

Code of Practice

Key Changes

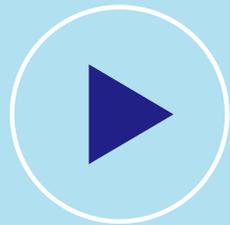


IFPMA

2019



Introduction



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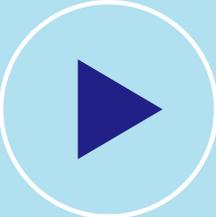
Melissa Barnes

Chair of the IFPMA Ethics and Business Integrity Committee (eBIC), Senior Vice-President of Enterprise Risk Management and Chief Ethics and Compliance Officer of Eli Lilly and Company

Melissa Stapleton Barnes

Introduction

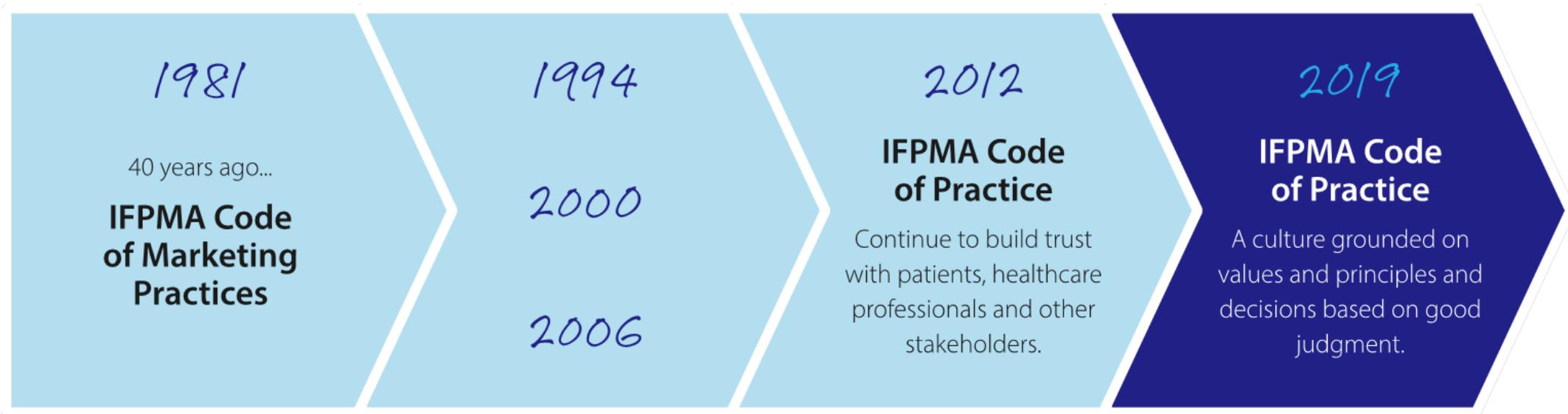



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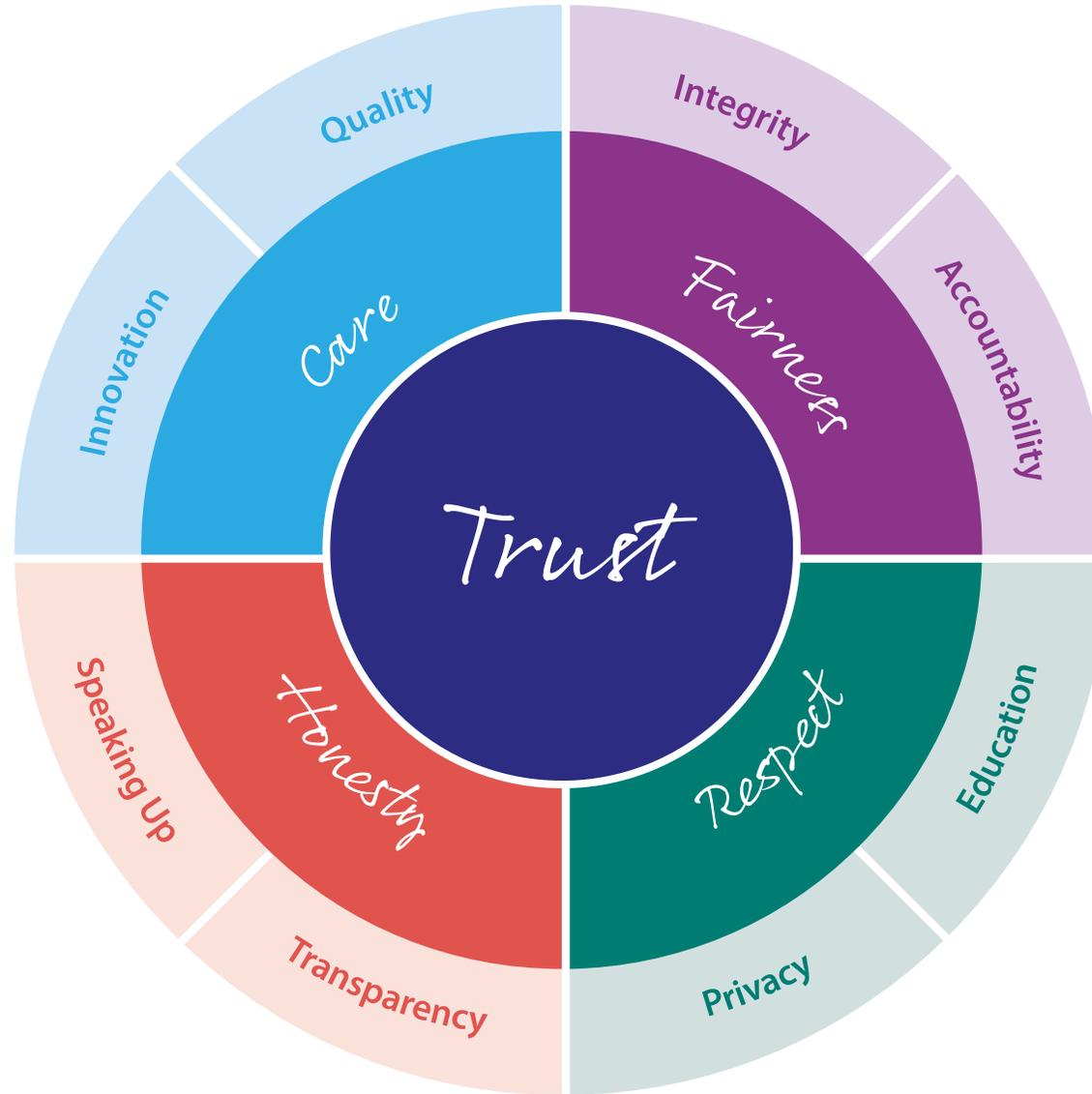
Sofie Melis
Senior Manager, Ethics & Compliance
IFPMA

