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INTERNATIONAL
SOCIETY OF
HEALTHCARE
ETHICS AND
COMPLIANCE
PROFESSIONALS

The Continued Evolution of Compliance as a Profession: Background, Training, Roles and Responsibilities

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Dominique Laymand

Executive Vice President, Chief Ethics and Compliance Officer, Ipsen; Honorary President, International Society of Healthcare, Ethics and Compliance Professionals (ETHICS)

ethics

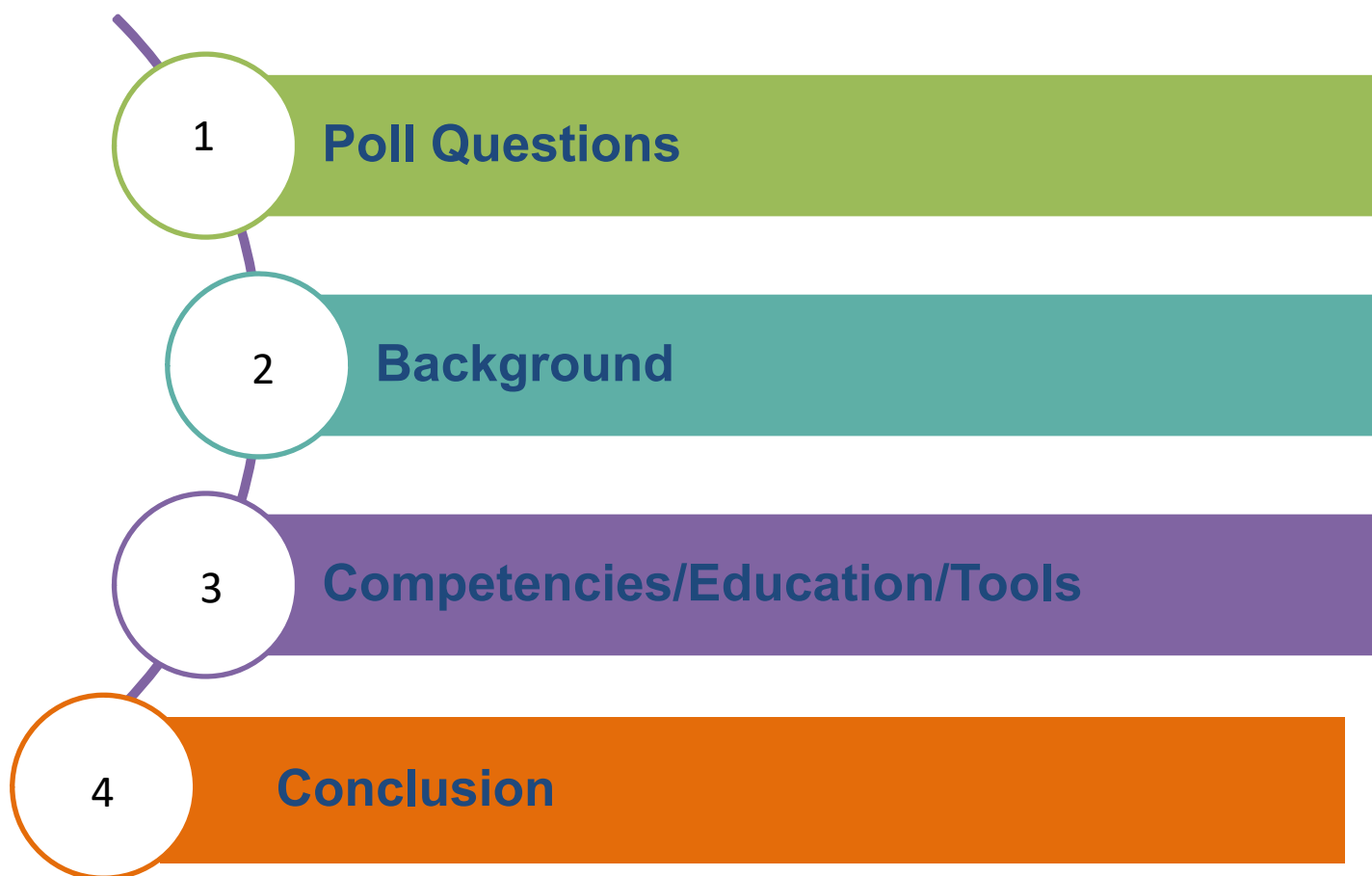


Disclaimer

Any statements made during the presentation or discussions represent only the speaker's personal opinion and does not reflect the current or past companies' position.



