as an advantage. “There is a saying that in crisis there is opportunity for those who are willing to take it,” notes Philipp Haas, chairman and CEO of Deva, one of Turkey’s largest domestic pharma companies. “This difficult moment has created several openings in the market for our portfolio. For example, there are some imported originator products, for which foreign originator companies are not supplying the market



Erdal Bozdoğan, general manager, Takeda; Erdoğan Çolak, president, Turkish Pharmacist Association; Dr. Ümit Dereli, secretary general, AIFD

anymore, most likely because prices are no longer covering their costs. Deva is taking such opportunities and supplies the market with its own, locally produced products.”

Abidin Gulmus, founder and chairman of Gen Ilaç, Turkey’s principle orphan drug distributor, similarly sees opportunity. “Looking at the drug prices in Turkey against the prices in Europe, it is incomparable. Being able to compete in Turkey, a very difficult market with low margins, has prepared Gen Ilaç to compete in Europe as well. With products manufactured in Turkey, we will be able to penetrate the European markets with more affordable products.”

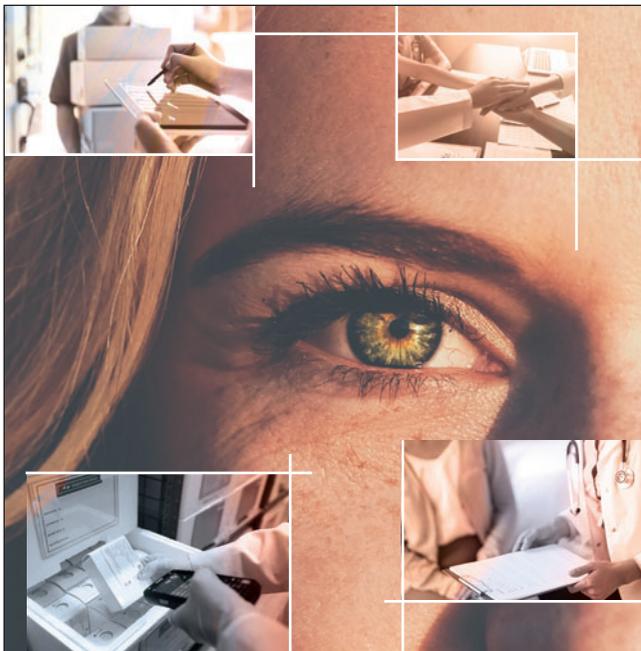
At the end of the day, while the pricing pressure is indeed shaping the Turkish market, some players believe that its significance is overstated. “There are rumors that some companies are going to leave Turkey, but at this stage, they are only rumors. I would be surprised if companies actually did pull out of Turkey, regardless of what we hear,” mentions Sonay Gürgen, chairman of the board and general manager at Selçuk Ecza Deposu, Turkey’s largest pharmaceutical distributor. “We are a country of 80 million people with tremendous growth potential in the pharmaceutical industry. Yes, they may grumble about leaving, but I haven’t seen it happen and I don’t expect it to. When things finally turn around for Turkey, they will all want to have a presence here.”

LOCALIZATION: LIFTING THE DOMESTIC INDUSTRY?

Alongside the debate over domestic reimbursement pricing policy, a key reform that has shaken the industry is the government’s localization policy, enacted in 2016 to encourage industry to set up shop in Turkey – and a little over two years later, it seems to be working.

“The share of locally produced medicines in the Turkish market increased from 42 percent (in value) in 2016 to 45 percent in 2017, while rising from 15 percent to 18 percent for locally manufactured medtech products,” notes Dr Hakkı Gürsöz. “Moving forward, a first satisfactory step would be to reach 60 percent of locally produced medicines and 20 percent of locally manufactured medtech products in the Turkish market.”