Sofie Melis

The Evolution of the Code



The IFPMA Ethos puts trust at its center



Agenda

→ Introduction

→ How did we get here?

→ What is new?

1. Ethos
2. Ban on Gifts / Promotional Aids
3. Complaint Procedure
4. Other minor changes
5. Notes for Guidance

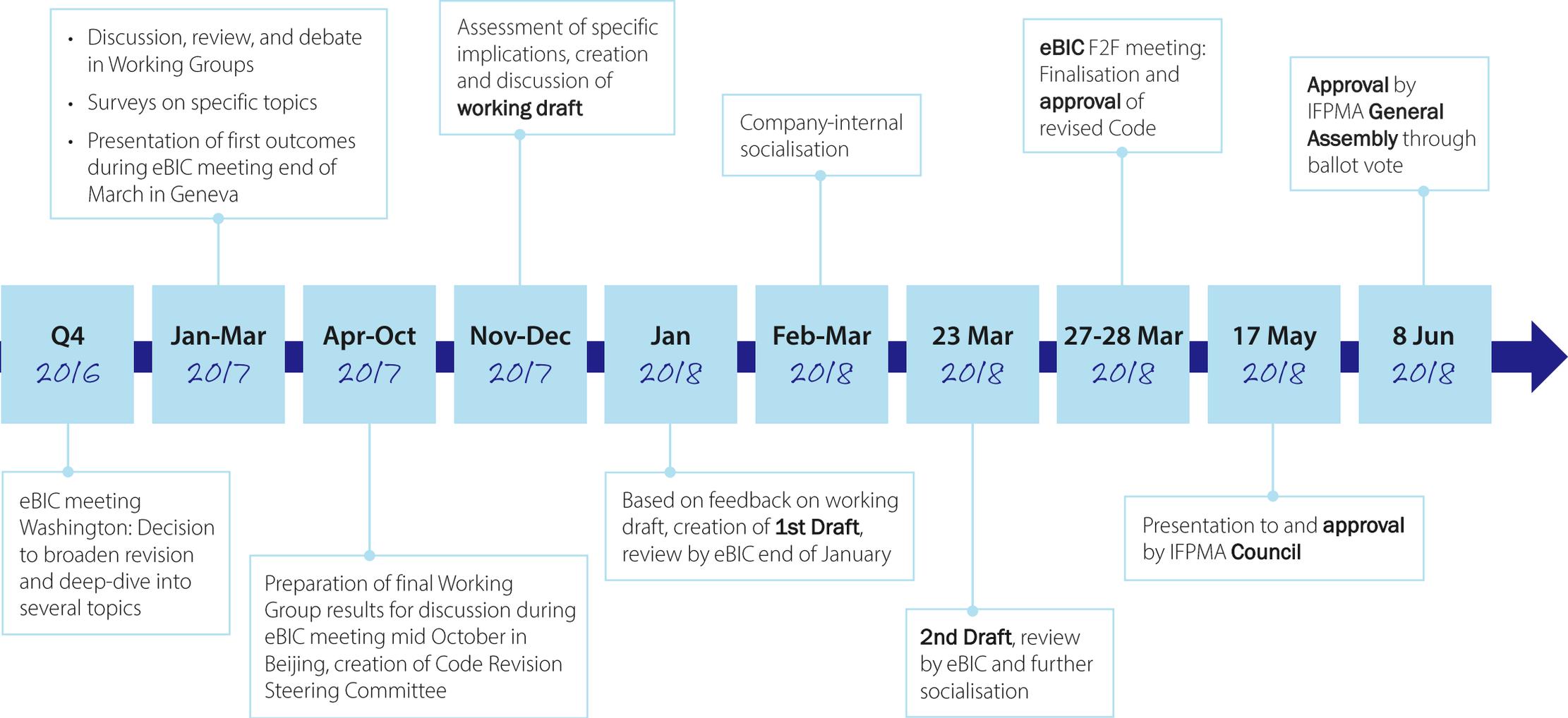
→ Next steps

→ Q&A

**How
did we
get here?**



Code Revision Roadmap



Global implementation and effective date



IFPMA members **must** incorporate the new provisions into their own codes by this date.

What is new?