Agenda





1 - POLL QUESTIONS



POLL QUESTIONS

What are the top 3 **opportunities** of pursuing the Healthcare Compliance Profession? Choose your top 3 from the list:

- 🅔 Innovative Industry
- 🅔 Providing value to patients and key stakeholders
- 🅔 Great professional growth development opportunities
- 🅔 Advance and promote a culture of integrity, ethics and compliance
- 🅔 Strategy and cross functional collaboration



POLL QUESTIONS

What are the top 3 **challenges** of pursuing the Healthcare Compliance Profession? Choose your top 3 from the list:

- ☞ Foster business accountability for ethical decision making
- ☞ Trusted Business Partner
- ☞ Risk awareness in the fast changing regulatory and complex environment
- ☞ Internal and external stakeholder management



POLL QUESTIONS

Of the 3 core competencies, which one comes first:

- ⓔ Strategic Partner
- ⓔ Change Manager
- ⓔ Ethics & Compliance Advisor Leader



2 - BACKGROUND



Background

Is Ethics & Compliance a profession?

- Development of a profession:
 - Occupation
 - Training
 - Association
 - Code of Conduct
 - Support of law
- Characteristics of a profession:
 - "Hard", e.g. Legal, accountancy - high barriers to entry and discipline if get it wrong
 - "Soft", e.g. Teaching, journalism, Good practices and ethical rules
 - Is there a "Middle" type? If so, does Ethics & Compliance sit in the middle?



Background

- Where did Ethics & Compliance professionals come from originally?
 - Legal
 - Finance / Audit – initially linked to risk management activities
 - Regulatory



Background

- Where do Ethics & Compliance professionals come from today?
 - Legal
 - Finance / Audit
 - HR
 - Sales
 - Medical
 - Marketing / Business
 - Regulatory
 - Quality
 - IT
 - Other areas

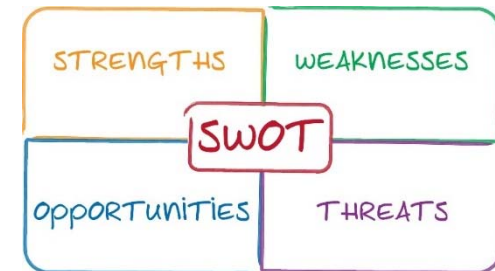


3- COMPETENCIES/EDUCATION/TOOLS



Competency

- Ⓢ What is it that I want?
- Ⓢ What are the key competencies for this profession?
- Ⓢ Self-Assessment and SWOT Analysis?
- Ⓢ Technical skills?
- Ⓢ Personal skills?





HCC Professional Function: Vision & Mission, Strategy

Vision: Healthcare Compliance (HCC) Professional facilitates regaining and sustaining of stakeholders, governmental and public trust of Health Care/Life Science Industry as valuable partner in finding treatment solution for patients

Mission: HCC Professional advances and promotes culture of business accountability of ethical business decision making with a focus on mitigating risks of non-compliance

Strategic Pillars of the HCC Professional Function

Strategic Pillars of the HCC Professional Function		
STRATEGIC PARTNER	CHANGE MANAGER	COMPLIANCE LEADER/ADVISOR
To get alignment on ethical behavior, integrity and transparency		Leading by example & without authority
<ul style="list-style-type: none"> Identify business needs in compliance training, advisory, advisory, advisory, advisory Identify development of compliance Identify training Identify content development in training Identify advisory services in compliance Identify advisory services in compliance <p>Key objectives/activities</p> <ul style="list-style-type: none"> Identify the responsibility for ethical business decisions Identify the ethical decision-making process Identify the ethical decision-making process 	<p>Compliance, Compliance Development</p> <ul style="list-style-type: none"> Identify business needs in compliance training, advisory, advisory, advisory, advisory Identify development of compliance Identify training Identify content development in training Identify advisory services in compliance Identify advisory services in compliance <p>Key objectives/activities</p> <ul style="list-style-type: none"> Identify the responsibility for ethical business decisions Identify the ethical decision-making process Identify the ethical decision-making process 	<p>Compliance, Compliance Development</p> <ul style="list-style-type: none"> Identify business needs in compliance training, advisory, advisory, advisory, advisory Identify development of compliance Identify training Identify content development in training Identify advisory services in compliance Identify advisory services in compliance <p>Key objectives/activities</p> <ul style="list-style-type: none"> Identify the responsibility for ethical business decisions Identify the ethical decision-making process Identify the ethical decision-making process



