Creating a stable drug pricing strategy in an unstable global market

May 2019
<table>
<thead>
<tr>
<th>Action taken</th>
<th>Company</th>
<th>Treatment</th>
<th>Product (Date)</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>New products launched at an equal or lower list price than on-market competitors</td>
<td>Sanofi and Regeneron</td>
<td>Rheumatoid arthritis</td>
<td>Kevzara, May 2017</td>
<td>Launched at a list price 30% lower than the two most widely used competing products&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>AstraZeneca</td>
<td>Severe asthma</td>
<td>Fasenra, November 2017</td>
<td>Launched at a price equal to competing therapies. After one year, the price was dropped &quot;below the treatment cost of all other biologic therapies for severe asthma&quot;&lt;sup&gt;9&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Novartis</td>
<td>Multiple sclerosis</td>
<td>Mayzent, April 2019</td>
<td>Launched at a 7% discount to its legacy MS drug, Gilenya&lt;sup&gt;10&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Roche</td>
<td>Multiple sclerosis</td>
<td>Ocrevus, March 2017</td>
<td>Launched at a 25% discount to an older drug it outperformed in clinical trials&lt;sup&gt;11&lt;/sup&gt;</td>
</tr>
<tr>
<td>Launching lower-cost versions and “authorized generics” of patented products using a separate National Drug Code (NDC) and reduced list price</td>
<td>Eli Lilly and Company</td>
<td>Diabetes</td>
<td>Humalog authorized generic, March 2019</td>
<td>Launched at a 50% lower list price to its branded equivalent&lt;sup&gt;12&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Amgen</td>
<td>Cardiovascular</td>
<td>Repatha, October 2018</td>
<td>Introduced a new NDC at a 60% reduction in list price&lt;sup&gt;13&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Sanofi and Regeneron</td>
<td>Cardiovascular</td>
<td>Praluent, February 2019</td>
<td>Introduced a new NDC at a 60% reduction in list price&lt;sup&gt;14&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Asegua (subsidiary of Gilead)</td>
<td>Hepatitis C</td>
<td>Epclusa, authorized generic, September 2018</td>
<td>Launched at a 60% discount to its branded equivalent&lt;sup&gt;15&lt;/sup&gt;</td>
</tr>
<tr>
<td>Commitments to hold annual price increases of products below 10 percent, or below inflation rates</td>
<td>Merck</td>
<td>All therapeutic areas</td>
<td>All products</td>
<td>Committed to not increasing average net prices above the rate of inflation annually&lt;sup&gt;16&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Allergan</td>
<td>All therapeutic areas</td>
<td>All products</td>
<td>Published a &quot;social contract with patients,&quot; including a commitment to limit drug price increases to less than 10% annually&lt;sup&gt;17&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Novo Nordisk</td>
<td>All therapeutic areas</td>
<td>All products</td>
<td>Committed to limit annual price increases to single digits&lt;sup&gt;18&lt;/sup&gt;</td>
</tr>
<tr>
<td>Publishing price information, or a website containing price information, in direct-to-consumer (DTC) advertisements for individual products</td>
<td>PhRMA's 37 member companies</td>
<td>All therapeutic areas</td>
<td>All products</td>
<td>Ahead of a proposed regulation requiring list prices to be included in broadcast advertising, PhRMA members committed to including &quot;direction as to where patients can find information about the cost of the medicine, such as a company-developed website, including the list price and average, estimated or typical patient out-of-pocket costs, or other context about the potential cost of the medicine&quot;&lt;sup&gt;19&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
Figure 2. Among US-based executives, participation in value-based contracts has increased substantially since 2017

Does your organization currently use value-based drug contracts of any kind?

- 2017:
  - Yes: 25%
  - No: 61%
  - Don’t know: 14%

- 2019:
  - Yes: 57%
  - No: 43%
  - Don’t know: 0%
Figure 3. Pharma executives across the globe are using subscription, mortgage and indication-specific pricing models

Aside from value-based contracts (risk, outcomes, etc.), what other financial models is your organization using? Select all that apply.
Figure 4. Drug value can be assessed in different and conflicting ways

- **Quality-adjusted life year**
  Drug affordability is calculated according to strict thresholds set by government payers

- **ICER framework**
  Affordability and benchmark price determinations are set based on impact to health care budgets

- **Cost avoidance**
  Drug value may be calculated in terms of savings associated with the avoidance of medical interventions typically associated with a disease area

- **Innovative drugs for previously unmet needs**
  Curative therapies for rare diseases target smaller patient populations and carry high price tags

- **Incremental improvement**
  Drugs offering incremental advantages over competing therapies may be valuable to specific patient types

Source: PwC Health Research Institute
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Figure 5. A quarter of executives surveyed agreed that the FDA should implement a quality-adjusted life year measure for assessing new drugs and making approval decisions.

