Development of guiding principles for human performance for the WHO pharmacovigilance strategy

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SUMMARY

The WHO has both a human factors strategy and more recently published a global pharmacovigilance strategy although the latter does not refer to devices which continue to be regulated in a parallel system. However, many medicines depend for their effective use on devices (including kits), and some products are integrated drug-devices. Unlike other safety critical sectors, there are no international guiding principles for all stakeholders which might unify the optimal use of both medicines and devices.

Based on discussion with pharmaceutical manufacturers, we have drafted the world's first set of guiding principles for human performance and safety of medicines and devices. We position these principles as a practical bridge between pharmacovigilance and existing human factors and usability frameworks for medical device design (such as IEC 62366-1), making them relevant and usable for designers, regulators, and industry across both medicines and devices.

KEYWORDS

Guiding Principles, Medicines, Safety, Medical Devices

Scope and relevance of guiding principles

International Guiding principles are a well-established concept for safety in other sectors of society which are regarded as safety critical, notably, aviation, space, oil and gas and nuclear. Guiding principles for food safety are largely produced by the FAO/WHO Codex Alimentarius and cover all stakeholders. Chemical are governed by several sets of guiding principles for safety. WHO has produced guiding principles for the regulatory systems medical devices although there are no international guiding principles for all stakeholders for medicines and, in particular, combination products.

In October 2025, the WHO released the global smart pharmacovigilance strategy which provides a framework for building systems for assuring that the balance of benefits and risk for medicines is acceptable and that such systems that are resilient, responsive, and sustainable. However, each stakeholder group in pharmacovigilance is striving to optimize his or her performance and goals within the existing incentive structure around them and different regulations. Optimizing organisational interests, however, does not necessarily add up to or align with the best interest and values of a connected society as a whole. Furthermore, this lack of agreement and impaired transparency can undermine trust and confidence between stakeholders including the wider public.

The ideal goal would be to determine how best to design a global pharmacovigilance system in a way that aligns incentives for the achievement of patient and societal goals covering all forms of medical product. An effective, connected system would make it easier for all stakeholders to do the

right thing, both scientifically and ethically, to which they can link their own organisational goals. However, what does "the right thing" look like for stakeholders?

An enabler to this system design is to develop a set of international Guiding Principles for all stakeholders covering all forms of medical product (medicines, devices, herbal). Currently, those principles and standards which do exist for medicines and devices apply only to certain groups of stakeholders and none address how human performance underpins product safety and quality. Such Principles should address vigilance for all forms of product (pharmaceutical and device) and provide direction for a road map to help stakeholders to deliver both the aims of the WHO pharmacovigilance strategy and WHO medical device guiding principles. These Principles will build on our current thinking and evidence base about human factors shaping culture and performance, quality systems, and patient safety systems by taking these concepts further to include all stakeholders including Healthcare Product Companies and patients.

Method

In 2020, a consensus report arising from a collaboration of about 90 pharmaceutical companies was produced about human performance and how to get there. Following a series of conversations and discussion with members of this group that produced this report we propose five guiding principles for assessment and development so that they are adequate and appropriate for the entire healthcare product system.

Results

Based on group discussions the following draft principles have been created:

- INCLUSION: Help everyone to have a voice to share ideas and concerns safely and constructively. Key groups would include Patients, Healthcare providers, Regulators, Pharmaceutical and Device Industry.
- VALUES: show that a values-based implementation of the principles of just and fair culture and learning culture can result in beneficial and positive outcomes where leaders focus on improvement
- SET PEOPLE UP FOR SUCCESS: Embracing the excellence of our people as they are the solution rather than the problem to solve.
- FOCUS ON IMPORTANT: Balancing financial, compliance and human benefits against reactive fixes, always linking back to positive patient and organisational outcomes
- MEANINGFUL MEASURES: Measurements of performance that that provide positive reinforcement for patient outcomes, regulatory ambitions, and pharmaceutical industry goals. The lead measures should be patient centred, helpful and can be acted upon.

Key takeaways and learning points

1. Understanding the successful use of guiding principles in other high-risk industries and how they improved safety.
2. Identifying mechanisms for assessing, developing, and refining guiding principles.
3. Exploring implementation strategies and methods to assess real-world impact.
4. Developing recommendations for rollout, adoption, development, and oversight across the global medical product system focusing on the WHO Smart Pharmacovigilance Strategy and Medical Device guiding principles.

References

The global smart pharmacovigilance strategy World Health Organization 2025.

Shared Risk Management in complex systems: “Blue-Sky” Human Performance and How to Get There, Amy Wilson, Biogen; Clifford Berry, Takeda; Brian Chviruk, Takeda; Elaine Speirs Biophorum April 2020.

Medical device regulations: Global overview and guiding principles 2003