



## Joint Note for Guidance on Industry Support for Education and Access to Telemedicine

by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and  
the European Federation of Pharmaceutical Industries and Associations (EFPIA)

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The *Ethos* of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is centered on *trust* to “act with integrity and honesty to improve patient care and build trust with those we serve and to respect the independence of healthcare providers, patients and other stakeholders.”

The ongoing global COVID-19 pandemic has led to an acceleration in the use of new and advanced technologies, including telemedicine, resulting in the need for guidance for member companies and industry associations in this space.

The purpose of this Note for Guidance is to serve as a non-binding and evolving resource for members when considering their role in supporting telemedicine-related activities. It must be read with the spirit of the IFPMA [Code of Practice](#) (the “Code”) in mind and always in accordance with applicable laws and regulations and other applicable industry codes. In the event of a conflict between the provisions of the applicable laws, regulations, and codes, the more restrictive of the conflicting provisions applies. Where no or limited law, regulation or code apply to these activities, companies should abide by ethical decision-making principles.

The overall intention of this Note for Guidance is that the cooperation between companies, healthcare professionals (HCPs) and other stakeholders is always based on high ethical standards and clearly aims to benefit patients. Moreover, IFPMA acknowledges and commits to supporting the [World Medical Association \(WMA\) Statement on the Ethics of Telemedicine](#), with a view to a closer collaboration to develop ethical norms and practice guidelines in this evolving space as appropriate.

### Key Definitions

- Digital health is the field of knowledge and practice associated with any aspect of adopting digital technologies to improve health, from inception to operation,<sup>1</sup> and encompasses both telemedicine and telehealth.
- Telemedicine is the “practice of medicine over a distance, in which interventions, diagnostics and treatment decisions and recommendations are based on data, including voice and images, documents and other information transmitted through telecommunication systems<sup>2</sup>.”
- Telehealth: Telehealth is a broader term, referring to “the use of information and communications technology to deliver health and healthcare services and information over large and small distances<sup>3</sup>.”

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<sup>1</sup> See WHO Global Strategy on Digital Health 2020-2040, dated March 2019.

<sup>2</sup> See WMA Statement on Guiding Principles for the Use of Telehealth for the Provision of Health Care, updated February 2017.

<sup>3</sup> See WMA Statement on Guiding Principles for the Use of Telehealth for the Provision of Health Care, updated February 2017.



## **Biopharmaceutical industry support for the use of telemedicine**

While biopharmaceutical companies are still defining their approaches to supporting telemedicine in the countries and communities in which they operate, this support could potentially include supporting access to third party telemedicine programs or platforms, providing financial support for these platforms, and investing in education for HCPs, payors and patients. Biopharmaceutical companies might also consider creating their own telemedicine-related platforms and tools; however, this activity is out of scope for purposes of this Note for Guidance.

Examples of in-scope biopharmaceutical company activities in the telemedicine space include:

1. Education and awareness:
  - a. Educating HCPs on the availability and provision of telemedicine;
  - b. Sharing informational and/or disease awareness materials with patients to support their access to and experience around telemedicine; and
  - c. Engaging with stakeholders (e.g. governments, payors) to optimize approaches to telemedicine for patients.
  
2. Supporting access:
  - a. Supporting access to telemedicine programs or platforms for the benefit of patients through the provision of licenses and/or subscriptions where these are not considered routine business expenses; and
  - b. Supporting the development of third-party telemedicine platforms.

## **General applicability of existing laws, regulations and codes**

Depending on the type of support being contemplated, telemedicine-related initiatives may present a novel and evolving context for ethical and compliance risks warranting continuous assessment. These risks may include bribery and corruption, perception of undue influence or preferential treatment, inappropriate promotional content, potential safety reporting, information security and/or data privacy considerations, among others.

Common to all types of telemedicine support are risks related to the local regulatory environment, which in many instances is still developing and differs widely both between and within countries. Thus, companies will often be operating in a grey area, highlighting the criticality of abiding by ethical decision-making principles and engaging in internal dialogue across relevant functions to ensure a robust analysis.

However, though some telemedicine activities may be new, existing laws, IFPMA, EFPIA and local industry codes governing interactions with HCPs, healthcare organizations (HCOs) and patients still apply.

### IFPMA and EFPIA Codes of Practice

The specifics of a telemedicine project will determine the applicability of IFPMA and EFPIA's Code of Practice. However, certain principles and provisions apply to all projects:

- IFPMA's core value of **integrity** prohibits companies from providing anything of value to inappropriately influence a decision or gain an unfair advantage;

- Companies should be transparent with the support they provide and in the materials they produce<sup>4</sup>;
- Companies may not provide any support to offset routine business/operational costs; therefore, careful analysis is required to ensure that projects intended to support access to telemedicine do not offset an individual HCP or HCO routine business expenses<sup>5</sup>;
- Services must serve a legitimate need and be remunerated at fair market value (FMV)<sup>6</sup>.

The following recommendations and guidance are based on the above principles, IFPMA and EFPIA Codes, and general industry ethical practices.

#### Categorization of telemedicine support

**Education and awareness** activities will likely take the form of events, meetings, or print and digital content provided to HCPs, HCOs, patients and payors, and will therefore be subject to the relevant provisions of IFPMA and EFPIA's Codes of Practice depending on the nature of the activity and recipient<sup>7</sup>.

