Pharma intelligence
informa

Trends In Generics 2019

Powered by
Generics Bulletin & Pink Sheet

Sponsored by

West

AccelTRA™
Quality. Speed. Simplicity.

These are exciting and challenging times for generic manufacturers. On the one hand, the reauthorization of the Generic Drug User Fee Act (GDUFA) in 2017 has led to a greater number of generic drug approvals than ever before and this trend continues into 2019. On the other, the downstream effects of distributor consolidation have margin implications for generic manufacturers and, consequently, controlling costs and diversifying their business remain key.

Generic organizations will be required to continue to provide high quality in their manufacturing processes and products, as well as, bring their products to the marketplace faster for quicker penetration. They must also have a mindset that fosters operational simplicity and excellence to enable these further. The West AccelTRA® Elastomer Components Program was created recognizing these needs by generic manufacturers. West has built a program that offers a high-performing, quality elastomer formula that leverages the company's greater than 95-years of industry expertise. Additionally, AccelTRA® components offer optimized lead times to help customers speed their products to the market quickly, as well as, aid in simplicity when customers desire to standardize on one elastomer formula platform that has global compendial compliance to help lower their inventory costs.

This year, we've enhanced the program further by having the AccelTRA® Elastomer Components Program become part of our new component offering, which incorporates our Westar® Select wash process. The Westar® Select wash process offers customers components with a better particle specification profile providing even higher quality on pharmaceutical washed and sterile products and a simplified regulatory strategy for greater supply chain risk mitigation, all under one formula platform with the regulatory support customers need from West to file their products.

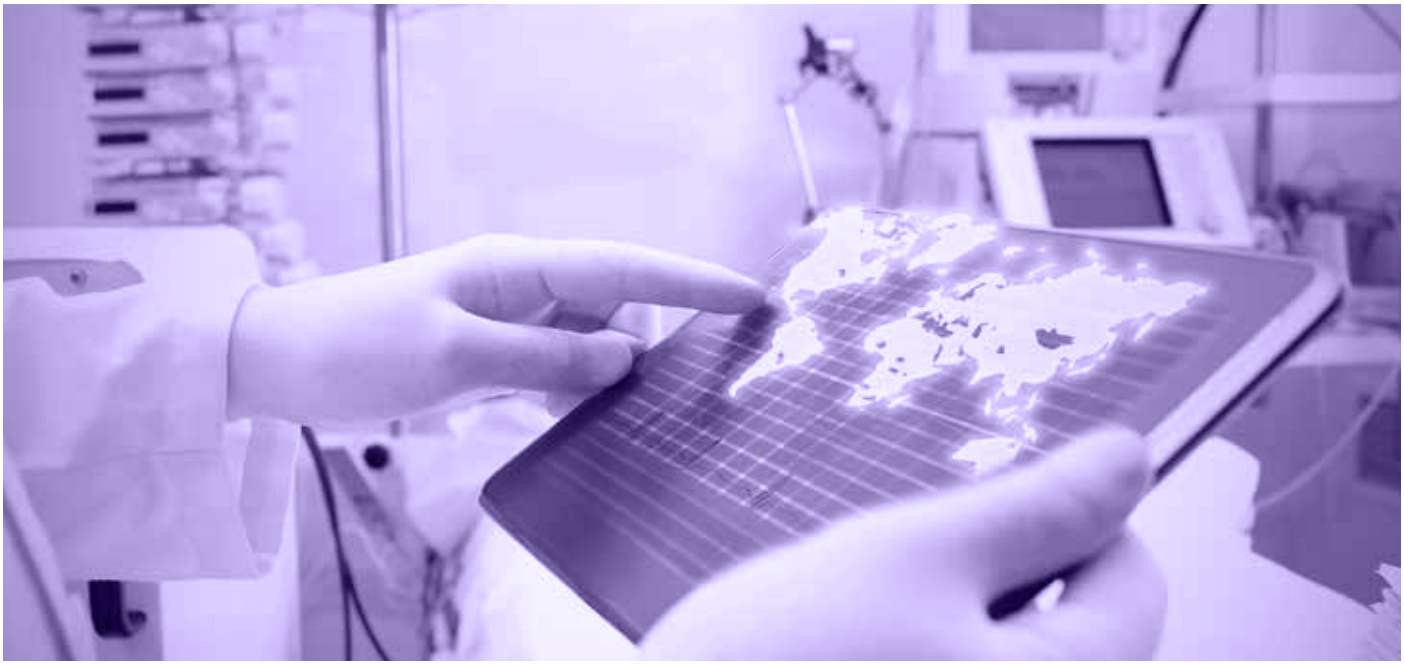
We hope you enjoy this eBook and find these articles informative and relevant to your business needs. To learn more about how AccelTRA® components can help your organization leverage quality, speed and simplicity to bring products to market quickly, please contact one of our West account managers or visit www.westpharma.com/AccelTRA to download relevant information and order samples.