Competency: Core Competencies

HCC Core Competencies		
Strategic partner	Change manager	Compliance leader/advisor
<p>Strategic skills Business acumen, understand and develop strategy (analytical skills, synthesis), planning, seeing hidden problems,</p>	<p>Communication skills listening, asking the right questions, assertive communication, presentation skills, negotiation skills, identifying &</p>	<p>Leadership skills - leading without authority self-confidence/courage, self awareness, motivate & inspire, delegate & empower,</p>
<p>Personal skills Self management: prioritization, stress management, work-life balance Positive attitude: celebrating success (self & team), sense of humor Use of common sense</p>		
<p>Context Knowledge (experience & training) Non-HCC knowledge: business strategy / process / systems, budget planning, finance for non-finance HCC knowledge: HCC strategy / process / systems, monitoring/leading/building, regulatory environment</p>		



Competency: Self - Assessment

KEY SKILLS	Sub-skills	DESCRIPTION
RTNER: gets alignment on ethical behavior, integrity and transparency BUSINESS ACUMEN/STRATEGIC SKILLS: ability to understand, develop strategy and get it implemented		
	Analytical ability	<ol style="list-style-type: none"> 1 Open minded, looks for different perspectives/sources for analysis 2 Differentiates between facts and assumptions and understands relevance 3 Performs risk analysis (retrospective, prospective; with weighting of risk/feasibility) 4 Identifies root causes, including hidden problems
	Supports the decision making process	<ol style="list-style-type: none"> 1 Identifies cultural differences, screens for the Ethical & Compliance/Integrity Compliance program 2 Influences individual & account mindsets toward ethical decision-making based on stakeholder mapping 3 Manages cultural differences to get the compliance messages through effectively 4 Influences positive and power structures appropriately to achieve the right outcomes 5 Builds and maintains strategic alliances 6 Builds trust within and outside the company
	Strategic partner	<ol style="list-style-type: none"> 1 Understands organizational/compliance governance structure 2 Becomes influential in the organizational/compliance governance structure 3 Leads independently
Strategic partner Change manager Compliance leader, advisor Personal skills Content knowledge		



Education

- ☉ Formal, specialised training, e.g.
 - Seton Hall Law Asia-Pacific Healthcare Compliance Certification Program
 - INSEAD Healthcare Compliance Implementation Leadership Programme
 - Universities specialized programs (e.g. in Ethics, or Healthcare Compliance)
- ☉ “on the job” training, continuous education through conferences
- ☉ Learning from peers, e.g. ETHICS members



Tools

- Healthcare Compliance Profession Peer Associations such as Ethics
- University Courses
- Literature, books, articles
- Leadership Courses
- Company projects and initiatives participation and contribution (global, regional, local, cross-functional)
- Job shadowing and “on-the-job” learning
- Congresses and other networking opportunities