1. Ethos

2. Ban on Gifts / Promotional Aids
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Care

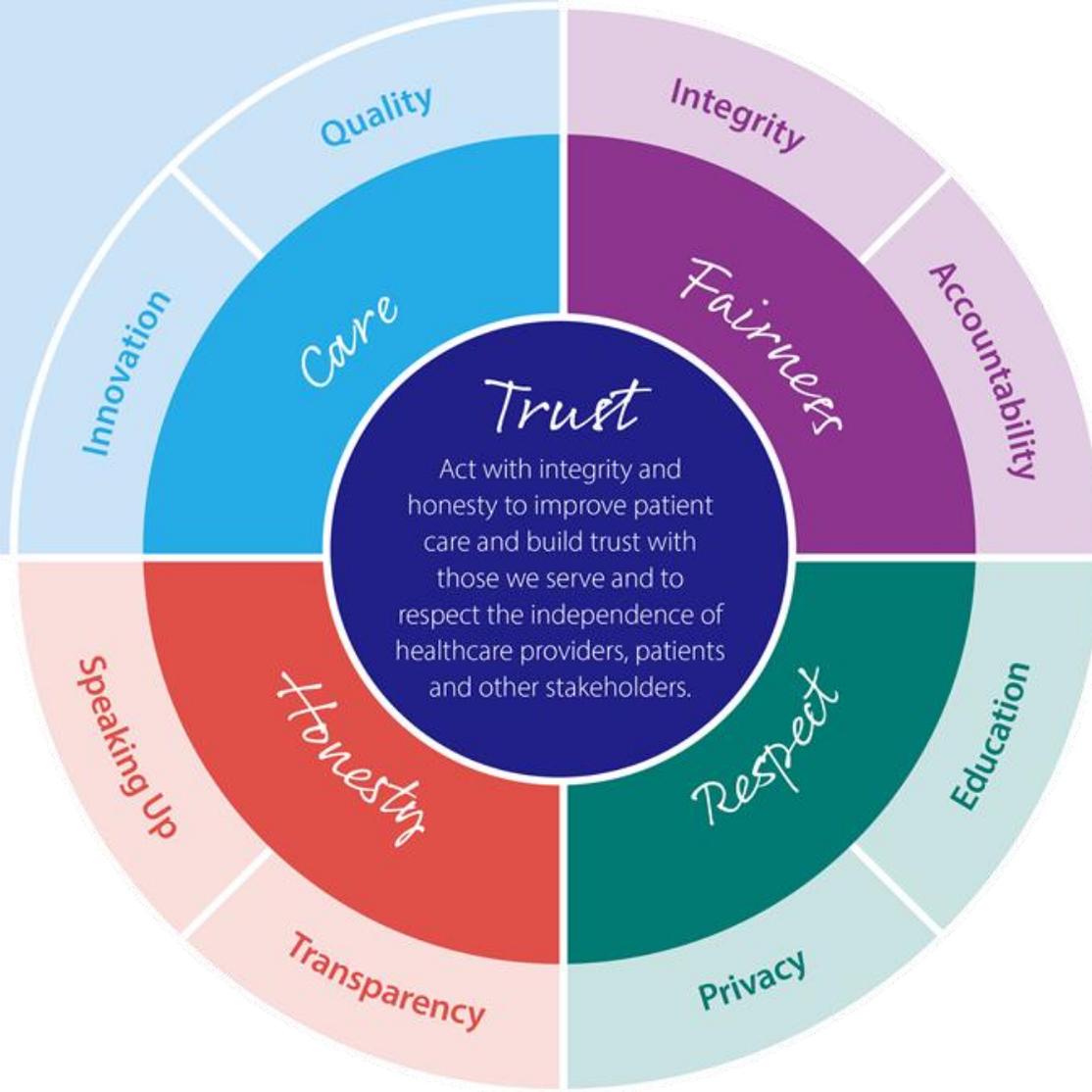
Protect the safety of those who use our products – from the conduct of clinical trials and throughout the product lifecycle.

Innovation

Improve global health through innovative products and services, upholding the highest ethical, scientific, and medical standards.

Quality

Commit to providing high-quality products that have proven clinical efficacy and have a reliable safety profile.



Care

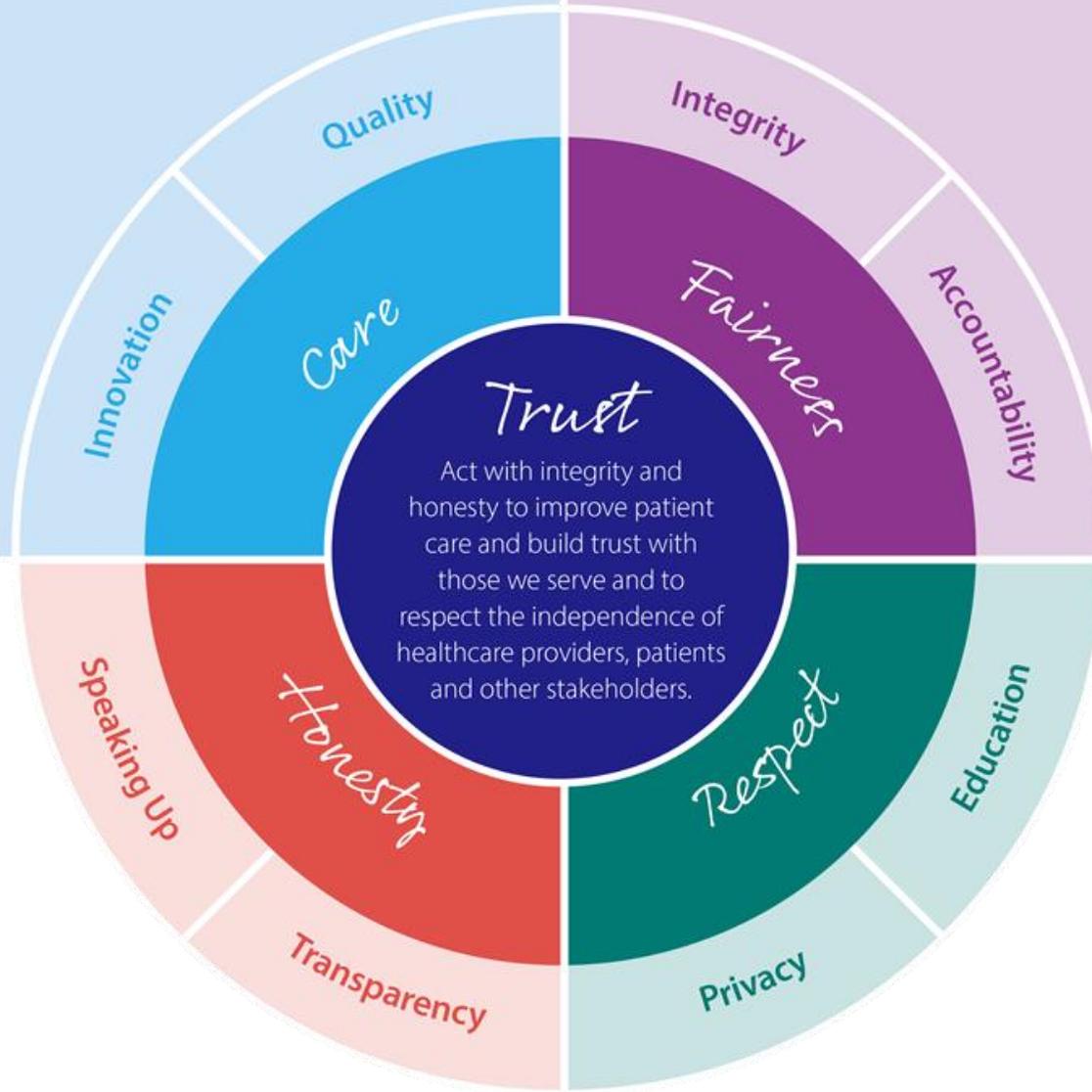
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Fairness