Milagro E. Lopez
Global Marketing Director, Generics

Contents

Azar: International Regulatory Harmonization Will Create More Stable Generic Markets

By M. Nielsen Hobbs



NEW ORLEANS – HHS Secretary Alex Azar highlighted the symbiosis of the generic industry and the Trump Administration in his address at the Association for Accessible Medicines annual meeting here on Feb. 6. Just as the generic industry needs policy reforms to strengthen its business model, the Trump administration needs a strong generic industry to help achieve its goal of lowering list prices for drugs.

Azar didn't make that connection explicitly, but he noted "two of the many ways we're looking to address situations where generic competition has been anemic."

First, the US FDA "is examining how safe importation of drugs without patents or exclusivities could help inject new competition in the event of price spikes that restrict access to medicines," he said.

"Second, we're also looking at another way to leverage competition from abroad, by further harmonizing the work of FDA and our peer nations. While fundamental changes to our generic drug application process would require statutory reforms, FDA and our peers are exploring new potential areas for alignment."

In particular, FDA is considering whether biosimilar sponsors could rely on studies of foreign reference products, an idea that has already gotten considerable pushback from the brand industry. *(Also see "Biosimilar Bridging Study Waivers: Public Health Prerogative Or Trade Secret 'Taking'?" - Pink Sheet, 10 Sep, 2018.)*

Azar noted that "in some cases, the U.S. market for a generic drug may not be big enough to attract a second or third manufacturer to keep prices low, but the combined market of the United States and other wealthy nations certainly would be. We also know that many low-volume generics aren't on the market in all of our peer nations, so a harmonization effort could help expand access both at home and abroad."

Azar's well-crafted address then transitioned into his anti-rebate stump speech as he noted that "we could have the most efficient approval process for safe and effective medicines in the world, but it wouldn't matter if we don't have a market where competition thrives and lower-cost options are incentivized."

"Unfortunately, even as more than 90 percent of prescriptions dispensed today are generic, there's still room for improvement."

> **"Unfortunately, even as more than 90 percent of prescriptions dispensed today are generic, there's still room for improvement."**

"An HHS report last year found that Medicare Part D plans spend $9 billion on brand-name drugs that have a generic alternative. By our calculations, choosing generics in these situations would mean $3 bil. in total savings for Part D, including $1.1 bil. in out-of-pocket savings for patients."

"Why are American seniors paying billions of dollars for drugs that are more expensive than they need? In many cases, it's because of the non-competitive, non-transparent nature of our drug market. Often, our drug market really isn't a market at all. There is no other way to describe a system in which products with higher prices regularly beat out products with lower prices."

"As all of you know, one of the major distortions in this market is today's system of rebates," Azar continued, going on to describe the administration's proposed reg to curtail rebating that was released last week. *(Also see "HHS Rebate Plan A Leap Of Faith? Lower Costs Hinge On Drug Firm, Plan Response" - Pink Sheet, 2 Feb, 2019.)*

Generic firms certainly have their issues with rebating, but they usually see the villains as their ancient enemies, the brand firms, not PBMs. The pharmacy benefit "middlemen" are often the target of administration rhetoric on pricing, but ANDA sponsors have traditionally seen PBMs as drivers of generic substitution.

Several Historic Firsts

AAM President Chip Davis noted in his introduction that Azar was the first HHS secretary to ever address a generic industry group. Azar expressed some doubt about this claim, but noted that when he was deputy HHS secretary in the George W. Bush administration he spoke to a predecessor group, the Generic Pharmaceutical Industry Association, that used to have its annual meeting in Boca Raton.

Indeed, generic outreach by HHS seems like it has traditional been the role of the deputy secretary: Eric Hargan addressed AAM last year. *(Also see "At US Generic Association Annual Meeting, Worries About Sustainability" - Pink Sheet, 12 Feb, 2018.)*

If the Secretary-level address was a big milestone, Azar noted an even bigger one. "The other day at a White House roundtable, in fact, the President took the time to go into just how crazy it is that we're sometimes paying for brand name products when a generic is available."