In addition to the rules set out in the Code, companies should consider the following:

- *Appropriate expertise*: Recognizing that companies may still be developing their expertise in the telemedicine space, companies should be especially mindful to share only appropriate and up to date information, engage speakers and consultants with the requisite expertise and support only high-quality third-party programs. For example, when supporting educational activities, companies should establish criteria to appropriately assess telemedicine experts/speakers' capabilities or third-party meeting content.
- *Appropriate content*: Companies should ensure that materials shared with HCPs, HCOs, patients and payors are non-branded, impartial, objective and evidence based. Companies must also disclose their involvement in the development of such materials.
- *Industry standards*: No universal standard for what makes a good telemedicine provider currently exists, which should be considered when raising awareness of telemedicine with HCPs, HCOs, patients, payors and other stakeholders to ensure low quality healthcare services are not promoted.
- *Fair Market Value (FMV) for telemedicine consultant engagements (e.g. speakers, advisors)*: Existing FMV calculations may not be applicable to the qualifications of telemedicine experts. Therefore, the FMV compensation for telemedicine experts engaged as speakers or consultants should be carefully assessed.

**Support for the development of third-party telemedicine platforms**, including applications (e.g. HCO, local authority and/or professional/medical association) should likely be categorized as an independent donation/grant or partnership which cannot be provided to individual HCPs, subject to any local legal or regulatory restrictions<sup>8</sup>. Companies should consider the following:

<sup>4</sup> See IFPMA Code of Practice Article 2.2; EFPIA Code of Practice Articles 7, 22, 23, and 24

<sup>5</sup> See IFPMA Code of Practice Article 7.5.2; EFPIA Code of Practice Articles 11, and 17

<sup>6</sup> See IFPMA Code of Practice Article 7.4; EFPIA Code of Practice Article 15

<sup>7</sup> See IFPMA Code of Practice Articles 7, 10 and 11; EFPIA's Code of Practice Articles 10, 13, 15, and 16

<sup>8</sup> See EFPIA Code of Practice Article 12, 21 and [Additional Questions to IFPMA Code of Practice 2019/ Practical examples](#) – Question 8.

- *Purpose of the initiative:* Companies should assess whether there is a true objective need for the support provided based on the local healthcare system and infrastructure.
- *Transfer of value:* Companies should consider the primary beneficiaries of the telemedicine support (e.g. patients, HCPs, HCOs, local authorities) to understand whether they are permitted to receive this kind of support (i.e. it might constitute a transfer of value to a HCP and/or government official), whether this support is appropriate, and how the support should be documented and disclosed, based on IFPMA and local ethical codes and laws.
- *Risk of undue influence:* Consideration should be given to the rationale for supporting specific recipients, and the duration and frequency of the support to avoid the perception of reward for past, or as undue influence on future, prescribing or other business-related decisions.
- *FMV:* Companies should consider how to assess, and, where required, how to disclose, the FMV of that support.
- *Personal data and security:* Companies should take care to address any data privacy/information security risk, and in particular not seek or receive any information that would violate confidentiality/privacy rights.

**Supporting access to a telemedicine platform via licenses and/or subscriptions** may be permissible as an independent grant/donation where the goal is to enhance patient access and/or reduce existing health disparities. As such, these cannot be provided to individual HCPs. Companies should consider the following:

- *Routine business expenses:* Covering routine/operational costs for a HCO or medical practice is prohibited, and companies must closely analyze whether providing licenses/subscriptions can be permitted in the specific circumstance in which it is requested. This may depend on whether the technology is emerging rather than established in a particular healthcare system, and whether it is appropriately time-bound.
- *Undue influence:* Care must be given to avoid the perception of preferential treatment, undue influence of anti-competitive behavior, and companies should ensure that the selection of recipients is based on fair and objective criteria.
- *FMV:* If access via licenses and/or subscription is provided, companies should consider how to assess the FMV of that support.

**Supporting patient access to a telemedicine platform** may also be permissible as part of a Patient Support Program (PSP). Key considerations include an assessment of the true beneficiary of the support (e.g. patient, HCP, or HCO) and an analysis of whether the support is appropriate, permissible and in line with PSP principles.

#### **Additional ethical considerations and mitigation**

Companies should carefully consider, articulate and document the business rationale of any telemedicine initiative to ensure that it is:

- Guided by patients' legitimate unmet needs;
- Intended to enhance access and/or reduce existing health disparities;
- Not intended to promote or be perceived as promoting the company's products; and
- Does not interfere with the HCP/patient relationship or dialogue.



Companies should in addition consider the nature and sustainability of the support provided, and in particular whether the recipient will be able to cover/ fund future maintenance/ update costs of the platform and not rely long-term support, so as not to undermine independence of the recipient.

Finally, companies should also be aware that certain telemedicine technologies may be unaffordable for patients and should be mindful of not exacerbating health inequities in designing or implementing initiatives.

### **Industry association role in assisting their members as they consider supporting telemedicine activities**

Industry associations can support their members by providing them with the guidance necessary as they become involved in the education of HCPs in the telemedicine space. HCPs may not be tech-savvy and may benefit from medical education, supported by member companies, to enable them to navigate the complexities of delivering care through technologies, especially as HCPs may not yet be familiar with telemedicine, including the ethical and legal implications as laid out in WMA's Statement on the Ethics of Telemedicine.

Industry associations may also consider their role in educating their membership in the telemedicine area and/or supporting the development of global standards for telemedicine platforms, potentially in partnership with other industry stakeholders (e.g. WMA).

### **Conclusion**

In summary, companies may seek to support the establishment of high-quality and effective telemedicine services. As the scope and implications of telemedicine develops, so will norms and best practices, and eventually countries will enact cohesive regulatory frameworks for telemedicine. In the interim, companies must navigate this area by applying the general ethical principles and guidelines contained in the IFPMA and other industry codes, taking care to document their activities, support and rationale prospectively, and to consult their internal ethics and compliance or legal colleagues when in doubt.