To what extent do you agree or disagree with the following statements?

The FDA should implement a QALY metric for assessing new drug applications and making drug approval determination

Third party drug value assessors like ICER should play a role in negotiating prices paid by government health plans

0% 20% 40% 60% 80% 100%

- Strongly agree
- Somewhat agree
- Neutral
- Somewhat disagree
- Strongly disagree
Figure 6. International reference pricing, reimportation and rebates top the list of concerns in the US

Which of the following three US policy ideas are most concerning to your organization?

- Benchmarking Medicare reimbursement prices to an international price index: 18.8%
- Allowing drug reimportation from markets outside of the US: 15.5%
- Changing the drug rebate safe harbor to lower drugs’ list price: 15.5%
- Mandatory value or outcome-based payments in Medicare or Medicaid: 15%
- Indication-based payments in Medicare: 8.7%
- Requiring list prices to be included in drug advertising on television: 7.2%
- Allowing product exclusions in Medicare “protected classes”: 6.3%
- Allowing Medicare Part D to negotiate prices as a block: 5.3%
- Removal of pharmacist “gag clauses”: 3.4%
- Changes to catastrophic coverage thresholds in Medicare: 2.4%
- Mandated point-of-sale rebates for consumers: 1.9%

Source: PwC Health Research Institute global biopharmaceutical executive survey, February 2019

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**Figure 7. Price transparency, changes to public health plans and curative therapies are the biggest threats to traditional drug pricing**

List, in order, the three items exerting the highest pressure on the traditional drug pricing model:

<table>
<thead>
<tr>
<th>Item</th>
<th>Highest pressure</th>
<th>Second highest pressure</th>
<th>Third highest pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price transparency</td>
<td>8.1%</td>
<td>3.2%</td>
<td>14%</td>
</tr>
<tr>
<td>Changes to Medicare/Medicaid</td>
<td>2.3%</td>
<td>9.9%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Curative therapies</td>
<td>5%</td>
<td>4.5%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Global health assessment groups/public payers</td>
<td>3.2%</td>
<td>3.6%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Private insurers</td>
<td>2.3%</td>
<td>2.3%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Drug wholesalers/distributors</td>
<td>2.7%</td>
<td>2.3%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Individualized or personalized therapies</td>
<td>2.7%</td>
<td>2.3%</td>
<td></td>
</tr>
<tr>
<td>Trump administration</td>
<td>1.4%</td>
<td>2.7%</td>
<td></td>
</tr>
<tr>
<td>Not-for-profit drug manufacturing</td>
<td>1.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>US state-level actions or policies</td>
<td>1.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>2.8%</td>
<td>3.7%</td>
<td></td>
</tr>
</tbody>
</table>

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Figure 8. Key biopharma markets outside the US are focusing on drug prices

<table>
<thead>
<tr>
<th>Country</th>
<th>Detail</th>
</tr>
</thead>
</table>
| France  | • Biosimilar interchangeability is permitted, and the country intends to reach a goal of 80% biosimilars penetration by 2022  
• Clawback clauses are in place within drug contracts whereby manufacturers will be liable to refund the government any money spent on drugs over the capped revenue negotiated for the specific product or therapeutic area |
| Germany | • A bill to allow for biosimilar substitution was announced in February. This is planned to be phased in over the coming three years  
• Draft legislation is in place that would require manufacturers of orphan drugs to provide real world efficacy data to support pricing |
| Canada  | • In March, it was announced that Canada would establish the Canadian Drug Agency. This agency will negotiate drug prices, assess the cost-effectiveness and recommend which drugs to add to a newly created national formulary  
• The Canadian Drug Agency’s negotiating power is expected to save $3 billion in annual prescription costs in the long term, according to the proposal |
| China   | • China joined the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use in June 2017  
• In March, it was announced that the national reimbursement scheme would be expanded to include oncology and orphan drugs |
| Japan   | • Japan launched a new cost-effectiveness scheme for the reimbursement of pharmaceuticals and medical devices in April. Companies are now required to submit cost-effectiveness assessments for selected products that demonstrate the product’s incremental cost effectiveness ratio  
• This metric will be used to determine the level of adjustment to product reimbursement |
Figure 9. Six financial models are being used to create more sustainable product pricing

**Volume-based pricing**
- Useful where large quantities of drugs are needed (e.g., flu shots)
- Less relevant for high cost speciality drugs
- Attractive to government payers buying in bulk