Support and respect fair trade practices and open competition.

Integrity

Act responsibly, ethically and professionally. Do not offer, promise, provide, or accept anything of value in order to inappropriately influence a decision, gain an unfair advantage.

Accountability

Be accountable for our actions and decisions, including the appropriate oversight of external third parties that act on our behalf.

Care

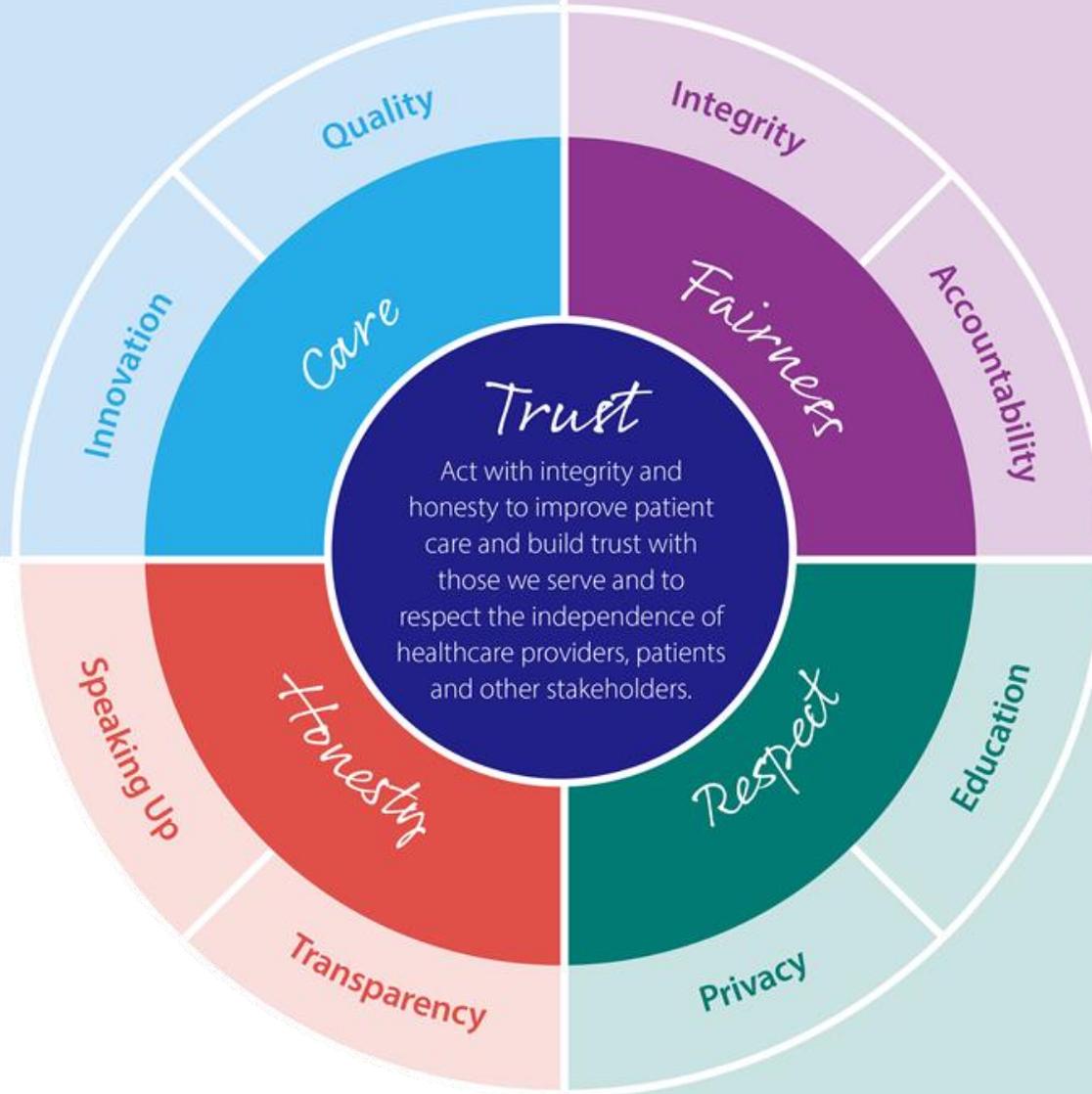
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Respect

Respect all people and embrace a culture of diversity and inclusion. Protect the environment. Treat animals under our care responsibly.

