

# **Position paper of the Swiss Health Alliance (SHA) Promoting quality and standards in the healthcare sector**

## **1. Introduction**

The Swiss Health Alliance (SHA) considers quality and compliance with internationally recognized standards to be key prerequisites for an efficient, equitable, and sustainable healthcare sector. Quality assurance along the entire value chain—from the production of healthcare goods to the provision of healthcare services—is crucial to ensuring patient safety, using resources efficiently, and strengthening the trust of the population, partners, and investors.

Against the backdrop of increasing integration of national health markets into global value chains and growing regulatory requirements, the SHA sees its role as supporting policymakers, institutions, and the private sector in the systematic establishment and expansion of quality infrastructures and conformity assessment systems. This position paper outlines the background, objectives, key areas of action, and indicative impact indicators of the SHA's engagement in the area of quality and standards.

## **2. Normative framework and strategic anchoring**

The Swiss Health Alliance (SHA) understands quality and standards in the health sector not exclusively as a technical or regulatory issue, but as an integral part of responsible governance in the sense of sustainable development.

The SHA Health (PPP) Certification explicitly anchors the promotion of quality and standards in an internationally recognized normative framework. It is based on the ten principles of the United Nations Global Compact in the areas of human rights, labor standards, environmental responsibility, and corruption prevention, as well as the 17 Sustainable Development Goals (SDGs) of the United Nations.

Within the framework of SHA Health (PPP) Certification, (PPP) stands for **Planet, People, and Prosperity**.



Planet refers to the ecological impact dimension (Environment), People to the social impact dimension (Social), and Prosperity to the economic-institutional control dimension (Governance).

The SHA thus combines ecological responsibility, social integrity, and rule-based, transparent corporate and system governance in an integrated certification approach.

Quality infrastructure, conformity assessment, and regulatory systems are not viewed in isolation, but are understood as control instruments for implementing sustainable development goals.

## **2.1 Governance as a control dimension**

Governance is the central governance dimension within the framework of SHA Health (PPP) Certification. It comprises:

- the development of coherent, transparent, and evidence-based quality policies,
- the institutional anchoring of clear responsibilities,
- ensuring integrity, accountability, and corruption prevention,
- the systematic integration of sustainability criteria into regulation and market supervision.

Governance in the health sector thus means the binding integration of quality requirements, sustainability principles, and internationally recognized standards into all political, regulatory, and institutional processes.

## **2.2 Connection to the Sustainable Development Goals**

The promotion of quality and standards in the health sector makes a structural contribution in particular to:

- SDG 3 Good Health and Well-being,
- SDG 9 Industry, Innovation, and Infrastructure,
- SDG 12 Responsible consumption and production,
- SDG 16 Peace, justice, and strong institutions,
- SDG 17 Partnerships for the Goals.



Linking governance structures, quality infrastructure, and sustainability-oriented management creates a systemic framework for action that takes into account both economic performance and environmental and social responsibility.

### **2.3 Quality infrastructure as an implementation tool**

Standardization, accreditation, metrology, conformity assessment, and quality management systems are operational instruments for implementing this governance logic.

They serve not only to secure market access or technical conformity, but also to structurally ensure:

- patient safety,
- transparency,
- regulatory integrity,
- sustainable value creation,
- international comparability, and recognition.

The SHA thus positions itself as a strategic platform that integrates governance, international standards, and sustainable development goals into a coherent quality ecosystem in the healthcare sector.



### **3. Background and problem definition**

International trade in health products and services is now heavily influenced by multilateral trade rules and technical requirements, such as the WTO agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS). At the same time, expectations regarding product safety, patient protection, environmental compatibility, decent working conditions, and sustainability are constantly increasing.

Many countries – especially low- and middle-income countries – face the challenge of demonstrating compliance with these requirements. There are often gaps in the quality infrastructure, e.g., insufficiently developed standardization and accreditation systems, a lack of or weak testing laboratories, fragmented regulatory regimes, and limited capacity in the private sector. This restricts market access and export opportunities, weakens the competitiveness of and increase risks to patient safety and consumer protection.

However, experience from a wide range of regions shows that the systematic development of a national and regional quality infrastructure – including clear quality policies, harmonized standards, accredited conformity assessment bodies, and quality-oriented companies – leads to measurable improvements in competitiveness, employment, and trade.

The SHA builds on this experience and addresses the specific challenges in the healthcare sector: from quality control of medicines, diagnostics, and medical devices to quality management in healthcare facilities and digital health infrastructure.



## **4. Goals of the Swiss Health Alliance in the area of quality and standards**

The SHA pursues the following overarching objectives in the area of quality and standards in the healthcare sector:

### **1. Strengthening policy and governance**

- Supporting partner countries and regions in developing and implementing coherent national quality policies for the health sector that are compatible with regional and international frameworks.
- Promoting transparent, evidence-based, and inclusive governance structures in the areas of regulation, market surveillance, and quality control.

