Ethos in Action
Decision-Making Framework

IFPMA
Background Deck
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Introduction

Turning the IFPMA Ethos into action through the Decision-Making Framework
IFPMA Ethos

The foundation that shapes how the R&D based biopharmaceutical industry sustains trust based on the core values of care, fairness, respect and honesty in order to meet society’s increasing expectations of fair, respectful, honest and thoughtful business practices.
Business Ethics by Design

The IFPMA Decision-Making Framework (DMF) and Toolkit helps industry organizations put the Ethos into action and enable Ethos-based decision-making.

**Decision-Making Framework:** Rooted in the IFPMA Ethos, this framework enables decision-making that balances patient needs and expectations of the medical community, society and regulators with business objectives.

**Decision-Making Framework Toolkit:** A suite of guidance materials to help organizations put the Ethos into action. The toolkit includes:

- **Decision-Making Framework**
  A downloadable pdf describing the Decision-Making Framework.

- **Background Deck**
  A comprehensive background guide to the IFPMA Decision-Making Framework.

- **Business Leader Meeting Slides**
  A customizable presentation deck that business leaders can use to introduce the DMF to their teams.

- **Business Leader Facilitation Guide**
  Companion guide to the Meeting Slides with talking points and instructions for creating an interactive meeting experience.
Why Use the IFPMA Decision-Making Framework?

In an increasingly complex and ever-changing environment, the path forward is not always clear.

The IFPMA Decision-Making Framework:

- Enables decision-making when faced with complex, ambiguous or novel circumstances or ethical dilemmas
- Enhances and supports proactive risk management
- Integrates compliance with ethical considerations
- Encourages ongoing business engagement and accountability
- Fosters a culture of integrity and ethical decision-making

Decision-making that integrates **compliance, integrity** and **ethical considerations** into day-to-day business activities **bolsters patient and public trust**, which is **essential for innovation** and **critical to partnerships** and interactions with patients, HCPs, HCOs, third parties, peer companies, the industry, and society.
A Framework for Developing Innovative Models

A Decision-Making Framework designed to support our evolving industry:

- Advancing innovation using an agile approach
- Fostering patient-centricity
- Ethics based
How is the Role of Pharma Evolving with Changing Expectations?

“It is no longer enough to simply make good medication.”

<table>
<thead>
<tr>
<th>What Does Pharma Provide Today?</th>
<th>How Does Pharma Need to Evolve?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Society</strong></td>
<td><strong>Traditional focus areas remain as key contributions. Potentially opportunities:</strong></td>
</tr>
<tr>
<td>• Innovative treatment options.</td>
<td>• Building infrastructure to support treatment, e.g., new clinics or hospitals.</td>
</tr>
<tr>
<td>• Disease awareness education.</td>
<td>• Free medication to low-income patients.</td>
</tr>
<tr>
<td>• Product donations and other donation support.</td>
<td>• Market development for rare diseases and new disease areas.</td>
</tr>
<tr>
<td></td>
<td>• Universal healthcare is UN goal and pharma’s role in this is likely to develop.</td>
</tr>
</tbody>
</table>

**Challenges/Questions:** Perception risk of undue influence if pharma is required to contribute towards country or regional health costs.

<table>
<thead>
<tr>
<th><strong>HCPs / Nurses / KOLs</strong></th>
<th><strong>Traditional focus areas will remain as key contributions. Potentially opportunities:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Medical education.</td>
<td>• Digital solutions to support diagnosis, treatment and follow-up.</td>
</tr>
<tr>
<td>• Facilitating scientific exchange on new products/treatment options.</td>
<td>• Tools to provide better patient data, e.g., connected pens or real-time apps.</td>
</tr>
<tr>
<td>• Funding of independent research projects.</td>
<td>• Education to improve clinical competencies beyond theory.</td>
</tr>
</tbody>
</table>

**Challenges/Questions:** Perception risk of undue influence if pharma is providing something the HCP would otherwise pay for.  
Same can be said for supportive tools that are not strictly related to patient treatment – where do we draw the line?