Privacy

Respect privacy rights and appropriately manage and protect personal information.

Education

Support the advancement of the scientific and medical education for the ultimate benefit of patients.

Care

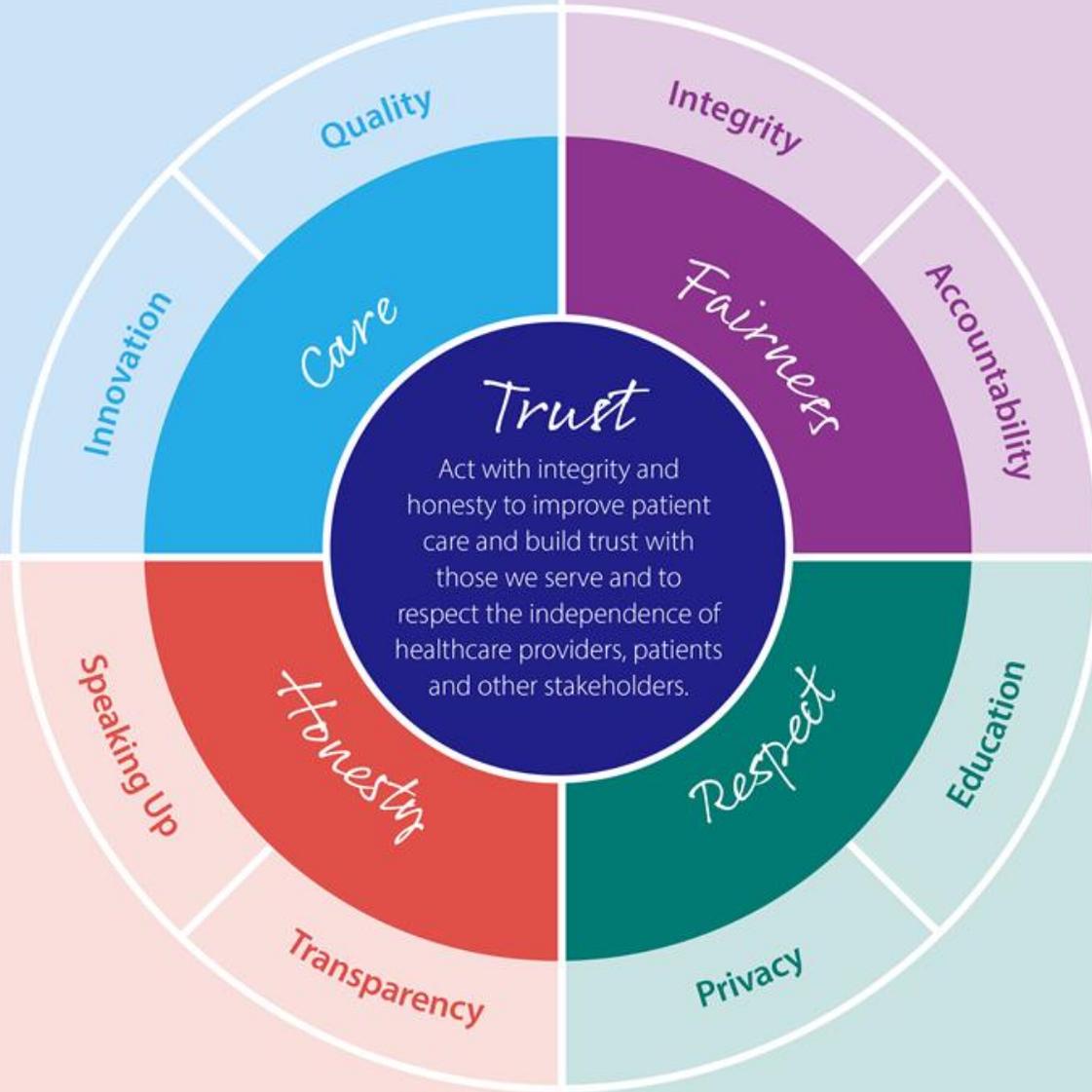
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Be accountable for our actions and decisions, including the appropriate oversight or external third parties that act on our behalf.

Honesty

Ensure truthful and balanced communication with governmental authorities, healthcare professionals, patients and other stakeholders.

Speaking Up

Foster a culture in our respective organisations where concerns are shared openly and honestly so that we learn from mistakes and continuously improve.

Transparency

Advance science and patient care by sharing industry-sponsored clinical trial data in a responsible, accurate and appropriate manner.

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- 2. Ban on Gifts / Promotional Aids**
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Gifts and other Items to HCPs (section 7.5)



Added general spirit to chapter 7.5:

“Items in this section, where permissible, must never constitute an inducement to prescribe, recommend purchase, supply, sell or administer a pharmaceutical product.”



Ban on Gifts: Gifts for personal benefit already banned since 2012 but as of January 2019, no more exceptions, i.e. cultural courtesy gifts (e.g. mooncakes, condolence payments) also prohibited.



Gifts and other Items to HCPs (section 7.5)



Added clarification: “gifts, whether provided directly or through clinics and institutions”.



Aligned IFPMA Code to member association codes such as EFPIA and PhRMA where a ban has been in force for several years (gifts and promotional aids).