The government believes it is a crucial step to achieving technology transfer and building the country’s healthcare industry



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Elif Aral, country manager, Pfizer; Tahsin Yüksel, general manager, TEVA; Selim Giray, VP, general manager, GSK

– however, it is very aware that the execution of the policy will be key. Says Hakan Yurdakul from the Presidency Office, “Although localization has gained momentum in the agenda of almost all emerging countries, it is a very broad concept that does not have the same meaning across markets. In some cases, localization entails manufacturing products in a given country by exclusively leveraging its resources and human capital – a 100 percent domestic model.”

“On the other hand, the second common model of localization is to mandate that multinational companies in the market locally manufacture products while still using their own IPs

and procedures – and just outsource low added-value manufacturing to local companies while completely blocking the latter’s development, presales and sales functions that would enable growth potential. These are the two models of localization typically enacted across the world, but we do not believe either option can satisfy the needs of the Turkish ecosystem.”

“In the grand scheme of things, we believe that balance is achievable only through extensive collaboration and coordination between local and multinational companies, under the guidance of the government,” continues Yurdakul. “The crucial aspect at hand is however to identify the key competencies a country needs to nourish localized production: there must be a strong base of market resources, a close partnership with already existing, local entities, and – finally – strong trade relationships with other countries to meet the scale of size needed to sustain localization from an economic perspective.”

“The pharmaceutical industry for Turkey falls under the top five most important areas for economic development. Our approach explicitly involves the cooperation of private sectors, university and state sectors to domestically produce and export medicines. We do not make any distinction between a domestic and foreign company that produces in our country, as long as they support us we will also support them,” clarifies health minister Koca.



Recordati, established in 1926, is an international pharmaceutical group, with a total staff of more than 4,100, dedicated to the research, development, manufacturing and marketing of innovative pharmaceuticals in many therapeutic areas, including a specialized line dedicated to treatments for rare diseases, that improve quality of life and help people to enjoy longer, healthier and more productive lives. Recordati has operations throughout the whole of Europe, including Russia, Turkey, North Africa, the United States of America, Canada, Mexico, some South American countries, Japan and Australia. Recordati is present **in Turkey since 2008** with its subsidiary Recordati Ilac.





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Hasan Ulusoy,
chairman, Nobel

Several firms in the Turkish market are fine with the localization policy, as Turkey is already a strategic country. “The country has historical and geographic advantages that make trading with the Balkan countries, Russia, the CIS region, North Africa and the Middle East quite easy,” comments Recordati İlaç’s İsmail Yormaz. “Turkey has a strong transportation infrastructure and it is accessible – within a two-hour flight, we can reach dozens of countries. Our potential for expansion from this affiliate is nearly limitless.”



M. Sonay Gürgen,
chairman of the
board and general
manager, Selçuk
Ecza Deposu

Many companies are sympathetic to the government’s viewpoint, yet only so long as Ankara holds up their end of the bargain. “In the grand scheme of things, one should nonetheless keep in mind that many emerging markets are pushing for localization, and the Turkish affiliate is competing with Russia, Algeria,

and others for corporate funding to cope with the trend,” says Sanofi’s Fabrizio Guidi. In order for Turkey to be the emerging market of choice in the region, Servier’s Gilles Renacco, stresses, “more predictability and stability are however required to convince multinational companies’ top management to further invest in the country. This applies to registration timelines, price levels, reimbursement negotiations, as well as to the control of parallel exports, which has been a growing problem in Turkey.”

Nonetheless, the government has also faced outright pushback from companies, particularly internationals that

feel their products are either capriciously de-listed from reimbursement or believe that the government is not putting in place proper incentive structures. “Furthermore, medicines impacted by these localization policies are off-patent generics, a product category where economies of scale truly matter to reach targeted affordability,” observe Dr Ümit Dereli and Cengiz Aydın of the Association of Research-Based Pharmaceutical Companies (AiFD). Pfizer’s Elif Aral echoes this sentiment, insisting, “instead of forced localization policies, strategies and actions to enhance R&D and therefore global competitiveness would do better in strengthening Turkey’s overall investment ecosystem.” Many worry that the government’s policies will simply set up a hotbed for simple generics producers, chasing away firms that are focused on innovation.