**Financial risk-based contracts**
- Predetermined financial metrics
- Potential full/partial reimbursement to purchaser
- Mitigates purchaser risk

**Indication-specific pricing**
- For products approved in more than one disease type
- Price is based on specific treatment
- Drugs that are more effective in one therapeutic area can be priced appropriately

**Health outcomes-based contracts**
- Predetermined health metrics
- Potential full/partial reimbursement to purchaser
- Metrics can be challenging to control/monitor

**Subscription model**
- Pay for unlimited access for a set time period
- Promotes patient access
- Patient population should be clearly defined

**Mortgage model**
- Spreads payment over time
- More affordable model for customers
- Works best in drugs with limited competition
Figure 10. Biopharma shareholders are most responsible for increased public and political pressure on prices

How responsible is each industry sector or group for the increase in public and political pressure on drug prices?

<table>
<thead>
<tr>
<th>Industry Sector/Group</th>
<th>Very responsible</th>
<th>Somewhat responsible</th>
<th>Not responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopharmaceutical shareholders</td>
<td>70%</td>
<td>24%</td>
<td>6%</td>
</tr>
<tr>
<td>Public insurers</td>
<td>65%</td>
<td>30%</td>
<td>5%</td>
</tr>
<tr>
<td>Private insurers</td>
<td>58%</td>
<td>33%</td>
<td>9%</td>
</tr>
<tr>
<td>Drug wholesalers/distributors</td>
<td>47%</td>
<td>43%</td>
<td>10%</td>
</tr>
<tr>
<td>Drug manufacturers</td>
<td>45%</td>
<td>51%</td>
<td>4%</td>
</tr>
<tr>
<td>Pharmacies</td>
<td>22%</td>
<td>53%</td>
<td>25%</td>
</tr>
<tr>
<td>Provider groups</td>
<td>21%</td>
<td>60%</td>
<td>19%</td>
</tr>
<tr>
<td>Pharmacy benefit managers</td>
<td>21%</td>
<td>41%</td>
<td>38%</td>
</tr>
<tr>
<td>Consumer/patient advocacy groups</td>
<td>14%</td>
<td>69%</td>
<td>17%</td>
</tr>
<tr>
<td>Third party drug value assessors (e.g., ICER)</td>
<td>8%</td>
<td>77%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Source: PwC Health Research Institute global biopharmaceutical executive survey, February 2019

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Figure 11. Generic drugs are facing pricing pressure in four important areas

- **Drug policy reform**: Global drug policies continue to support lower drug prices and increasing generic access and competition.
- **Key buyer consolidation**: Consolidation amongst distributors and pharmacies have increased price transparency and customers' buying power.
- **Ex-US manufacturers**: Increased competition from generic manufacturers in India and other low cost countries.
- **Increased approvals**: Increased competition due to FDA's record number of generic drug approvals (see Fig. 12).
Figure 12. In 2017 and 2018, FDA approved record numbers of generic drugs

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of full approvals</th>
<th>Number of tentative approvals</th>
<th>Number of first generic approvals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>421</td>
<td>87</td>
<td>96</td>
</tr>
<tr>
<td>2015</td>
<td>580</td>
<td>146</td>
<td>74</td>
</tr>
<tr>
<td>2016</td>
<td>630</td>
<td>183</td>
<td>72</td>
</tr>
<tr>
<td>2017</td>
<td>843</td>
<td>184</td>
<td>69</td>
</tr>
<tr>
<td>2018</td>
<td>810</td>
<td>211</td>
<td>99</td>
</tr>
</tbody>
</table>

Source: PwC Health Research Institute analysis of FDA generic drug approvals
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Figure 13. Pricing transformation can help generics manufacturers in four key ways

- **Minimize cost of API**
  Active pharmaceutical ingredient (API) cost is minimized as part of the pricing process for stock keeping units (SKUs) which are too costly to be sustainable in a competitive marketplace.

- **Incremental margin dollars**
  A data-driven pricing approach managed by pricing rules and alerts, and precision pricing at a customer SKU contract level, can prevent revenue leakage.

- **Facilitate contract revisions**
  Customer compliance and performance reviews conducted through post-deal analyses or feedback loop processes can help manufacturers revisit pricing terms such as bill backs, on-invoice discounts, price protections and volume incentive rebates.

- **Portfolio rationalization**
  Assessing the economic viability of individual products based on historical data and market changes—such as new product filings—can help determine if divestitures, discontinuation or market entry makes sense for low-volume or low-profitability products.