Ban on Promotional Aids (for Rx-based medicines)



Non-monetary reminder items:

Examples: post-its, mouse pads, calendars, plasters, bags or binders etc.



2012 Code allowed if relevant to the practice of the HCP, but now full ban in relation to the promotion of **prescription-only medicines.**

Please communicate to your marketing teams (to manage stock & production)



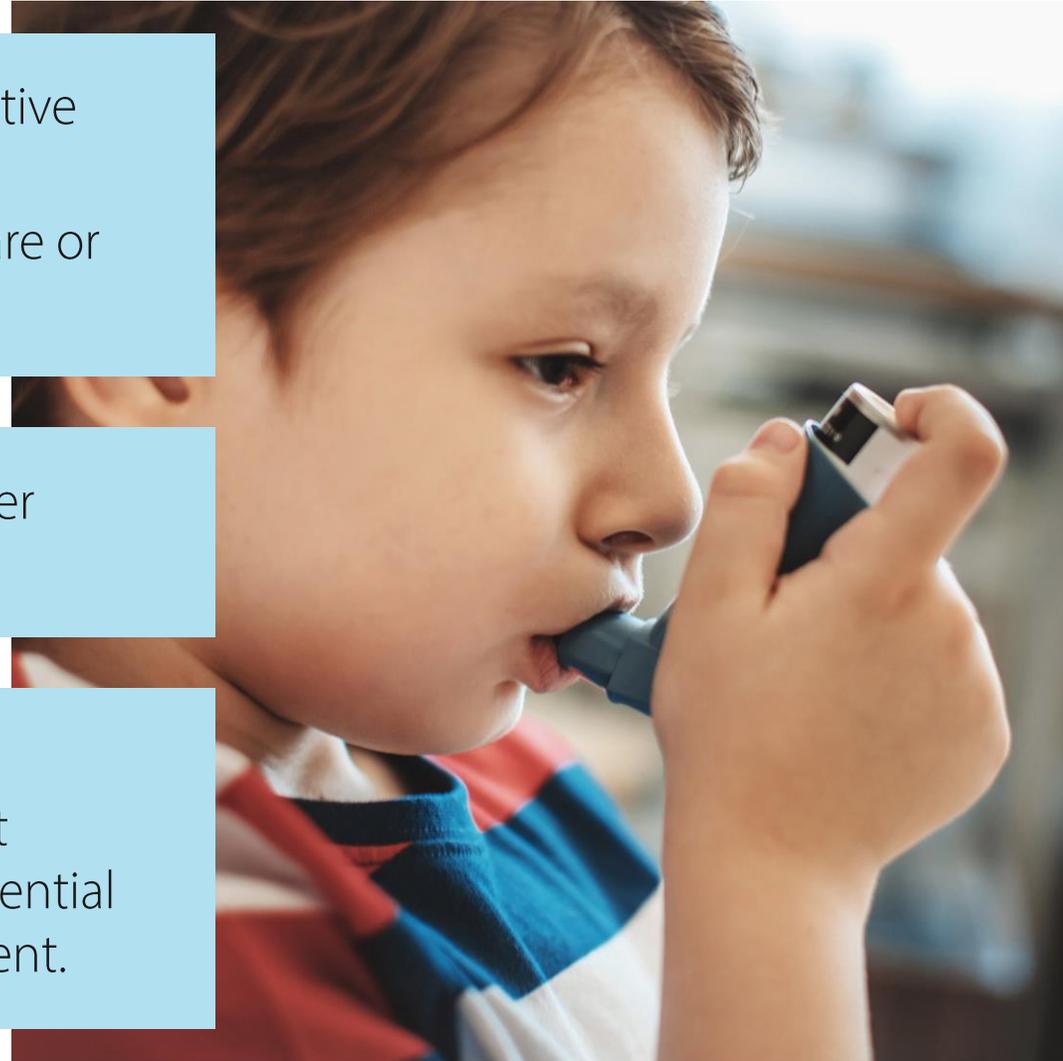
However excluded for:

- The promotion of over-the-counter medicines if relevant to the practice of the HCP.
- Pens and notepads at company organized events for the **purpose of taking notes during the meeting.** (Not product, only company branded, of minimal value and in the necessary quantity for the purpose of the event).

✓ *Covered in new Q&A*

Items of Medical Utility

- **Examples:** inhalation devices (without active ingredient) or devices intended to assist patients to learn how to self-inject, software or mobile apps (e.g. BMI calculator).
- **Already restricted** in 2012, but now further clarified.
- **Items of Medical Utility can include the company name**, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.



Items of Medical Utility



Such items may only be offered if:

- They are of **modest value**
- They are **not expected** to be supplied by the HCPs themselves or their employers i.e. for routine business practice (e.g. stethoscopes, surgical gloves, blood pressure monitors and needles)
- They are **beneficial** to enhancing the provision of medical services and patient care
- They are **not offered** on more than an occasional basis, even if each individual item is appropriate.



Informational or Educational Items that enhance Patient Care

→ **New** section under chapter 7.5 “Gifts and other Items to HCPs”.

→ **Such items may be provided to HCPs** for their education or for the education of patients, provided that the items are primarily for educational purposes and do not have independent value.

