

Reflections on Challenges ahead

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Our Journey mirrors the Business Model



Past

- Predominantly prescriber focused
- High share of primary care



- Increasing specialty care
- Prevalence of payors





- Targeted therapies
- Big data and digital transformation

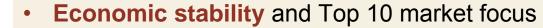
Evolution of Integrity & Compliance



Past

Healthcare Landscape







 Branded treatments for chronic conditions, large share of primary care spend, emergence of payors





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





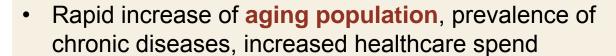




Present (1/2)

Healthcare Landscape







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
- Laws and regulations "lagging behind", emergence of selfregulation







Anti-Bribery; perception of conflict of interests

Medical Compliance (post registration activities)

Third Party Management (outsourcing)



Future

Healthcare Landscape







- Value-based purchasing (using outcomes)
- Products marketed to healthcare payors
- Symmetry of mature <u>and</u> 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....



- 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?

tone of the top



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



From the tone of the top

to credible tone of the top

backed by **actions** in the **middle**

for impact on / with associates