Others see empowering local manufacturing and researchers as a necessary first step to development. “Some foreign companies decided to forge strategic partnerships with Turkish companies, including contract-manufacturing services. However, conceptually speaking, we do not want our domestic industry to turn itself into a contract manufacturing basis for foreign companies, and we expect that the extra resources gained through manufacturing partnerships will be channeled into R&D projects, the development of these companies’ product portfolios, as well as into the expansion of their own manufacturing capacities,” posits TiTCK’s Hakkı Gürsöz.

“If you can find success as a contracting hub, money will flow, investments will be made, and technology will be transferred,” opines Turgut Tokgöz. “Sometimes, contract manufacturing sectors can become so successful that they turn into formidable exporters. Contract manufacturing is not inherently something to undermine, particularly when a country has excess capacity.” And there is merit to this claim, as evidenced by the wave of Turkish firms that have their sight set on overseas markets.

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Levent Canyurt,
CEO & founder,
BIEM İlaç

For many home-grown Turkish pharma players, the road to export has been one of great internal transformation. Orphan drug producer, BIEM İlaç, for instance, started out as the exclusive Turkish importer-distributor of Cutter, Miles Bayer and Talecris for products treating blood-related diseases. Then, in 2011, the company terminated these distribution agreements electing instead to produce its own products right from scratch. The subsequent leap forward, in 2015, was to spread its wings and commence penetrating overseas markets to the point where it today maintains a presence in 22 markets spread out across 4 continents.

The secret to such prolific expansion lies in shrewd partnering. "In general, crafting smart partnerships has been our preferred way to internationalize... Our experiences tell us that joining forces with distributors, that know the target market inside out can be very fruitful and has worked very well for us in the past, so we tend to

favour this option over just going into unfamiliar markets and setting up our own affiliates," reasons Levent Canyurt the company's CEO & founder. "As such, we have already forged strong collaborations with entities like UrsoPharm in Germany, Panacea Biotech in India, Farma-Derma in Italy and Dongkook in Korea among others.

Interestingly, the willingness to partner in the quest to go global also extends to teaming up with other contract manufacturers. "The European market is our preoccupation at the moment, however, our long-term vision is, of course, to introduce our products to the United States as well," confides Canyurt. "Right now, we are working with three contract manufacturers with regard to the European marketplace, whom don't yet hold the requisite GMP certification from the EU...Our manufacturing partners nowadays include such highly-prized players as Birgi Mefar, İdol İlaç and Mustafa Nevzat, which is actually owned by Amgen. Targeted product acquisitions, in-licensing new opportunities and forming mutually beneficial business alliances are thus central to our strong growth performance," he explains.

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EYING THE EXPORT MARKET

Seizing the cost competitiveness of the Turkish market and the government's nurturing of local manufacturing, Turkish companies are looking to harness their geographic positioning and export to developed and developing markets alike.

"Although Turkey constitutes our manufacturing base, our objective is to supply our products to both developing and mature markets, such as the US and Europe. When preparing for such a strategy, we have anticipated the need to

develop our manufacturing capabilities to serve not only the Turkish market, but also abroad. Currently Deva manufacturing sites have US FDA approval. Since 2011, all our production facilities have also been approved by European health authorities, so we already operate under US and EU GMP standards, both for the Turkish and international markets," says Philipp Haas, Chairman and CEO of Deva, the first sustainable mover to the US market to emerge from the Turkish industry.

The country seems to have all the pieces in place for establishing a strong export sector. "The country possesses a well-educated, highly motivated, and professionally ethical workforce. This is very important in regard to exporting; establishing credibility with foreign regulators is imperative to our strategy," continues Deva's Haas. "By leveraging Turkey's image of professional reliability, we can circumvent many of the challenges being faced by other pharmerging markets."