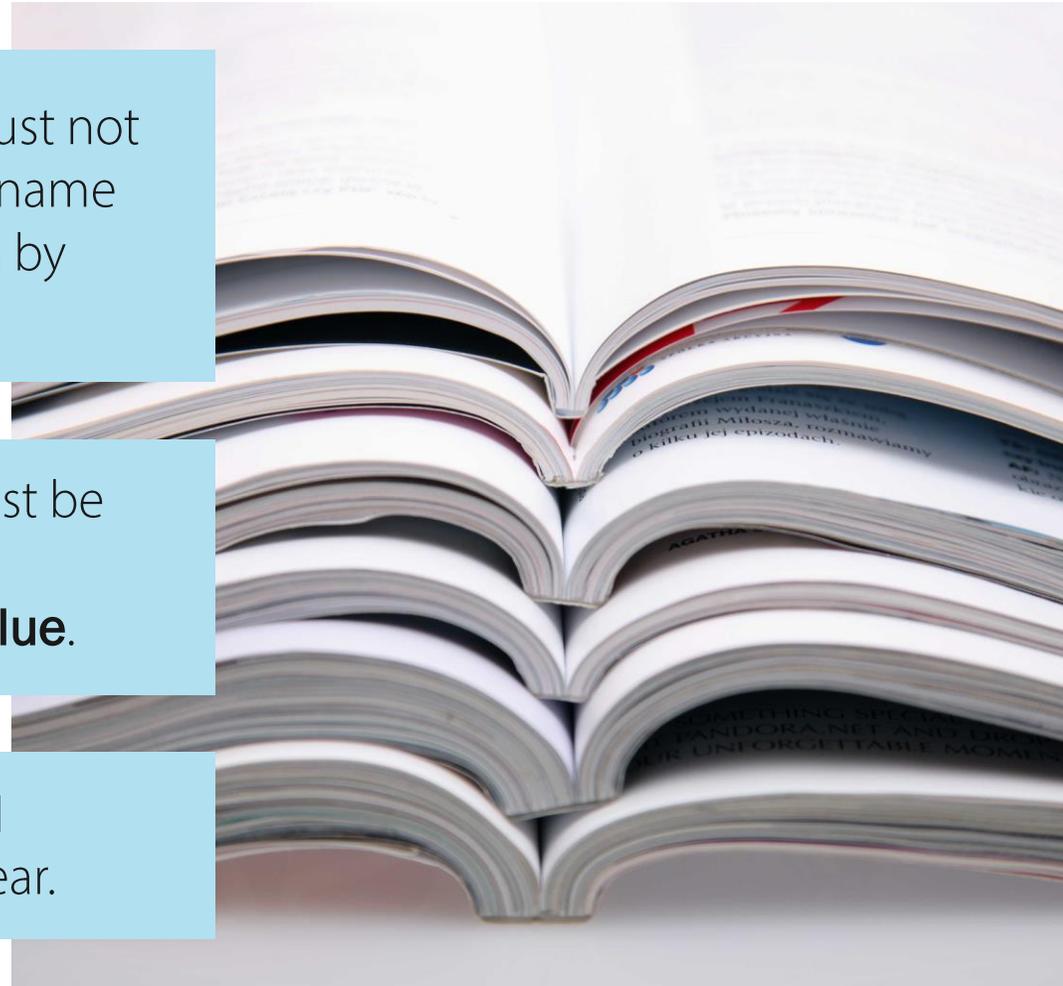
Examples:

Scientific books, journal subscriptions, memory sticks with educational data.

- **Memory sticks pre-loaded with educational or informational data** may be appropriate if the storage capacity is commensurate with the materials provided.
- **Tablet computers have independent value to a HCP** and must not be provided, even if they could also be used to deliver education to patients.

Informational or Educational Items that enhance Patient Care

- **Can include the company name**, but must not be product branded, unless the product name is essential for the correct use of the item by the patient.
- The value of books and subscriptions must be **reasonable**. Other informational or educational items must be of **modest value**.
- **Consider the cost as well as the overall benefit** to an individual HCP in a given year.



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IFPMA Complaint Procedure

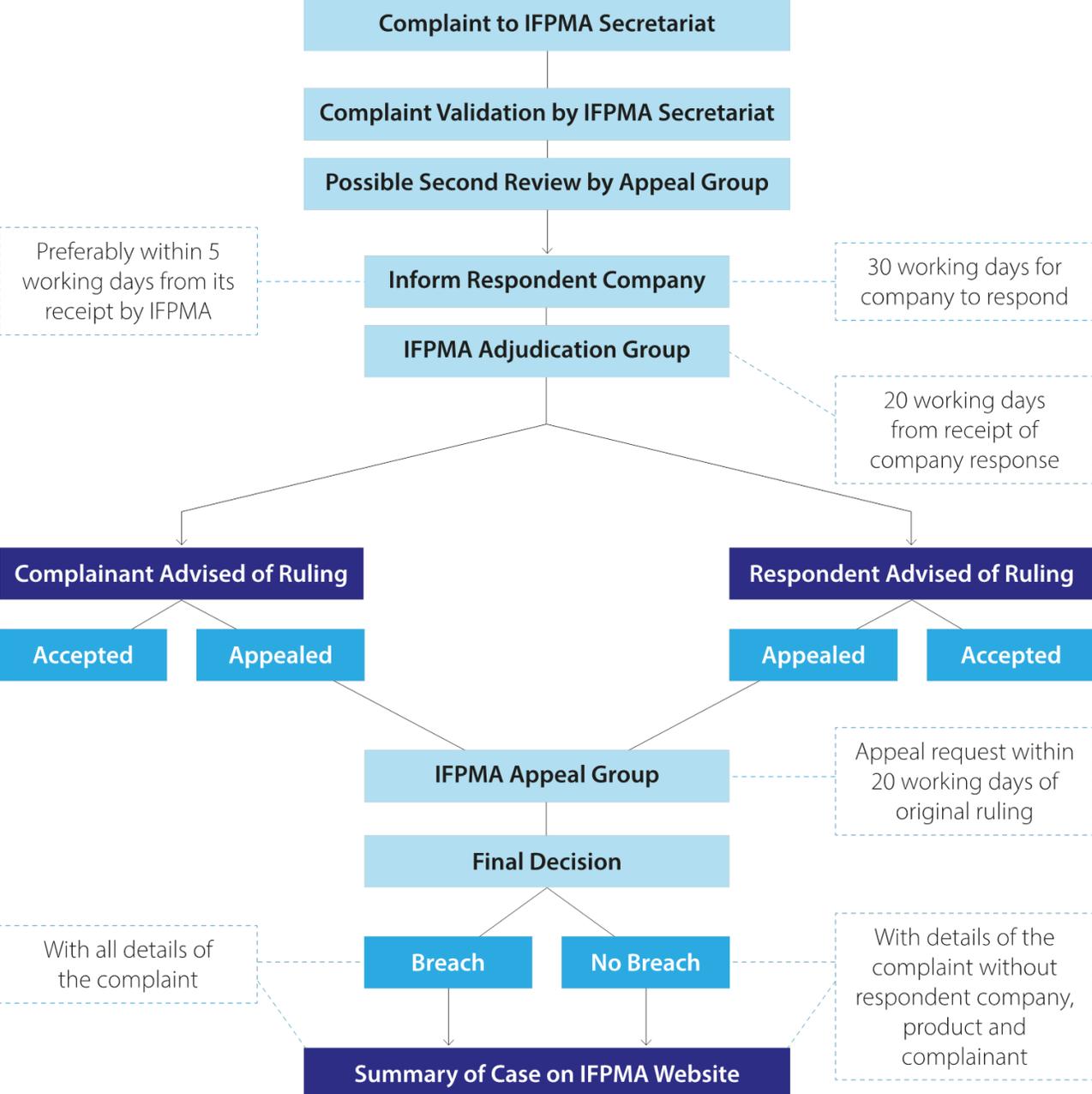
→ **Scope has not changed**, but alignment with the requirements in the Preamble has been ensured