Trump asked "'What's the difference between the generic and a big-name drug where you pay much more money? … 'Absolutely no difference,'" Azar said.

"Did anyone in this room, ever, in their wildest dreams, think a President of the United States would someday explain the benefits of pharmacy-level generic substitution – in the Roosevelt Room of the White House?" Azar asked to applause.

Now that the generics industry has gotten that kind of recognition at its annual meeting, it may need to consider what can top it. The brand industry, for its part, seems to have tired of open discussion of its policy successes, and hasn't even held an annual meeting for the past few years, avoiding an event that could become a lightning rod for public criticism.

As Davis has noted, it will probably take a long while if ever for generic firms to match the influence of the brand industry. But, in a break with tradition, the date and location of next year's AAM annual meeting wasn't announced at end of this event.

China Steps Closer To Offering An SPC System

By Aidan Fry

Supplementary protection certificates (SPCs) have taken a step closer to being implemented in China after the National People's Congress completed a one-month public consultation period on draft amendments to the Chinese Patent Law. The proposed amendments form part of a broader move towards stronger intellectual property (IP) protection in China that also includes pharmaceutical data exclusivity.

Acting on a State Council resolution, China's National Medical Products Administration (NMPA) proposed a general framework for patent linkage and data protection. Building on that framework, the national People's Congress in early January launched its one-month consultation on amending patent law.

According to the local offices of law firm Marks & Clark, Article 43 of the draft amendments allows for novel drugs introduced to the Chinese market concurrently with overseas markets to be eligible for protection certificates with a maximum term of five years. The remaining patent term, including the extension, is to be no greater than 14 years.

Marks & Clark believes it is likely that the National People's Congress will review the draft amendments "at least once more, so it remains to be seen whether the SPC provisions will be sustained and/or revised".

Possibility Of First-Mover Generic Exclusivity

Various proposals for extending China's current six-year data protection regime have been put forward, including plans for a 12-year term for novel biologics that would mirror provisions in the US. Generic market exclusivity to reward successful patent challenges, akin to the US Hatch-Waxman 180-day exclusivity, has also been mooted, but Marks & Clark believes "it is likely that this protection term will not be specified until the detailed provisions of the patent-linkage system are set forth".

A recent National Health Commission on introducing patent linkage was, Marks & Clark observes, "somewhat cautious" in merely stating that the Chinese government would "gradually explore a patent-linkage system". "The draft amendments to the Patent Law released on 4 January 2019 do not mention patent linkage," the law firm notes.

And while ideas around stays on generic approval of up to 24 months have been floated, "there is a lack of clarity as to how this proposed regime would be implemented in actual practice".

Generic CEOs Need To Act Like Brand Execs, Association Head Says

By M. Nielsen Hobbs

NEW ORLEANS – The Association for Accessible Medicine's annual meeting here featured king cakes and a jazz band at its opening reception. Less predictably, it has also included an exhortation from association President Chip Davis that generic firms should start behaving like their brand-name rivals.

In his "State of the AAM" address, Davis listed several policy victories that the generic industry has achieved over the past year, including FDA's biosimilar action plan and suits to block unfavorable legislation in New York and Maryland.

"I think it says something about the association working with its members to be able to deliver a significant return on a comparatively modest investment of dollars," Davis said, noting that while AAM had the "biggest budget in the history of our association … our record year is still a rounding error compared to others in our industry, many of whom often stand in direct opposition on a number of our top priorities."

For brand CEOs, personal advocacy "is a lot like DTC advertising. They do it because it works." – Chip Davis

Regardless of the association's budget, however, "there's another type of investment that is equally important. That is the investment of time. I gained a great appreciation of the importance of investing time early in my career when I worked on the brand inside of ecosystem." Davis joined AAM three and half years ago from the Pharmaceutical Research and Manufacturers of America, where he was executive vice president for advocacy and member relations.

Davis explained that "in addition to the enormous amount of money they spend in Washington and at the state level, one of the things that sets the brands apart is the commitment of their executives by investing their time in cultivating relationships with policymakers. Branded company CEOs fly in from literally all over the globe, Europe, Asia, all corners of the planet to take time regularly to meet with policymakers in Washington."

Brand CEOs "grasp the importance of engagement," Davis said. "Of course they do, because it is reflected in their bottom lines. For them, advocacy is a lot like DTC advertising. They do it because it works."

"Now I'm a realist. We will never match the brand's dollar for dollar anytime soon," Davis acknowledged, "but where we can compete and win is related to our story because of how compelling it is," as he zipped through the key talking points: "90% of all prescriptions and only 23% of costs. $6 average co-pays versus $40 average co-pays for the brands. Declining prices compared to all the focus and attention on relentless price hikes."