Deva is not alone in leveraging and exporting Turkey's expertise, and the government's gamble in protecting local industry seems to be paying off – Birgi Mefar and Berko İlaç serve as other examples. "We did not shy away from entering the most advanced healthcare ecosystems," says Berko İlaç's general manager, Barış Özyurtlu, whose company - one of the fastest growing pharma companies in Turkey - has already caught the attention of several partners in the US and Canada. "We completed US FDA certification in 2016 and today we are providing our US and Canadian customers with our flagship iron solution FeriFer. We pride ourselves on being one of the very few Turkey-based companies to already export products to North America. More importantly, we are delighted to highlight that it is our proprietary presentation form – Berko's 5 ml single-use PET/PE spoon – that caught the attention of these partners, rather than our business development efforts. This unique



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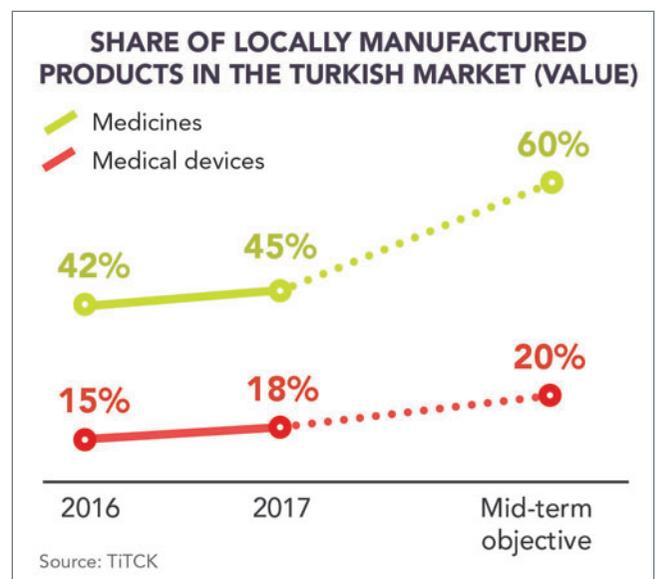
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Birgi Mefar: From CMO to Exporter



Mehmet Baharoğlu,
logistics and
export business
development
director



Beril Tezcanli,
quality group
director and QP

Through enacting localization policies, Turkey hopes to bolster its pharma sector and eventually foster an environment in which domestic contract manufacturers become exporters themselves. As a case study that shows the viability of this strategy, stakeholders need look no further than Mefar.

“Birgi Mefar is an integrated group of three companies. Mefar, the toll-manufacturing arm of the group created in 1985, stands out as Turkey’s leading CMO for small and medium volume injectable dosage forms with full-service analytical labs,” says Mehmet Baharoğlu, the Group’s logistics and export business development director. But, the group has become much more than a contract manufacturer in recent years.

“We pride ourselves on having one of the most comprehensive portfolios in the world in our areas of focus, even in comparison to the largest CMOs globally. As a specialized manufacturer of sterile and injectable solutions, Mefar leverages the unique expertise and flexibility of its sister company, Birgi, Turkey’s largest primary packaging manufacturer of empty ampoules and empty vials which was founded in 1963. Overall, Mefar utilizes around 60 percent of Birgi production, while the rest is exported to international customers based mainly in the EU. Moreover, the Group also includes a GMP logistics operation, Defar.”

“The overarching strategy of the group has always been to develop itself into a vertically integrated player,” agrees Quality Group Director and QP, Beril Tezcanli. “Birgi Mefar’s scope of services covers laboratory and regulatory support services (Mefar), the production of empty ampoules and vials (Birgi), toll manufacturing and packaging of products (Mefar), and – finally –services through Defar. We are truly able to operate as a one-stop shop service provider for a large part of the Pharmaceutical value chain, which has caught the attention of 100+ leading, domestic and global customers,” she adds.

Having become a vertically integrated company, Birgi Mefar has shifted his focus overseas. “Over 30 percent of our turnover comes from international operations, and our current partners hail from over 37 countries, so we are far from being newcomers on the global stage. We already are well known among parts of the global industry and – through decades of experience with international clients – have built a strong customer network, which we aim to further leverage to increase our international business through making our customers’ more competitive in their given markets,” confides Baharoğlu.