<table>
<thead>
<tr>
<th><strong>Patients</strong></th>
<th><strong>Clinical trials will remain, but virtual trials will increase.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Opportunity to participate in clinical trials.</td>
<td>• PSPs likely to evolve and expand as digital health solutions are developed, but also more simple technologies like telemedicine, coaching etc.; preventive care options likely to be required.</td>
</tr>
<tr>
<td>• Patient support programs (PSPs).</td>
<td>• PAPs likely to expand and be regulated further?</td>
</tr>
<tr>
<td>• Patient assistance programs (PAPs).</td>
<td>• Channels of interaction will evolve.</td>
</tr>
<tr>
<td>• Provide feedback to pharma on unmet and improvement needs within treatment offerings.</td>
<td></td>
</tr>
</tbody>
</table>

**Challenges/Questions:** Perception risk of undue influence if pharma is required to contribute towards country or regional healthcare costs.  
How much responsibility should pharma have for the holistic care of a patient? How much is patient’s own responsibility?
Today’s Evolving Key Risk Areas

The future risks and how to navigate them are less clear.

<table>
<thead>
<tr>
<th>Anti-bribery / Anti-corruption</th>
<th>Off-label Promotion</th>
<th>Potential Conflict of Interests</th>
<th>Confidentiality / Data Privacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Money Laundering / Tax Evasion</td>
<td>Transparency Requirements</td>
<td>Trade Association &amp; Other Local Requirements</td>
<td>Competition / Anti-trust</td>
</tr>
</tbody>
</table>

Breach of these rules may have significant potential negative impact on the company and individuals concerned, including their reputation and potential liability. These risks apply directly to companies or indirectly through third parties.
Using the Framework

Guiding the Decision-Making Flow
The Decision-Making Framework

Five Steps to Navigate Decision-Making Flow

1. **Why**
   - Identify and Evaluate

2. **Who**
   - Define Accountability and Responsibility

3. **What**
   - Determine and Decide

4. **How**
   - Execute and Implement

5. **Impact & Control**
   - Monitor and Control

This Decision-Making Framework is principles-based and enables leaders to:

→ **Assess new and innovative business models** and
→ **Ensure decisions are grounded in ethics and integrity**
Integrating Ethos into Decision-Making

**C1:** How do we play our part in helping solve societal challenges?

**C2:** How do we ensure patients are first in everything we do (e.g., safety, quality, well-being, innovative solutions)?

**C3:** In which ways do we adhere to the highest possible scientific and ethical standards from discovery to delivery of our products?

**C4:** To what extent do we act with integrity in applying scientific medical principles demonstrating the safety and efficacy of our products?

**C5:** How do we ensure that we move “as fast as we can, but as slow as we must”?

**H1:** What measures are we taking to ensure active, timely, balanced and truthful communication?

**H2:** How are we ensuring transparency throughout our activities and processes, both internally and externally?

**H3:** What are the legitimate needs for patients, healthcare providers, ourselves and society that we intend to meet?

**H4:** How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges?

**H5:** How are we learning from mistakes as well as best practices and communicating these within the organization?

**F1:** How do we act with integrity to earn the trust of patients, healthcare providers, other stakeholders and the society we serve?

**F2:** How do we ensure that we do what is right, even when no one is watching?

**F3:** Through what measures do we hold ourselves and our partners accountable?

**F4:** How do we properly assess and mitigate all the risks associated with our innovative products/services?

**F5:** How do we ensure that we treat our third parties, customers and stakeholders fairly?

**R1:** What measures do we take to respect human rights and/or animal rights?

**R2:** How do we take our environmental impact into account in our actions?

**R3:** What are we doing to ensure respect for privacy rights?

**R4:** In what way are we driving scientific advancements to ensure a more educated industry, communities and society?

**R5:** Through what measures do we ensure and display our appreciation of the value of diversity?
# Decision-Making Flow Summary

