Medicines Australia

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Scientific Exchange – Frequently Asked Questions

Scientific exchange means the legitimate exchange of medical and scientific information, in a non-promotional manner, concerning (but not limited to) an unregistered product or use. This information or activity must be without any reasonable likelihood to influence the intent to prescribe or use a product and must not constitute promotion.

*Code of Conduct Glossary

Scientific exchange can occur in relation to registered products and/or indications and unapproved products, uses or other off-label topics. Scientific exchange may occur in a variety of contexts, such as a one-to-one exchange between a company employee and a healthcare professional, a meeting with government officials, or at a company-organised meeting with a number of healthcare professionals (HCPs) or other stakeholders.

KEY PRINCIPLES

- Scientific exchange must be non-promotional in intent, content and nature and clearly distinguished from promotional activities
- The focus should be on two-way communication
- Scientific exchange must be overseen by the Company Medical Director or their delegate

Q1: What needs to be considered when engaging in scientific exchange with HCPs or other stakeholders?

Code of Conduct Section 7 provides parameters that will enable company personnel to engage in non-promotional, scientific exchange with HCPs or other relevant stakeholders. Whilst all scientific exchange should be non-promotional, particular care should be taken where scientific exchange relates to unapproved products or unapproved use of products, as their promotion may be contrary to the Therapeutic Goods Act.

A non-promotional, scientific exchange with HCPs or other stakeholders will be characterised by the following:

- The exchange is overseen by the Company Medical Director or their delegate and is conducted by a person with a non-promotional role* in the company.
- The exchange is not conducted by a person with a promotional role in the company.
- The interaction/activity is not promotional, including the intent, content and nature of the exchange. This should be evident to the other stakeholder(s), otherwise the company may need to mitigate a perception risk.
- The reasons for engaging in scientific exchange are appropriate, as described in Section 7.
- Any information (verbal or written) provided about unregistered products or unapproved use is clearly identified as such and any materials provided are approved by the Company Medical Director or their delegate.

*Defined in the Code glossary: Non-Promotional Role is not commercial in intent, without likelihood to influence the intent to prescribe or use a product.

Q2: Can scientific exchange be proactive, or only reactive?

Scientific exchange can be reactive as affirmed in Section 7a) or proactive as affirmed in Section 7b). The focus should be on the exchange being a two-way communication.

A reactive response to a query from an HCP or other stakeholder may be more easily justified as a non-promotional, two-way, scientific exchange; for example, responding to a healthcare professional's query about an unregistered product or unapproved use.

Proactive provision of scientific and medical information in scientific exchange should be carefully considered to ensure it is non-promotional, especially when in relation to unregistered products or off label use. By being proactive, there is an increased risk of the exchange being perceived as promotional. Consider mitigating this risk by weighing up the following issues:

- What is the rationale for the exchange being proactive and how can you demonstrate it?
- Why does the stakeholder need the information for their role? And how can you demonstrate the stakeholder needs the information?
- How can you demonstrate that there was two-way communication between the company and the stakeholder/s, particularly if the exchange is proactive by the company?
- How will proactively engaging in scientific exchange with the stakeholder/s improve patient care, or improve access to medicines, or support QUM, or assist research or assist the stakeholder in budgetary planning?
- As a result of the exchange, is it likely that the stakeholder receiving the information might be persuaded or encouraged to use or prescribe the product?
- Is the information specific or tailored to the stakeholder's needs, or is it general information useful to many?
- How is the information being distributed, and to how many stakeholders? Wide distribution of the information may be perceived as promotional in nature.

Q3: Can members of the company's commercial team (with promotional roles) be present during a scientific exchange activity?

Further to the response to Q1 above, the Code describes which roles in the company should engage in scientific exchange, to demonstrate that the purpose is non-promotional.

Code section 7(c) recognises that it is appropriate for certain personnel who are part of the company's commercial team to engage in scientific exchange if their role is non-promotional such as market access and regulatory affairs. Non-promotional roles are not restricted to market access and regulatory affairs, but the personnel engaging in the exchange should not have a promotional role in the company and the activity must be overseen by the Company Medical Director or their delegate.

Whilst those with promotional roles cannot engage in or deliver scientific exchange, the Code does not require company personnel with promotional roles to be excluded whenever scientific exchange with HCPs or other stakeholders occurs. However, the presence of personnel with promotional roles during a scientific exchange activity can risk giving the appearance that the exchange is promotional in intent.