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Taking the Lead in Clinical Research



Sule Mene,
founder and CEO,
MENE Health
Group

Alongside the boom in local manufacturing and exporting, Turkey is witnessing a burgeoning of its research ecosystem. Sule Mene, co-founder and CEO of Mene Health Group, explains how her company is capitalizing on its strength in the research sphere to become a vertically integrated, internationally-minded company.

“Mene Research was the first Ministry of Health-approved CRO in Turkey and experienced initial success,”

comments Mene. “In the meantime, we swiftly understood the importance of providing a complete set of services for investigational medicinal products (IMPs). As a result, we incorporated Depot Meridian, the drug storage arm of the group, the first clinical trial specific warehouse to be accredited by the Ministry of Health.”

“With the increase of temperature-sensitive biotechnology products, handling IMPs has become even more challenging, while an increasing emphasis is put on cold chain management from a regulatory standpoint,” continues Mene. “As a result, we built another department focusing only on the temperature-controlled transfer of IMPs, Merid-

ian CSL, which is responsible for distribution and collection of clinical supplies, transportation of temperature-sensitive products in controlled vehicles or passive shippers, management of destruction services, as well as document management and biological sample retrieval for storage.”

On top of the aforementioned services, Mene Health Group has opened MENE SMO, which provides site management organization services. With strength in the Turkish market established, Mene is now focusing on overseas markets. “Expanding overseas, Mene Health Group opened an arm in the US focused on medical device studies and recently established operations in Europe, the Balkans and Asia,” she says. “We are also planning to enter two additional countries in Europe. In 2018, there are many economic difficulties both in Turkey and globally, but we will not be stopped by this challenge. On the contrary, we continue to grow and in the next few years, we plan on being present in five countries across three continents.”

With a highly educated population and increasing government support, Turkey is eyeing a strengthened research capacity in coming years – and Mene Health Group serves as a model to follow for other Turkish research organizations.

spoon-shaped presentation form required six years of in-house development to meet requirements in terms of product stability and it is particularly adapted to the needs of children and elderly patients. Moving forward, we are ready to transform any of our international partners’ products into single-use spoons or other reservoir capped syrup presentation forms.”

The government is dedicated to helping groups like Deva, Mefar and Berko Ilaç further penetrate international markets. “We have already reached a great milestone on the inspection side with Turkey’s entry into PIC/S (Pharmaceutical Inspection Co-operation Scheme), and we are now looking at replicating a similar success for regulatory matters,” exclaims Hakkı Gürsöz. “In this vein, we want to strengthen our collaboration and relationships with leading health organizations such as the WHO as well as with the most respected regulatory authorities in the world, including the US FDA and the EMA.”

Industry has noticed the government’s efforts. “In terms of exporting opportunities, the government is doing well to encourage the development of this area,” comments Gen Ilaç’s Abidin Gulmus. Moving forward, the obstacle standing in between Turkey and the international marketplace will be the country’s ability to help their companies maximize profitability on the international stage.

“Unfortunately, foreign markets look at the price of our products in Turkey and ask for the same price, which is impossible to adhere to due to the discounted prices we sell our products

to Turkey’s SGK to in order to be reimbursed,” mentions Koçak Farma’s CEO Hakan Koçak. “The only solution to this would be to keep the discounted price – which is on average reduced by 28 percent – a secret, in order to increase competition and fairness when exporting our products abroad.” “The government’s pricing policy holds strategic importance, and one must ensure the latter allows domestic companies to re-invest their profits into value adding activities: R&D and exports. In this regard, one may regret that government support is so far essentially limited to R&D endeavours and there must be some developments for strategic export support, given the fact that developing an international presence also requires high marketing investments,” highlights Berko’s Özyurtlu. “Reducing Turkey’s trade deficit is a priority of the government and we believe that the pharmaceutical sector has a great role to play in fulfilling this objective; however, we need dedicated support to accelerate the penetration of Turkish products or Turkey-made technology into international markets.”