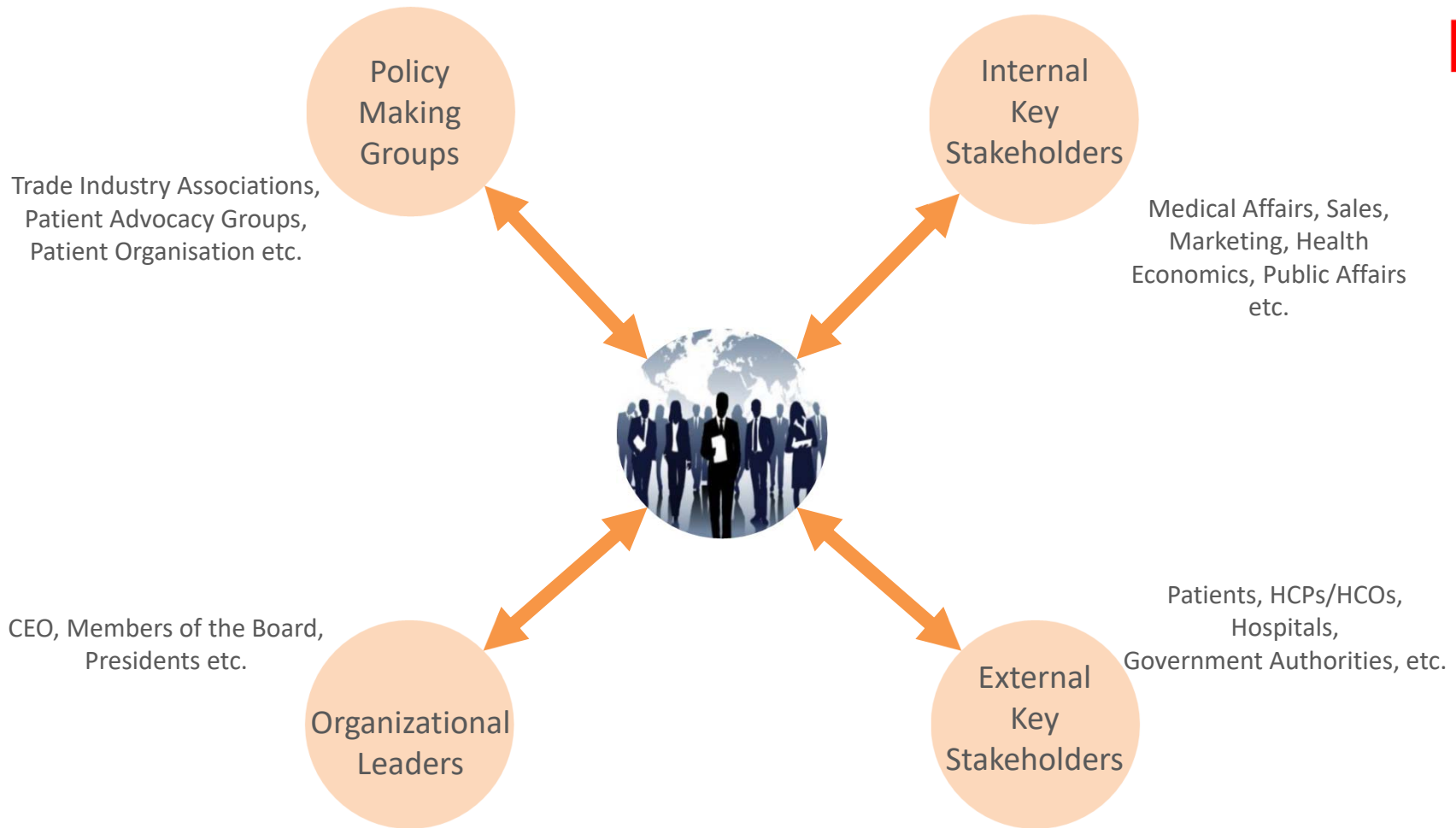
4 - Conclusion



Continued evolution of Ethics and Compliance Function

- e From a rule based function, to a strategic Business enabler, addressing ethical culture
- e Becoming more and more a Profession

Interactions with key stakeholders





BACK-UP SLIDES



Why ETHICS?

- Ⓞ An **informal "Ethics Group"** had been created between professionals from different Healthcare companies
- Ⓞ From the creation, the possibility to **formalize the existence** of this Group through the creation of such an Association was foreseen
- Ⓞ Permanently **increasing complexity** and **importance of tasks** of Ethics and Compliance Professionals justified the move to this next step be achieved quickly
- Ⓞ Need to be **resourced** to be sustainable
- Ⓞ There was a **vacuum** as far as a Professional Society for Healthcare Ethics and Compliance professionals is concerned



ETHICS Vision

“We aim to be recognized as an independent international association of professionals, which sets standards of Ethics and Compliance and shapes and influences strategies in the changing Healthcare environment for the ultimate benefit of Patients and Society at large.”



ETHICS Mission

- ④ **Visible and transparent network** and a **think tank** of diverse International Ethics and Compliance professionals in the Healthcare sector
- ④ **Add sustainable value** to Ethics and Compliance professionals by enabling them to **manage their professional responsibilities** and supporting them in the **development of their careers**
- ④ **Developing and sharing best practices** to anticipate and **facilitate new business models** in the healthcare sector including through effective education and training, closer collaboration between MedTech and Pharma and other initiatives
- ④ Delivering Ethics and Compliance perspectives to **multiple external Healthcare sector stakeholders**, as well as to Ethics and Compliance professionals from other sectors
- ④ **Independent, not-for-profit association** governed by a Code of Conduct



Legal Organization

With the help of Clifford Chance Law firm

- Ⓞ Creation of an Association governed by the French law of 1901
- Ⓞ Headquarters in Paris (hosted by Clifford Chance)
- Ⓞ Article 1 defines the association as "*the convention by which two or several people share, in a permanent way, their knowledge or their activity with a different aim than to share benefit*"



Members and Funding

- ☉ Currently around 100 members from different (mainly European) countries
- ☉ Membership per individual – not per company
- ☉ The Association is essentially funded by members' fees and contributions
- ☉ 3 different categories of membership fees:
 - Founding and Contributing members pay €1,500
 - Active members pay €250
 - Honorary members (proposed by the Board) do not pay any membership fee
- ☉ All members treated equally, regardless of fees paid



Governance

e Board

- Meets at least twice a year
- Broadest powers to act in the name and on behalf of the Association
- **Bureau of the Board** composed of (at least) President, Secretary General and Treasurer of the Association

e Strategic Committee

- Meets face to face at least once a year
- Around 20 members
- Determines the main guidelines, field of actions and priorities of the Association

e General Assembly of members

- Meets at least once a year
- Possible extraordinary meetings of the members, as needed