



# 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?

**Demographic  
and  
epidemiological  
pressures**

**Globalization**

**Banking,  
financial and  
sovereign debt  
crises**

**Healthcare  
reforms**

Advances in  
**communication  
technologies**

**Emergence  
of new  
technologies**

**Shift in  
direction of  
R&D**

Pathway revolution,  
**targeted  
therapies**

Source: PwC: *From vision to decision* Pharma 2020; <http://www.pwc.com/gx/en/pharma-life-sciences/pharma2020/assets/pwc-pharma-success-strategies.pdf>



# 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 ...

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- 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

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tone of the top

# Going forward

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From the tone of the top  
to **credible** tone of the **top**

# Going forward

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

# Going forward

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