Biosimilar Success Story

"If those of you in this room make a conscious decision to invest the time to tell that your legislators and administration officials, I can assure you it makes a huge difference," Davis said. "Let me give you an example."

The US FDA biosimilar action plan released last summer was "a tremendous milestone," Davis said. "That also did not happen in a vacuum. Some of our member company CEOs made the time and the investment of their time to talk to the FDA including direct dialogue with the commissioner and our staff lead by Christine Simmon, our head of policy, worked around the clock to make sure that the final product was the most effective that it can be."

> **"We're very pleased with the biosimilar action plan and how it turned out and that was in many ways a direct result, as Commissioner Gottlieb has said himself, of the time that AAM and some of our members spent advocating for industry," – Chip Davis**

"We're very pleased with the biosimilar action plan and how it turned out and that was in many ways a direct result, as Commissioner Gottlieb has said himself, of the time that AAM and some of our members spent advocating for industry," Davis noted. *(Also see "Interchangeability Won't Solve US Biosimilar Market's Woes, FDA's Gottlieb Says" - Pink Sheet, 18 Jul, 2018.)*

A Warning On Price Increases

While Davis urged more personal engagement on advocacy, he discouraged a different business decision – raising prices.

"I know that you are acutely aware that generic prices have fallen precipitously over the last three years ... and some policymakers" – including HHS Secretary Alex Azar – "have gone so far as to tell Congress that generic prices are actually too low and are therefore aware of the concerns about the market impact facing our members."

"But the flip side is that many politicians will also seize on any price increase, no matter how small in real dollar terms, to score political points. ... We have entered a political environment where are no price increase, brand or generic, is considered justifiable or acceptable."

"And some of you may think that generic price increases fly under the radar against the backdrop of brand price increases. Let me assure you could not be more wrong about that. In the first week of this year, the same week that many brand companies noted price spikes consistent with the January 1 historical practice, I got more than one phone call from administration officials asking pointed questions about generic price increases," Davis said.

"Prices are not the only issue that poses a threat," he acknowledged. "On the same day that committees in both the Senate and the House held hearings on brand-name price inflation, Bloomberg News launched a multi-part series challenging and attacking the quality of generic pharmaceuticals and the FDA inspection process."

It's a chilly reminder that, even as generic firms hope for more policy success through greater advocacy, they still need to primarily focus on making the same medicines for less.

ICH Sets Out Proposals On Harmonizing Standards For Generics

▶ By David Wallace

Globally-applicable guidance on bioequivalence standards for generics is being developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), according to a reflection paper just published by the organization.

Initial steps planned by the ICH as part of harmonization efforts on generics include guidelines on bioequivalence standards for non-complex oral dosage forms, followed by guidelines on complex dosage forms, as well as the creation of a generics-oriented discussion group that will identify further opportunities for harmonization, including where generics can fit into existing ICH guidelines.

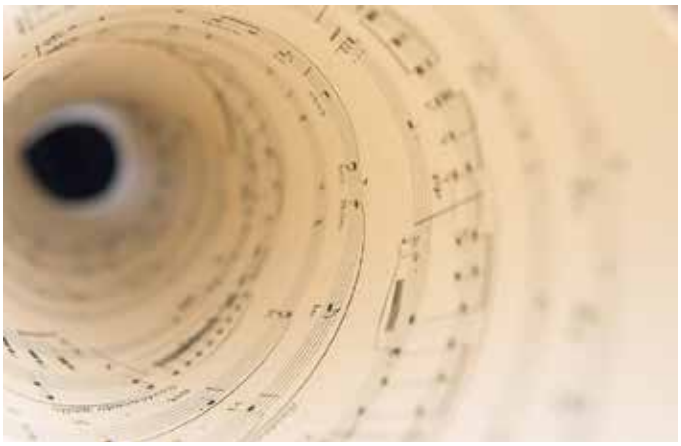
The US Food and Drug Administration (FDA) had last year proposed that a set of "internationally harmonised guidelines on scientific and technical standards for generic drugs" should be developed through the ICH. *(Also see "Global development path proposed to ICH by FDA" - Generics Bulletin, 26 Oct, 2018.)*

"Harmonization of technical and scientific standards for generic drugs presents an opportunity for significant public health benefits by streamlining drug development across regulatory jurisdictions and increasing patient access globally to high-quality affordable pharmaceuticals," the ICH stated.