**Ethos in Action Guiding Questions for Each Phase of the Decision-Making Framework**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Guiding Qs</th>
<th>Steps</th>
</tr>
</thead>
</table>
| **1. Why** Identify and Evaluate | C1 C2 F1 F5 R1 R2 R4 H3 | • What is the rationale and purpose for conducting an activity? What are the business objectives, stakeholder needs (e.g., HCPs), and patients’ unmet medical needs to support legitimate purpose?  
  • Describe issues or challenges to be addressed; do you have all the information you need?  
  • Identify impact on stakeholders.  
  • Provide data sources and information contributing to assessment. |
| **2. Who** Define Accountability and responsibility | F3 R3 R5 H2 H4 | • The accountable decision maker is an individual in the organization, not a committee.  
  • Explain who is the owner of the project or activity. If cross-functional, which department owns the activity. Explain the various company departments involved, if relevant and their roles and responsibilities.  
  • Decision must be informed by and based on cross functional insights and context. |
| **3. What** Determine and Decide | C3 C4 F2 F4 R1 H1 H5 | • Describe potential options and solutions proposed to meet the needs or to resolve the problem.  
  • If several options could be considered, explain the option you propose or if options will be sequential.  
  • Define clear objectives and deliverables.  
  • What type of activity will best satisfy the rationale and purpose identified?  
  • What are the key elements to take into consideration in conjunction with IFPMA Ethos? Explain the ethical principles that you are going to apply and consider for ethical dilemmas, if any. |
| **4. How** Execute and Implement | C5 R3 H1 H2 H4 H5 | • Assess the applicable laws, regulations, codes and internal procedures to help ensure compliance.  
  • Trust your judgment – is the action fair, the “right” thing to do, consider the public perception if made public.  
  • Describe detailed action plans, timelines, deliverables for each owner at each stage of the project (before, during and after).  
  • Explain total and detailed costs and payment terms based on deliverables. |
| **5. Impact and Control** Monitor and Control | F5 H2 H5 | • Document all decision-making steps and details of the activity in order to maintain a record of all activities.  
  • Notify appropriate persons (open and transparent communication, disclosure of potential issues).  
  • Describe what the key success factors are and align measurements (KPIs) with objectives and deliverables. Ensure an appropriate owner of these factors/KPIs is assigned.  
  • Set up reporting and financial controls on costs and monitor the effects of decisions/project; adjust actions to new information as necessary. |
1. Why

Identify and Evaluate

- What is the rationale and purpose for conducting an activity?
- What are the business objectives, stakeholder needs (e.g., HCPs), and patients’ unmet medical needs to support legitimate purpose?
- Describe issues or challenges to be addressed; do you have all the information you need?
- Identify impact on stakeholders.
- Provide data sources and information contributing to assessment.

Remember!
Support legitimate purpose with:
- Rationale and purpose for conducting an activity.
- Business objectives that address stakeholder needs (e.g., HCPs).
- Patients’ unmet medical needs

Ethos in Action Guiding Questions:

Care
- C1: How do we play our part in helping solve societal challenges?
- C2: How do we ensure patients are first in everything we do (e.g., safety, quality, well-being, innovative solutions)?

Fairness
- F1: How do we act with integrity to earn the trust of patients, healthcare providers, other stakeholders and the society we serve?
- F5: How do we ensure that we treat our third parties, customers and stakeholders fairly?

Respect
- R1: What measures do we take to respect human and/or animal rights?
- R2: How do we take our environmental impact into account in our actions?
- R4: In what way are we driving scientific advancements to ensure a more educated industry, communities and society?

Honesty
- H3: What are the legitimate needs for patients, healthcare providers, ourselves and society that we intend to meet?
Define Accountability and Responsibility

2. Who

The accountable decision maker is an individual in the organization, not a committee.

Explain who is the owner of the project or activity. If cross-functional, which department owns the activity. Explain the various company departments involved, if relevant, and their roles and responsibilities.

Decision must be informed by and based on cross functional insights and context.

Remember!
- Define the individual who is accountable to make the decision.
- Decide on the action plan and next steps.
- Describe roles and responsibilities and identify the Company’s department that owns the project/activity.
- Describe the interdependencies between the Company’s departments.

Ethos in Action Guiding Questions:

Fairness

F3: Through what measures do we hold ourselves and our partners accountable?

Respect

R3: What are we doing to ensure respect for privacy rights?

RS: Through what measures do we ensure and display our appreciation of the value of diversity?

Honesty

H2: How are we ensuring transparency throughout our activities and processes, both internally and externally?

H3: How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges?
Determine and Decide

→ Describe potential options and solutions proposed to meet the needs or to resolve the problem.

→ Define clear objectives and deliverables.

→ If several options could be considered, explain the option you propose or if options will be sequential.

→ What type of activity will best satisfy the rationale and purpose identified?

→ What are the key elements to take into consideration in conjunction with IFPMA Ethos? Explain the business decision-making principles that you are going to apply and consider the dilemmas, if any.