VISION 2023 AND BEYOND

Alongside the export push, Turkish pharma is focused on some of the global trends shaping the healthcare industry: namely, strengthening the biotechnology sector, bringing specialty care and orphan drugs to the market, and coping





Altan Demirdere,
president,
Novartis Group &
head, Sandoz

with an impending epidemiological shift. “Biologicals are the next big opportunity for the country, thus we are already investing in this area,” comments Hasan Ulusoy, chairman of Nobel, one of the country’s leading pharma companies. “The biotechnology landscape here is interesting, with the market share of these products in volume only worth two percent whereas their value already accounts for 20 percent of the market and is continuing to rise.”

Industrial actors think that the regulatory environment needs improvement insofar as biological development is concerned. “The government has created some incentives for the industry to participate in this vision, but sometimes this is not enough. The main idea is a purchasing guarantee that if a biological product is developed in Turkey, the government can give a payment guarantee for the next seven to ten years,” says Hakan Koçak. “In addition, they offer a tax allowance as financial support, but this is only once you sell the product after years of development and production. The government does not take any tax from this sale, but the process is long. If we make an investment today, we will only reap the rewards five to ten years later.”

Gen İlaç’s Abidin Gulmus concurs, urging the government to offer help in R&D. “Biosimilar products require a large investment to conduct clinical trials, occasionally greater than the cost of development for the drug itself,” he says. “Biosimilar products must be proven to be equivalent to the original; in order to do this, a trial of 200 to 300 patients must be conducted, the cost of which can range from USD 150 million to USD 250 million. It is impossible to take this financial risk without government support.”

A greater willingness on the part of companies to work with one another could also offer some respite. “Turkey is currently far behind other states in terms of cultivating a biotech ecosystem, with only eight to ten companies active at this point. Moreover, Turkish biotechs are usually developing products based on the same molecules, so greater collaboration would save a huge amount in terms of costs, as we are essentially working on products for the treatment of the same diseases,” muses Biem İlaç founder and CEO, Levent Canyurt.

On another note, given that 50 percent of the Turkish population is below the age of 32, healthcare companies and providers are busy devising ways to fit their portfolio to an impending epidemiological shift as this large, now-young demographic begins to age. “Adjustments to the current system are highly needed, which includes giving a higher level of prioritization to life-saving drugs,” Takeda’s Dr Erdal Bozdoğan comments. “Changes to the reimbursement system could easily provide the institution with a higher capacity to reimburse critical and lifesaving therapies. I believe that Turkey could be inspired by the best practices implemented in the world’s most mature healthcare ecosystems, which are already coping with issues related to the aging population.”

Exeltis Tackles Women’s Healthcare Head-On

In Turkish pharma, there are many multinationals that have purchased local companies to strengthen access to the domestic market – one in particular, though, has done so with their sights set on women’s health.

“Exeltis entered Turkey in 2014 with the acquisition of the domestic company Embil, which notably boasted well-established women’s healthcare brands,” explains Hülya Yalın, general manager of Exeltis Turkey. “In addition to this perfect match in terms of portfolios, the Embil acquisition also provided Exeltis with a top-notch manufacturing facility, located in Çerkezköy, which truly stands as one of our key differentiators in the competitive Turkish industry. This allows us to locally manufacture over 85 percent of the Exeltis products consumed in Turkey, which is particularly significant with regards to the localization policies recently enacted here. Finally, some Embil legacy brands – for vaginitis and pain management, for instance – are now exported from Turkey to the rest of the world and benefit other affiliates across the Exeltis ecosystem.”

With this new affiliate and accompanying production facility, Exeltis is poised to become one of the most prominent players in the women’s health market. “We want to establish ourselves as the partners of choice of Turkish women along all stages of their lives, starting with young women and young mothers up to the menopause phase and after,” continues Yalın.