Noting that the ICH would "initiate topics where a need for harmonization seems most feasible and where agreement exists among ICH parties", the organization nevertheless suggested that "as experience is gained, ICH may refocus its harmonization efforts to more complex topic areas where harmonization may not seem feasible at present".

While many ICH guidelines are applicable to generics, such as quality guidelines, the organization admitted that "historically ICH has focused on standards for new drugs".

"As a result, there are areas of great interest to generic drug regulators and developers where internationally harmonized guidance is lacking or where international harmonization could potentially lead to improved access to lower-cost generic medicines."



With generics accounting for more than half of the pharmaceutical market of ICH member and observer regions, "harmonization in this area presents opportunities for market competition, cost savings, and greater supply, thereby increasing patient access to pharmaceutical products globally", the organization said. "There would be a significant public health benefit in utilizing ICH's highly efficient and successful process to harmonize standards for generic drugs."

Access, Cost And Quality Benefits

Noting that the current lack of harmonized standards for generics "reduces the number of potential markets in which data and information submitted in support of a generic drug marketing application can be used by a developer to support marketing authorization in another jurisdiction", the ICH points out that this can lead to monopolies or limited sources of drugs in certain markets due to the additional development burden.

By harmonizing standards, however, developers would be able to use data submitted in one market in support of applications in another. This, the ICH believes, could increase the size of generics markets and therefore have the knock-on effect of attracting more competition from developers, lowering drug costs through greater competition and expanding access.

Cost reductions could also be seen for developers by reducing the number of duplicative bioequivalence

studies needed to meet different requirements in multiple jurisdictions.

The ICH observed that this could lead to ethical benefits via a reduced number of human subjects being required for studies, and could also reduce the risk of exhausting available human subjects in treatment areas with small patient populations.

"Finally, harmonization may increase the quality of generic medicines by establishing a globally consistent culture of quality and moving compliance with quality standards in a common direction," the ICH said.

"For example, a pharmaceutical company may have two or more manufacturing lines – one that is subject to domestic regulatory standards and others that are subject to different foreign regulatory standards. This potentially results in greater cost, an increase in the likelihood of error in applying the correct regulatory and scientific standards, and in the complexity of recordkeeping."

Legal And Regulatory Regimes Are Not Aligned

One obstacle to harmonization for generics acknowledged by the ICH is that "legal and regulatory requirements for generic drugs are not aligned across jurisdictions".

Examples cited by the ICH include the FDA not allowing generics and reference products to be different oral dosage forms, such as tablets and capsules, while European regulators allow different dosage forms providing bioequivalence criteria are met.

Also, while the FDA requires a US-registered reference product, the ICH noted, some ICH members allow the use of foreign-sourced reference products.

"Instead of harmonizing regional legal and regulatory requirements," the ICH said, "it is proposed to develop and enhance ICH guidelines in scientific and technical areas that would be valuable and achievable across multiple regulatory pathways and where there is common interest in harmonization."

Planned Guidelines Include Multiple Reference Products

Setting out details of its planned harmonization efforts, the ICH said its first step would be to "develop a series of ICH guidelines on standards for demonstrating equivalence for non-complex dosage forms". This would start with immediate-release oral dosage forms, "as these products constitute a significant portion of submissions to regulatory authorities".

The guidance is expected to cover bioequivalence study design as well as data analysis, including statistical methods for bioequivalence assessment. "As part of this work, a working group could consider the feasibility of harmonizing bioequivalence standards and work to align them to the extent possible," the ICH suggests.

"It is noted that such a harmonized bioequivalence study design could be expanded to include additional study arms to accommodate more than one reference product for bridging purposes," the reflection paper states. "For example, a three-way crossover study may allow generic drug manufacturers to submit data from the same study using one test product in support of marketing approval in more than one region."

Given that requirements to support waivers of bioequivalence studies for non-biostudy strengths are not harmonized, the ICH says, "the work under this series of guidelines could include developing harmonized requirements for biowaivers for additional strengths within a product line". Meanwhile, "another work stream under this topic may also include harmonization of biowaivers for solutions such as oral and injectable solutions".

Second Stage Will Address Complex Dosage Forms

After ICH guidelines on non-complex dosage forms are developed, the organization proposes a second set of guidelines to cover more complex dosage forms or products.

"One such guideline may address bioequivalence studies for modified-release oral dosage forms, which could address scientific considerations such as 'waivers' for additional strengths for modified-release products and when partial Area Under the Curve (pAUC) measurements may be important," the ICH indicates.