Ethos in Action Guiding Questions:

**Care**

- **C3:** In which ways do we adhere to the highest possible scientific and ethical standards from discovery to delivery of our products?
- **C4:** To what extent do we act with integrity in applying scientific medical principles demonstrating the safety and efficacy of our products?

**Fairness**

- **F2:** How do we ensure that we do what is right, even when no one is watching?
- **F4:** How do we properly assess and mitigate all the risks associated with our innovative products/services?

**Respect**

- **R1:** What measures do we take to respect human and/or animal rights?

**Honesty**

- **H1:** What measures are we taking to ensure active, timely, balanced and truthful communication?
- **H5:** How are we learning from mistakes as well as best practices and communicating these within the organization?

Remember!

- Design and analyze options or project to meet needs.
- Describe necessary steps to take to help ensure appropriate risk mitigation for bold or complex work/projects.
- Apply ethical principles (IFPMA Ethos).
- Decide and describe project purpose and key objectives.
 Execute and Implement

→ Assess the applicable laws, regulations, codes and internal procedures to help ensure compliance.

→ Trust your judgment – is the action fair, the “right” thing to do, consider the public perception if made public.

→ Describe detailed action plans, timelines, deliverables for each owner at each stage of the project (before, during and after).

→ Explain total and detailed costs and payment terms based on deliverables.

Ethos in Action Guiding Questions:

Care

C5: How do we ensure that we move “as fast as we can, but as slow as we must”?

Respect

R1: What are we doing to ensure respect for privacy rights?

Honesty

H1: What measures are we taking to ensure active, timely, balanced and truthful communication?

H2: How are we ensuring transparency throughout our activities and processes both internally and externally?

H4: How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges?

H5: How are we learning from mistakes as well as best practices and communicating these within the organization?
Monitor and Control

- Fully document all decision-making steps and details of the activity in order to keep evidence of all activities.
- Notify appropriate persons (open and transparent communication, disclosure of potential issues).
- Describe what the key success factors are and align measurements (KPIs) with objectives and deliverables. Ensure an appropriate owner of these factors/KPIs is assigned.
- Set up reporting and financial controls on costs and monitor the effects of decisions/project; adjust actions to new information as necessary.

Ethos in Action Guiding Questions:

**Fairness**

F5: How do we ensure that we treat our third parties, customers and stakeholders fairly?

**Honesty**

H2: How are we ensuring transparency throughout our activities and processes both internally and externally?

H5: How are we learning from mistakes as well as best practices and communicating these within the organization?

Remember!

- Check completeness of project implementation.
- Define monitoring & controls KPIs.
- Control the budget versus actual spend.
- Monitor and modify outcome, as needed.
Case Studies
The purpose of the case studies is to use IFPMA Decision-Making Framework to identify and discuss complex, innovative or “grey areas” and develop proposals that balance competing needs and obligations and ensure our decisions are consistent with the IFPMA Ethos.

Use slides 14 to 18 to guide the approach.

How to use the case studies?
The case studies are intended to facilitate cross-functional discussion. You do not need to solve the case. Use the Decision-Making Framework to discuss the impact of the different scenarios.

Adaptation and localization
The case studies provided are general fictitious examples for the purpose of discussion only. Local adaptation of the facts of each case study scenario might be needed to suit local market conditions and to ensure adherence to local laws, regulations and industry codes.

Disclaimer: These case studies are purely fictitious examples for the purposes of discussion. IFPMA does not endorse any of the views or scenarios in these case studies. All related compliance guidance should always be subject to applicable local laws, regulations and industry codes.
Case Study Summaries

**Case Study 1**

Innovative Opportunities: **Telemedicine**

New, innovative business models and technologies such as telemedicine can present significant opportunities as well as new dilemmas related to appropriate HCP interactions.

**Case Study 2**

Innovative Opportunities: **Market Development**

Entering a new therapy for a chronic disease and expanding an existing one presents a lot of new business opportunities but also gives rise to new challenges related to interactions with HCP, HCOs and patients.

**Case Study 3**

Hiring with Integrity: **Industry Associations**

Some association activities, such as hiring for policy-related positions, can pose significant risks that need to be mitigated, including potential conflicts of interest and reputational harm.
Innovative Opportunities: Telemedicine

Case Study 1
To pursue growth opportunities outside of the traditional pharmaceuticals space, your company is looking into a potential role in telemedicine. Telemedicine is a rapidly growing opportunity driven by changes in technology and patient and provider preferences.