→ **Procedure has been updated:**

- **Second review** by Appeal Group in validation of a complaint
- **Time limits:** calendar days replaced by working days
- **Adjudication and Appeal groups** elected for **two** instead of one year
- **Section added** on Anonymous Complaints (still accepted but provision of contact details is encouraged)
- **Oral hearing** in the context of the Appeal Procedure now possible



IFPMA Complaint Procedure



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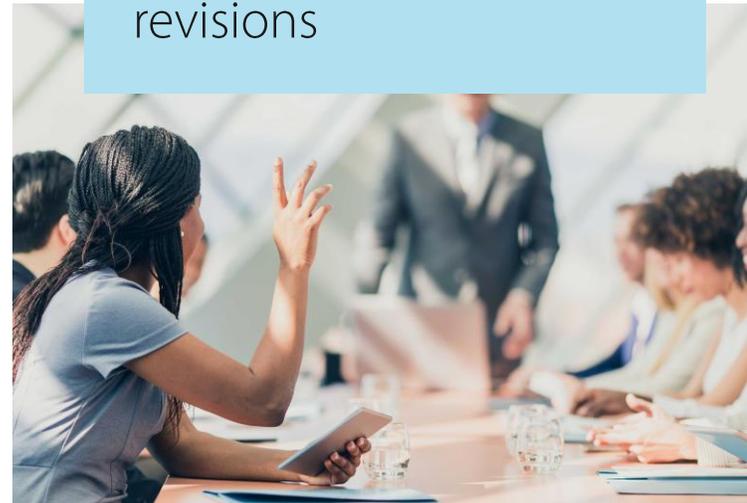


Other minor changes

1. IFPMA address
2. Name of Ethics Committee
3. Clarification on events involving foreign travel **(7.1.2)**
4. Accompanying guests **(7.3)**
5. Reimbursement of reasonable expenses for Fees for Services compensation **(7.4)**
6. Guidance on values **(7.5.4)**



Q&A adapted to Code revisions



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Note for Guidance on Sponsorship of Events and Meetings

- Update of 2014 version
- **Not binding, but additional interpretation** and further guidance to the Code.
- **Main changes to the 2014 Note for Guidance:**

- The location should aim to minimize travel for the attendees and take security considerations into account
- Exhibition areas should only be accessible to the intended audience
- Additional external resource (IPCAA Congress Healthcare Guidelines – ipcaa.org)

To be found on the IFPMA website under Resources/Publications:

ifpma.org/resource-centre/ifpma-code-of-practice

Note for Guidance on Sponsorship of Events and Meetings

Additional criteria to consider:

- Is there an expectation that sponsoring companies fund such activities?
- If there is leisure activity, are they self-funded by the participants?
(3.b. Entertainment)
- Are there references to personal services provided to attendees?
(4. Meeting Materials)

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Note for Guidance on Fees for Services

→ Newly created document

Further interpretation
of Code section 7.4 in
form of a non-binding
guidance document

**Practical
considerations**
regarding general
Fees for Services
arrangements

**Additional points to
consider** for Advisory
Boards

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Next steps



Next Steps

- Additional Code revision **webinars** to cover all time zones
- **eLearning tool** with Q&As on IFPMA website
- F2F Code capacity building **workshops and consultation meetings** in strategically selected regions
- Targeted communication at **conferences** and **Consensus Framework** roundtable meeting
- **Note for Guidance on Medical Education** ready by December 2018
- **Global Effective Date: JANUARY 1, 2019**
- Monitoring by IFPMA



Q&A

If your question cannot be answered today, please contact your company/association representative in the Ethics & Business Integrity Committee (eBIC) or send an e-mail to s.melis@ifpma.org



Thank you

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.

Many thanks for acting as a champion of business integrity every day!

**Learn more and
stay connected:
ifpma.org**