"In addition, other guidelines could address pharmaceutical equivalence and bioequivalence standards for products with complex active pharmaceutical ingredients such as peptides and oligonucleotides, products with complex

formulations such as liposomal products, locally acting products such as topical dermatological and orally inhaled products, and drug-device combination products."

The ICH believes that such harmonization could reduce the need for comparative clinical endpoint bioequivalence studies and improve the sensitivity and reproducibility of bioequivalence determinations.

Discussion Group To Explore Further Possibilities

Turning to further ways in which generics could be included in ICH harmonization efforts, the organization said it planned to establish "as a near-term next step" a discussion group to consider specific areas and opportunities.

The informal generic drug discussion group (IGDG) will be able to conduct a review of existing ICH Guidelines "to assess whether there are any gaps in existing guidance for generic drugs and make proposals for revision of ICH Guidelines as necessary", the ICH proposed. "Given that the harmonization process is resource-intensive and time-consuming, the discussion group could serve to prioritize work areas and ensure that priorities are set carefully."

Responsibilities for the IGDG will include:

- Revising the ICH reflection paper based on regional input;
- Establishing "an overarching vision for the harmonization of generic drug standards under ICH";
- Identifying new topics for harmonization of generic drug standards;
- Surveying existing ICH guidelines as well as relevant World Health Organization guidelines related to generic drug standards to identify any gaps in guidance for generic drugs;
- Working with the ICH implementation subcommittee to assess consistency in the regional implementation of ICH guidelines for generic drugs; and
- Prioritizing areas for harmonization and making recommendations to the ICH management committee

"The discussion group will serve for a period of one year," the ICH indicated. "Thereafter, the ICH management committee will consider whether this discussion group should sunset or whether additional work merits its continuation for another specified term."

Takes Into Account Other Initiatives

As part of its reflection paper, the ICH acknowledged that other international collaborations on issues relating to generics were ongoing.

"For example, the International Generic Drug Regulators Programme (IGDRP), now within the International Pharmaceutical Regulators Programme (IPRP), has published or provided input into several informative papers on international guidelines and expectations for generic products," the ICH noted. *(Also see "Regulatory initiatives consolidate into IPRP" - Generics Bulletin, 2 Mar, 2018.)*

In general, the ICH said, the IGDG "should leverage prior work that has been done to date and take measures to avoid duplication of work that continues in other international fora".

Follows IGBA Involvement In ICH

The ICH reflection paper follows the election last year of the International Generic and Biosimilar Medicines Association (IGBA) as a member of the ICH's management committee, a milestone that was celebrated by the international off-patent industry body as a "historical moment for our industry". *(Also see "Joining ICH committee is 'milestone' for IGBA" - Generics Bulletin, 15 Jun, 2018.)*

"Having contributed to the ICH work as an interested party during the last 20 years," the IGBA said at the time, "we can now open a new chapter of engaging fully in the ICH activities of developing the international standards applied to the pharmaceutical industry, including generic and biosimilar manufacturers."

Nick Cappuccino, IGBA representative to the ICH's management committee, last year pointed to several areas in which he suggested generics firms could get involved in ICH working groups, such as development and manufacturing guidelines as well as product lifecycle management guidance. *(Also see "Supporting ICH may harmonise standards" - Generics Bulletin, 22 Jun, 2018.)*

US Pricing Pressures Have Stabilized, Insists Teva Chief

▶ By Grace Montgomery

Following several years of pricing pressures, the US generics market has stabilized and will continue to do so, according to Teva president and chief executive officer Kåre Schultz.

Speaking at the 2019 J.P. Morgan Healthcare Conference in San Francisco, US, this week, he noted that there had been a "dramatic reduction in the total value of the US generics market space" over the last five years. "And a year ago, I think it's fair to say we were in a negative death spiral of pricing on generics, just everybody going lower and lower."

As a result, Teva in 2018 "took very decisive action", deciding to no longer supply products "that do not contribute to our profitability". The firm started the process of talking to its "key customers", noting that it had "three very big buying groups in the US". Schultz said the company had entered into a "constructive dialogue" with all of its customers "about the roughly 10% of our portfolio where the prices had gone below reasonable profitability levels".

"And I'm happy to say we are through that process," he continued. "Of course, we had to give up some of the volume, that didn't hurt us because we were not making money on it. And for some of the volume we got price increases."

Pricing Dynamic In US Generics "Changed"

"But I think the most important thing... is that the whole pricing dynamic in US generics changed, maybe as a factor of what we did, maybe due to our circumstances, maybe that was just a new balance, you never know why things like this change," Schultz stated.

