Reflections on Challenges ahead

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Our Journey mirrors the Business Model

### Past
- Predominantly **prescriber** focused
- High share of **primary care**

### Present
- Increasing **specialty care**
- Prevalence of **payors**

### Future
- **Targeted** therapies
- **Big data** and digital transformation

**Evolution of Integrity & Compliance**
Past

Healthcare Landscape
- Economic stability and Top 10 market focus
- Branded treatments for chronic conditions, large share of primary care spend, emergence of payors

Business Model
- Competition within industry
- Traditional physician (FF) focused business model

Novartis
- Novartis as industry conglomerate
- Ranking in the middle - looking to leaders for guidance
## What did change?

<table>
<thead>
<tr>
<th>Demographic and epidemiological pressures</th>
<th>Globalization</th>
<th>Banking, financial and sovereign debt crises</th>
<th>Healthcare reforms</th>
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</thead>
<tbody>
<tr>
<td>Advances in communication technologies</td>
<td>Emergence of new technologies</td>
<td>Shift in direction of R&amp;D</td>
<td>Pathway revolution, targeted therapies</td>
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</tbody>
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Present (1/2)

Healthcare Landscape

- Rapid increase of *aging population*, prevalence of chronic diseases, increased healthcare spend
- More *challenging economic* market conditions

Business Model

- *Evolved business model* (role of payors)
- Increasing importance of *medical /scientific exchanges*
- Competition is *intensifying* and *changing* (tech companies)

Novartis

- As one of the *leading healthcare* companies
- *Innovation* power, increased efficiency, global scale
- Moving from rules to increasingly *applying principles*
Present (2/2)

Society

- Increasingly **demanding societal** expectations access, intellectual property, pricing
- No longer good enough to be compliant; do **what is right** to enhance reputation

I&C risks

- Laws and regulations “lagging behind”, emergence of **self-regulation**
- **Medical Compliance** (post registration activities)
- **Anti-Bribery**; perception of conflict of interests
- **Third Party Management** (outsourcing)
Future

Healthcare Landscape

- Economic volatility
- Value-based purchasing (using outcomes)
- Products marketed to healthcare payors
- Symmetry of mature and emerging markets
- Treatments for rare/acute diseases

Trends & Challenges

- Big data, digital transformation and devices
- Immediacy of social media
- Lack of prospective regulations, need for self-regulation, principle-based behaviours
Selected Implications for Integrity & Compliance

- Understand the business today and how it will evolve thereby managing current risks and anticipating future risks
- Tactical execution and strategic business partner
- having the ability to have difficult conversation
- handling conflicts and being constructive
- stay close, yet independent enough to have impact
- Measuring Program effectiveness & reporting on business impact
- Promoting I&C Programs and an ethical culture
Selected Dilemmas faced by Integrity & Compliance

• I&C Function most **needed** but also most **challenged** in times of high **business pressure**

• High **visibility** often only in case of **compliance failure**

If Compliance Function is....

...too **weak**:  
• can’t really get the job done  
• leaders question value

....too “**strong**”:  
• leaders might relax and leave compliance to I&C
And there is more …

• Can we **(re-)connect** better with our key **stakeholders**?

• Is there a tension between **innovation** and **compliance**?

• **Compliance with laws helps avoiding sanctions** - but does it address societal expectations (**reputation**)?

• Will the companies/the industry have a **voice** in the **critical debates** to come?
Going forward

tone of the top
Going forward

From the tone of the top
to **credible** tone of the top
From the tone of the top
to **credible** tone of the top
backed by **actions** in the **middle**
Going forward

From the tone of the top
to **credible** tone of the **top**
backed by **actions** in the **middle**
for **impact** on / with **associates**