In assessing this opportunity, your team is investigating potential business model options. One option currently being discussed involves the following:

Case Study 1

Innovative Opportunities: Telemedicine

1. Background

Your company would provide selected HCPs with hardware (iPads) and software (free licenses to telemedicine video conferencing software) in exchange for collecting blinded patient diagnosis and prescription data through the platform.

Your company would also provide these HCPs with company-developed software that assists HCPs with diagnosis and treatment decision-making. The software uses AI to analyze the video, audio, and HCP notes from the telemedicine visit and recommends potential diagnoses and treatment options. While the software is designed to provide unbiased recommendations, its AI was trained in part with proprietary company data.
There are few guidelines or regulations in this space, and competitors have not yet adopted similar approaches. Therefore, your team should assess and balance the commercial and ethical considerations prior to making a formal recommendation to leadership.

Consider how your answers and reflections would change in the following circumstances:

- What if different stakeholders are potentially provided hardware/software to support the telemedicine, for example, patients, HCPs, hospitals, medical practices, and other providers. Does this impact the decisions or risk management?

- Local legal/regulatory considerations may impact the decision or local industry guidance exists on telemedicine that may impact the preferred approach (including potential near-term changes or regulations). What legal changes or advocacy may be needed for the group’s approach to be viable (e.g., industry, company, digital, stakeholder engagement).

- Are there different implications due to the country medical insurance/reimbursement system (e.g., public, private)?
### 3. Applying the Decision-Making Framework

A non-exhaustive list of questions to consider when using the DMF to support decision-making:

<table>
<thead>
<tr>
<th>Step</th>
<th>Question</th>
</tr>
</thead>
</table>
| **1. Why Identify and Evaluate** | - What are the legitimate business needs and the business objectives we are trying to achieve?  
- Are we respecting patients and protecting their privacy rights?  
- Was the IA algorithm designed ethically, avoiding biases and without creating any potential discrimination?  
- Was patient safety top of mind?  
- How would the society perceive these initiatives?  
- Do these initiatives help to build trust with the society? |
| **2. Who Define Accountability and responsibility** | - Discuss various roles and responsibilities.  
- If cross-functional, which department owns which activity? |
| **3. What Determine and Decide** | - What are the key ethical and risk management areas for consideration and related mitigation actions?  
- If several options could be considered, what decision will best satisfy the rationale and purpose identified and reflect business decision-making?  
- Are there other external developments on the horizon that may impact the decision and should be considered? |
| **4. How Execute and Implement** | - What are the existing laws and codes to be considered?  
- In light of applicable laws, codes, and industry guidelines, is the initiative permitted?  
- Is it appropriate to provide these benefits to individual HCPs?  
- Is the execution and implementation strategy sustainable? |
| **5. Impact and Control Monitor and Control** | - Describe what the key success factors would look like.  
- Are measurements (KPIs) aligned with objectives and deliverables?  
- How would these success factors be viewed by stakeholders?  
- Are there significant financial controls required and what are the costs to support effective controls (e.g., monitor the effects of decisions/project)? |
Case Study 2

Innovative Opportunities:

Market Development
Your company is entering a new therapy for a chronic disease where there have previously been no treatment options available. This means that the market will need to be developed to increase patient awareness of the disease and also, to train healthcare professionals in providing quality of care with the new treatment option your company has developed that is currently in phase 3 of clinics trials.

Your team is investigating potential development strategy and tactics for this area. The options currently being discussed include:

- **Your company would run company driven medical education events for the top disease specialists.** Attendees would be invited to discuss the phase 3 results of your company’s clinical trials. The new treatment option is not yet approved but there are no competitors in this therapy area and the results are so good, your team is sure it will be approved soon so why wait!

- **Your local affiliates will work with local patient associations to run a social media campaign for patients on disease awareness.** As part of this campaign, you will highlight that a new treatment option is on the way, and that patients should ask their doctor about it.

- As part of the social media disease awareness campaign, **patients will be asked to share their personal experiences of living with the disease in a Facebook group.** Your team will use these testimonials as part of the brand campaign to make sure they take into account the patient experience.
You should assess and balance the commercial and ethical considerations prior to making a formal recommendation to leadership about the suggested development strategy and tactics.