Contending that there had "been a dramatic change", he maintained: "We no longer have this death spiral of price declines, but we have a much more stable situation." Predicting that the US generics market would "in absolute value" be stable throughout the second quarter to the fourth quarter, he added: "I'm also predicting that to be the case for the future."

Restructuring And Consolidating Process Continues

"We think we are part of stabilizing the US generics in how we are behaving and, of course, we also believe that our restructuring and consolidating the manufacturing footprint gives us more competitive manufacturing cost," Schultz maintained, referring to restructuring plans first set out by the firm in December 2017. This included closing facilities worldwide and reducing its workforce by at least 14,000, as the Israeli firm sought to reduce its total cost base by about US$3 billion by the end of 2019.

"This is not something that happens overnight, it takes years to consolidate the manufacturing," Schultz stressed. "We are in the process of it, we'll continue for many years to consolidate, and hopefully we'll see gradual improvements on our gross margins for years to come."

By the third quarter of 2018, Teva had rid the firm of a number of its facilities and cut staff by over 9,000, produc-

ing efficiencies of US$1.8 billion. Schultz said Teva was "very much on track" to hit its US$3 billion target, adding that the company had now reduced its headcount by around 10,000 people.

Noting that the firm was "still executing on the plan" throughout 2019, Schultz revealed that there would be more plant closures. In the short-term, Teva's "ambition is to go from roughly 80 manufacturing sites down to around 60, and we are well underway with that, and there will probably be around 10 closures throughout this year".

One-Company Setup Will Increase Efficiency

To make the group more "efficient and competitive", Teva has created a "new setup where, instead of sort of being siloed into specialty products, generics products, OTC products, biosimilars and so on, we just have one company".

As the firm was consolidating sites and shutting down offices and research and development (R&D) facilities in "big countries such as Israel, Germany, and many other places", Schultz maintained that "the whole one-company idea is very important".

Teva recently revealed that "to fulfil its goal of working as One Teva", the company was consolidating its global headquarters in Israel and relocating to Tel Aviv from Petah Tikva *(Also see "Teva To Relocate Global HQ To Tel Aviv" - Generics Bulletin, 19 Dec, 2018.)*

More Targeted Approach In Generics

Looking ahead, Teva is keen to maintain its leadership in generics. "Given the changed dynamics in US generics, and in worldwide generics, we're having a more targeted approach now where we carefully analyze each and every generic project," Schultz stated.

With "hundreds" of pending abbreviated new drug applications (ANDAs) and filings in "Europe, China, Japan and so on", the firm is opting for a "very structured process where we look for the most profitable projects". As well as a "very proactive portfolio selection and ongoing management", Teva plans to focus on "areas where there are high barriers" – being first to market either by being first-to-file or choosing complex products.

Optimistic About Biosimilar Launches

While "not much success has been seen with biosimilars in the US marketplace", Schultz believes this is "slowly about to change". "There's a lot of pricing pressure on these kind of very expensive oncology therapies, and I believe we have something to bring to the party because we know how to manufacture these cheaply and efficiently."

He pointed out that Teva has "a complete biologics platform where we can develop both biosimilars and biologics in-house 100%". The company's in-licensing strategy "targets early-stage opportunities that fit [Teva's] core capabilities".

Schultz said he was "very optimistic" about future launches, after late last year receiving US Food and Drug Administration (FDA) approval for Teva and partner Celltrion's Truxima (rituximab-abbs) and Herzuma (trastuzumab-pkrb) biosimilars, anticipating launch "in the coming years". "I cannot disclose the exact settlement dates we have, but we are basically settling on these products and looking forward to launching them."

Teva Seeks Organic Growth And Targeted Investments

Contending that "organic growth is the path we are on", Schultz said: "We are not going to sell off anything major at all". "We're keeping all the business lines we have and we're integrating as well as we can and getting the most out of it that way."

While the company is focused on cash flow in its restructuring phase, Schultz stressed that it "hasn't stopped investing in the business, it's just targeted investments instead of big mergers and acquisitions". This includes supporting the launch of its Ajovy (fremanezumab-vfrm) migraine drug and its Austedo (deutetrabenazine) tardive dyskinesia treatment, as well as investing "hundreds of millions" in building a biopharmaceutical manufacturing site in Ulm, Germany.

Referring to the firm's debt as "the elephant in the room" a year ago, Schultz said that this "is more tamed now". "We came from around US$35 billion, and we've been doing our best to bring it down. We're now down to around US$27 billion, and we will continue in the coming years to bring it down."