If it is proposed that personnel with promotional roles could be present during scientific exchange, the Company Medical Director or their delegate (who will oversee the activity) should consider the following to reduce the risk of the exchange appearing to have a promotional intent:

- What is the purpose or need for the person with a promotional role being present? Could this purpose be achieved in another way?
- Is the scientific exchange with one or a few HCPs or other stakeholders? These situations may be higher risk than settings with larger groups.
- What role in the exchange will the person with a promotional role have if they are present at a scientific exchange event with a larger HCP audience? Being present to provide logistical support, such as delivering roaming microphones, may have a lower risk. Any active participation in the exchange, such as engaging in Q&A or other two-way communication would be at higher risk of giving the appearance of promotional intent and breaching the Code.
- As scientific exchange should be distinguished from promotional activities, how will it be clear to an attending HCP or stakeholder that the purpose of the activity is non-promotional? Blending of promotional elements, including the presence of personnel with promotional roles who are known to HCPs in that role, may increase this risk.
- Companies are empowered to make risk-based decisions and to consider appropriate actions that will mitigate any risk of the perception that scientific exchange is promotional.

Q4: Can scientific exchange occur at company organised symposium - either as a satellite during a congress or independently?

Yes, there are many forms scientific exchange can take, including a presentation with time for meaningful exchange whether as a stand-alone event or as part of a congress. The exchange could be Q&A, workshops or round tables, for example.

Such information might be presented and exchange facilitated by a healthcare professional or other expert engaged by the organising company – scientific exchange does not always need to involve the company medical personnel. Whatever the format, the organising company remains responsible for ensuring that the scientific exchange is consistent with the Code, particularly where the scientific exchange covers unapproved products, unapproved uses or other off label topics.

Q5: Does product-related material used in scientific exchange need to include mandatories described in Section 2.1?

Companies are reminded of Overarching Principles 3 and 7; that they are responsible for providing current, accurate, balanced, and scientifically valid information on products to support their appropriate use, and to provide access to sufficient prescribing information for a healthcare professional to appropriately prescribe the product.

All company-developed material directed to healthcare professionals needs to comply with Section 2 of the Code, and this includes materials used in scientific exchange where relevant.

The provision of product-related material as part of scientific exchange should not 'automatically' disqualify it as scientific exchange. Rather, the activity should meet the Code requirements for scientific exchange (Section 7) and any company-developed, product-related material for healthcare professionals should meet the relevant requirements of Section 2.

Section 2.1 steps out the required inclusions for product-related promotional materials only. Colloquially termed 'mandatories', they are not necessarily required for product-related materials that are used in scientific exchange, because scientific exchange material will not be promotional.

Although the requirements of Section 2.1 do not apply to scientific exchange, it is important that healthcare professionals are provided with the necessary information regarding a product to support its appropriate use. It is at a Company's discretion to determine what information is provided. For example, if the scientific exchange refers to a registered product, then a link to the approved Product Information could be provided. The inclusion of 'mandatories' as described in Section 2.1 does not trigger the classification of material as promotional.

Independently produced medical literature and reprints provided as part of scientific exchange are not required to comply with Section 2.

Q6: Who can we share and exchange scientific information with?

Whilst scientific exchange is predominantly undertaken with healthcare professionals, they are not the only possible participants in scientific exchange. The Code affirms that scientific exchange can be undertaken with the scientific community and other relevant stakeholders. Whilst examples are provided (payors and government officials), this does not necessarily include all the relevant stakeholders described in Code Section 10.Companies are empowered to make their own decision as to whether the stakeholder is appropriate to engage with in scientific exchange and that the reason for the exchange is consistent with Code Section 7.

If a company engages in scientific exchange with a Patient Organisation, it should carefully consider how it can demonstrate that the exchange meets the requirements of Section 7. In particular, that it is non-promotional in intent, content and nature and is clearly distinguishable from a promotional activity. Companies should consider the Patient Organisation's need for the information and whether the expertise of the Patient Organisation representative/s is relevant to their engagement in scientific exchange.

"Companies' interactions with all stakeholders are at all times professional, consistent with all legislative requirements, and appropriate to the information needs of the respective audience."

- OVERARCHING PRINCIPLE 6, CODE OF CONDUCT