Consider how your answers and reflections would change in the following circumstances:

- What if a competitor entered the therapy area with a new but unapproved product?
- What if a competitor product was already approved and available?
- What difference would it make (if any) if other treatment options existed?
- What if the company decides to run the disease awareness campaign by itself - are there other things you will need to take into account?
- What if your company’s new treatment option (which is the only one available) is approved but not available via the public healthcare systems or public reimbursement lists? What additional elements do you need to think about?
- Would you use social media as a tool in disease awareness in the same way if the chronic disease only affected adolescents? Or children?
3. Applying the Decision-Making Framework

A non-exhaustive list of questions to consider when using the DMF to support decision-making:

| 1. Why Identify and Evaluate | • What are the legitimate business needs and the business objectives we are trying to achieve?  
|                            | • Could these initiatives be or be perceived as pre-approval promotion/promotion to the public?  
|                            | • Are you respecting patients and their disease?  
|                            | • Is it ethical to make patients aware of a treatment option knowing that it might only be available on the private market?  
|                            | • Is it responsible to use social media to conduct disease awareness activities towards children and adolescents?  
|                            | • What are the implications of using patient testimonials in brand campaigns? Does the answer change if the patients are children?  
|                            | • How do you approach issues of affordability and patient access in these circumstances?  
|                            | • How would the society perceive these initiatives? |
| 2. Who Define Accountability and responsibility | • Discuss various roles and responsibilities.  
|                                      | • If cross-functional, which department owns which activity?  
|                                      | • What is the appropriate function to run these activities based on roles and responsibilities (medical versus commercial)?* |
| 3. What Determine and Decide | • What are the key ethical and risk management areas for consideration and related mitigation actions?  
|                                      | • If several options could be considered, what decision will best satisfy the rationale and purpose identified and reflect business decision-making?  
|                                      | • Are there other external developments on the horizon that may impact the decision and should be considered? |
| 4. How Execute and Implement | • What are the existing laws and codes to be considered?  
|                                      | • In light of applicable laws, codes, and industry guidelines, is the initiative permitted?  
|                                      | • Is it appropriate to provide these benefits to individual HCPs?  
|                                      | • Is the execution and implementation strategy sustainable?  
|                                      | • How do we ensure that we move “as fast as we can, but as slow as we must”? |
| 5. Impact and Control Monitor and Control | • Describe what the key success factors would look like.  
|                                      | • Are measurements (KPIs) aligned with objectives and deliverables?  
|                                      | • How would these success factors be viewed by stakeholders?  
|                                      | • Are there significant financial controls required and what are the costs to support effective controls (e.g., monitor the effects of decisions/project)? |
Case Study 3

Hiring with Integrity: Industry Associations
1. Background

Your Pharmaceutical Industry Association ("Association") is currently undergoing a hiring process, as there is an open full-time position for the Director of Public Affairs role. As the Executive Director of the Regulatory & Science Committee within the Association, you are part of the election panel.

Multiple applicants were screened, and the hiring process is close to final stage, with the three top candidates going through the defining election panel interviews with the Board Members in about a month.

The Regulatory & Science Committee raises a last-minute recommendation to hire a well-recognized consultant, whose vast professional experience would perfectly fit the needs for the role and who would be ready to start immediately. The candidate currently advises the government on public procurement decisions related to inclusion of new technologies.

The Association is invited to an important upcoming public Working Group meeting regarding the dialogue on procurement policies with government authorities and other industry stakeholders. The meeting is critical in advancing the Association's priorities, and the new Director of Public Affairs would play a pivotal role at the meeting, representing the Association.

A recommendation needs to be made to the Board Members in terms of:

1. Hiring the candidate recommended by the internal Committee, who would be ready to start immediately.
2. Continuing with the current selection process and likely not having the position filled until after the meeting.
2. Considerations

You should assess and balance the business and ethical considerations prior to making a formal recommendation to the Board.