West Pharmaceutical Services, Inc.

Committed to quality, collaboration, service and innovation

West is a leading global manufacturer in the design and production of technologically advanced, high quality, integrated containment and delivery systems for injectable medicines. We are a trusted partner to the world's top pharmaceutical and biotechnology companies—working by their side to improve patient health.

West Offers Proprietary Packaging, Containment and Drug Delivery Products

- **Stoppers and seals for injectable packaging systems:** to help ensure drug compatibility and stability, while also supporting operational efficiency
- **Syringe and cartridge components:** including custom solutions for the specific needs of injectable drug applications
- **Self-injection systems:** innovative, patient-centric technologies that are easy to use and can be combined with connected health technologies that have the potential to increase adherence
- **Containment and delivery systems:** including Daikyo Crystal Zenith®—a high performance polymer alternative to glass that can meet the challenges of sensitive biologics

Contract Manufacturing – Pharmaceutical, Biotech and Diagnostic

West contract manufacturing harnesses a powerful combination of innovation, technology, infrastructure and expertise to serve the pharmaceutical, medical and consumer industries. Along with more than 50 years of experience, we bring customers quality, safety and reliability in injection molding, contract assembly and finished packaging from our eight locations throughout North America and Europe.

- **NYSE: WST**
- **7,500 global employees**
- **Founded in 1923**
- **2017 sales: $1.6 billion**
- **West products used on a daily basis: approximately 112 million units***

*Based on 2017 annual sales.

For more information, contact us today at **westpharma.com**

North America 1-800-345-9800 option 8 | **South America** +55 11 4055 6061 | **Europe** +49 (0) 2403-7960 | **Asia Pacific** +65 6862 3400 | **India** +91 40 49401111

#10990 • 1118

West

By your side
for a healthier world™

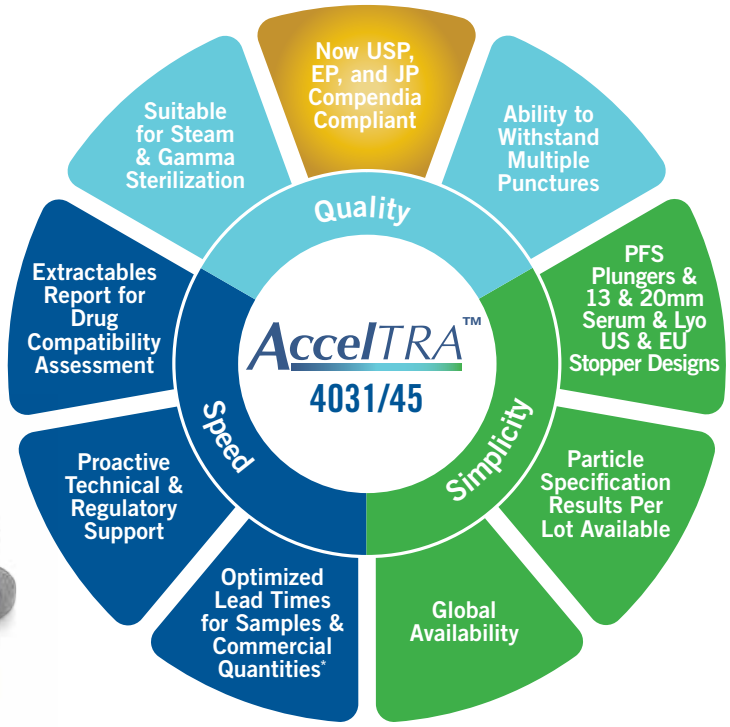
Are you a generic drug manufacturer wanting to standardize on a high-performing elastomer formula to reduce your inventory costs and operate more efficiently?

Do you need to move your product to market quickly?

✓ CHOOSE AccelTRA™

- ✓ 6-week commercial lead times*
- ✓ Robust extractables package to help identify extractables of concern
- ✓ Multi-puncture performance
- ✓ Low particulate levels

*Commercial quantities available for customers in 6 weeks with provision of 90-day notification and drug product forecast.



Rely on West's more than 95-year industry-leading technological expertise and quality – Choose AccelTRA™ components.

For more information, contact us today at **westpharma.com/AccelTRA**

North America 1-800-345-9800 option 8 | **South America** +55 11 4055 6061 | **Europe** +49 (0) 2403-7960

Asia Pacific +65 6862 3400 | **India** +91 40 49401111