“Our products show great potential for future growth in the dynamic Turkish market, and the women’s health segment is growing strongly,” comments Jana Mittmann, the company’s regional head for CEE and Turkey. “We believe that women’s health is the right segment in which to invest.”

On the whole, despite economic fluctuations and select debates over pharma/healthcare regulation, the feeling is that Turkey is truly ready to go beyond.

“In parallel to strong growth perspectives, economic and policy volatility often comes as a distinctive trait of emerging countries. Therefore, one should not assess the potential of such a dynamic country like Turkey on a six-month or yearly basis,” notes Selim Giray, vice president and general manager of GSK Turkey.

“When looking at how Turkey has been progressing since the 80s and particularly through the 2000s, the trend is clearly positive, and we should be confident that this will remain as such in the coming years.” ❁

Today, reports of organizations mishandling data are as common as political scandals or celebrity feuds. Yet every revelation about Facebook's treatment of consumer data always seems jarring. The company, positioned as a champion of friendship, connection, and community, has been repeatedly exposed as the mammoth tech machine that it is. It is this unsettling juxtaposition that has sparked consumer, political, and media outrage. And it all starts in the uncanny valley.

The uncanny valley is the eerie point at which machines take on many human characteristics, but still can't quite pass for being human. Think Transformers versus Disney's animatronic Hall of Presidents: the former are clearly identifiable robots, the latter awkward approximations of humanity, inner-workings masked. Like Facebook, many of today's companies are feverishly trying to become more like people, despite being anything but.

In attempts to be more relatable, brands are focusing on developing personalities and purposes, while sweeping activities like data collection under the rug. The problem becomes magnified when it involves healthcare companies—organizations that trade in some of the most sensitive and intimate information. Trendy healthcare startups like Hims and Roman may have cheeky advertisements, but according to a recent article in *The Outline*, the consumer data they collect “can still be sold to data brokers or used for third-party marketing services if anonymized, which could allow tech giants like Facebook, Google, and Amazon to make their ad targeting algorithms even more scarily accurate

Ascending the Uncanny Valley in Healthcare

Being more human in brand engagement doesn't mean being less transparent

by incorporating huge swaths of medical data.”

The article further explains that the websites for these brands have either Facebook social plugins or Facebook tracking pixels, allowing the platform to track how frequently users visit. The contrast of these companies' playful marketing tactics with their hidden data capabilities produces the same uneasy feeling that robot Abraham Lincoln does.

One positive aspect of these newer brands is that they lean into consumers' growing involvement in their own healthcare. From ordering home-delivered medications and supplements to tracking activity via wearables—not to mention having access to countless resources, articles, and forums online—people are now able to question established practices and take control of their care. While the healthcare industry clumsily attempts to be more human, consumers are becoming more industrious about caring for themselves.

Perhaps it's this independent care and tracking of personal data that has shifted the public's perception of larger companies. Ernst & Young's 2013 “Big Data Backlash” report, which deftly predicted the end of the “Golden Age” of free data at 2018, found that 78% of consumers believe companies collect personal data to make money, rather than to make improvements for their customers. Despite this cyni-

cism, the fact that they stand to benefit from sharing their information is not lost on the public. Roughly a third of those surveyed were happy for companies to target them with special offers and recommendations, or develop new products and services based on their personal data. Consumers have not written data collection off, but rather want to observe and understand that it's being put to good use.

So, where do healthcare brands go from here? For starters, they should recognize that,

Make consumers feel like active business partners when it comes to their healthcare data, rather than friends with blind trust

while companies should demonstrate human-like qualities, such as reliability and consistency, they are not people. Rather, they should exercise transparency, letting today's savvy consumers in on their business methods and information. They should make consumers feel like active business partners when it comes to their healthcare data, rather than friends with blind trust. By prioritizing transparency and engaging in knowledge-sharing with the public, healthcare companies and consumers may be able to climb, hand in hand, out of the uncanny valley. 

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