Consider how your answers and reflections would change in the following circumstances:

- There is no upcoming meeting requiring the role to be filled immediately.
- The recommendation did not come from an internal Committee but instead from a headhunter that is aware of the Association’s ongoing hiring process.
- A job offer was about to be released to a final candidate.
- Are there different implications if the candidate’s governmental advisory role is official (i.e., is formally appointed) or unofficial (i.e., not formally appointed but consulted due to publicly known key expertise)?
- Are there different implications if the candidate’s governmental advisory role is not related at all to the upcoming meeting topic and objectives?
3. Applying the Decision-Making Framework

A non-exhaustive list of questions to consider when using the DMF to support decision-making:

<table>
<thead>
<tr>
<th>1. Why</th>
<th>Identify and Evaluate</th>
</tr>
</thead>
<tbody>
<tr>
<td>• What are the legitimate business needs and the business objectives we are trying to achieve?</td>
<td></td>
</tr>
<tr>
<td>• Do we have all the information we need to make a decision?</td>
<td></td>
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<tr>
<td>• How might hiring the consultant recommended by the Regulatory and Science Committee benefit the Association?</td>
<td></td>
</tr>
<tr>
<td>• How might hiring the consultant recommended by the Regulatory and Science Committee harm the Association?</td>
<td></td>
</tr>
<tr>
<td>• Are we being fair to the 3 top candidates?</td>
<td></td>
</tr>
<tr>
<td>• How does the upcoming public Working Group meeting impact our hiring decision? Should it have an impact?</td>
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</tbody>
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<table>
<thead>
<tr>
<th>2. Who</th>
<th>Define Accountability and responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Discuss various roles and responsibilities.</td>
<td></td>
</tr>
<tr>
<td>• How is transparency throughout the activities and processes being ensured, both internally and externally?</td>
<td></td>
</tr>
<tr>
<td>• How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges?</td>
<td></td>
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<tr>
<td>• Through what measures throughout the hiring process do we ensure and display our appreciation of the value of diversity?</td>
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<tr>
<th>3. What</th>
<th>Determine and Decide</th>
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<tbody>
<tr>
<td>• What are the key ethical and risk management areas for consideration and related mitigation actions?</td>
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<tr>
<td>• How does the IFPMA Ethos and principles of EDM apply?</td>
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<tr>
<td>• If several options could be considered, what decision will best satisfy the rationale and purpose identified and reflect business decision-making?</td>
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<tr>
<td>• Are there external developments on the horizon that may impact the decision and should be considered?</td>
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<tr>
<td>• Why does it matter that we get this right and what happens if there are significant issues?</td>
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<tr>
<td>• How are we assessing reputational impact?</td>
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<th>4. How</th>
<th>Execute and Implement</th>
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<tbody>
<tr>
<td>• What are the existing applicable laws, regulations, codes and internal procedures to be considered?</td>
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<tr>
<td>• How are we assessing the applicable laws, regulations, codes and internal procedures to help ensure compliance?</td>
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<tr>
<td>• In light of applicable laws, regulations codes, and internal procedures, is it appropriate to move forward?</td>
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<tr>
<td>• How do we ensure that we move “as fast as we can, but as slow as we must”?</td>
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<tr>
<th>5. Impact and Control</th>
<th>Monitor and Control</th>
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<tbody>
<tr>
<td>• Describe what the key success factors would look like.</td>
<td></td>
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<tr>
<td>• Are measurements (KPIs) aligned with objectives and deliverables?</td>
<td></td>
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<tr>
<td>• How would these success factors be viewed by stakeholders?</td>
<td></td>
</tr>
<tr>
<td>• How do we ensure that we treat our third parties, customers and stakeholders fairly?</td>
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</table>
Business objectives must be balanced against other key considerations, including:

- Laws, regulations, policies, guidance
- The needs of patients, clinical trial participants, medical community, and healthcare systems
- Broader societal needs and obligations related to healthcare
- Key risk areas and related mitigations
- Ethical considerations and social expectations

The Decision-Making Framework:

- Helps to identify key business objectives, potential ethical issues, impacted stakeholders, and solutions that better meet our purpose and duty in bringing innovation to patients.
- Advances business objectives while putting the IFPMA Ethos in action to navigate ethical grey areas inherent to our industry and complex operating environment.
Thank you for your time and your interest to learn more about the IFPMA Code!

Your involvement will be essential to ensure that the new provisions, as well as our Ethos are reflected in business practices.

Enabling innovation and business decisions with Ethos in Action!

Learn more and stay connected: ifpma.org

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