### **2. Building and consolidating quality infrastructure**

- Supporting the establishment and strengthening of institutions for metrology, standardization, accreditation, and conformity assessment relevant to health products and services.
- Promoting regionally harmonized standards and recognition mechanisms to facilitate intraregional trade in health goods.

### **3. Promoting quality-oriented companies and health care facilities**

- Strengthening companies, laboratories, and health care facilities in the implementation and use of international management and technical standards (e.g., ISO 9001, ISO 17025, ISO 15189).
- Improving access to quality-related services, advice, and training for SMEs and healthcare providers.

### **4. Increasing quality awareness and transparency**

- Promoting a demand-oriented quality culture in which public institutions, companies, and consumers actively demand and control quality and standards.
- Highlighting good practices and outstanding achievements through quality competitions and award programs.

## **5. Strategic areas of action**

To achieve these goals, the SHA focuses on the following areas of action:

### **5.1 Policy advice and regulatory framework**

- Support in developing and updating national quality policies and sector-specific strategies for health.
- Advice on modern, risk-based, and proportionate regulation of health products and services, including market surveillance and import control systems.
- Support for dialogue processes between ministries, regulatory authorities, specialist institutions, and the private sector to ensure consistent policies.

### **5.2 Establishing and strengthening quality infrastructure**

- Supporting national and regional standardization and accreditation organizations in governance, procedures, harmonization, and international recognition.
- Promoting metrology and testing infrastructures necessary for pharmaceuticals, diagnostics, medical devices, and other health goods.
- Development and implementation of programs to strengthen quality infrastructure systems (QIS) in partner countries and regions.

### **5.3 Development of conformity assessment and laboratory capacities**

- Technical advice for testing laboratories, calibration laboratories, inspection and certification bodies on the introduction and implementation of quality management systems (e.g., ISO 17025, ISO 15189).
- Support for accreditation processes, including training of auditors and technical assessors.
- Support in the development of business models, customer relationships, and market strategies for laboratories and certification bodies to ensure their long-term economic viability.

#### **5.4 Promotion of quality-oriented companies and healthcare facilities**

- Advising companies and healthcare facilities on the introduction of quality management systems (e.g., ISO 9001) and industry-specific standards in the healthcare sector.
- Conducting training for quality managers, internal auditors, technical specialists, and consultants in key quality areas.
- Supporting the use of standards to open up new markets and value chains, particularly in regional and global trade in healthcare products.

#### **5.5 Quality awareness, communication, and awards**

- Design and implementation of quality promotion programs, including national and regional quality competitions and awards for companies and institutions in the healthcare sector.
- Information and awareness campaigns that raise public awareness of quality, patient safety, and regulatory compliance.
- Establishment of platforms and networks for the exchange of best practices, learning experiences, and innovations in quality management.

### **6. Partnerships and international cooperation**

The SHA relies on close cooperation with international and regional standardization and accreditation organizations as well as with relevant global health actors. These include, in particular, ISO, IEC, ITU, BIPM, OIML, IAF, and ILAC, whose standards and recognition mechanisms are central to the development of robust quality infrastructures.

Through coordinated programs, the SHA works with governments, regional organizations, health ministries, regulatory authorities, specialist institutes, the private sector, academia, and civil society. The aim is to exploit synergies, avoid duplication of effort, and maximize the impact of quality-oriented investments in the health sector.

## **7. Indicators and expected impacts**

Quantitative and qualitative indicators are used to measure the progress and impact of the SHA's commitment to quality and standards. Based on international experience, these include:

### **7.1 Policy and governance**

Number of partner countries with adopted national quality policies that explicitly address the health sector.

- Number of countries/regions with harmonized quality policies or frameworks.
- Existence of clearly defined, institutionalized coordination mechanisms between relevant authorities in the area of quality/standards in the health sector.

### **7.2 Quality infrastructure and conformity assessment**

- Number of functioning national and regional standardization and accreditation bodies related to the health sector and their degree of international recognition.
- Number of accredited testing laboratories, calibration laboratories, and certification bodies covering health products or services.
- Number of accredited testing procedures ("scopes") in the health sector and proportion of exported health products for which national conformity assessment is available.

### **7.3 Companies, institutions, and professionals**

- Number of companies and healthcare facilities that have implemented quality management systems (e.g., ISO 9001, ISO 15189) with the support of the SHA.
- Number of certified auditors and quality managers in the healthcare sector.
- Percentage of supported companies/institutions that report a measurable improvement in their operational processes and service quality.

## 7.4 Quality culture and market integration

- Number of national and regional quality competitions and awards in which companies and institutions in the healthcare sector participate.
- Increase in demand for quality-related services (accreditation, certification, laboratory services) in the health sector.
- Development of intra- and interregional trade volume with compliant healthcare products from partner countries (where available).

## 8. Concluding remark

Promoting quality and standards in the health sector is an effective lever for increasing patient safety, fostering innovation, and strengthening the integration of partner countries into regional and global health markets. With its expertise in policy advice, quality infrastructure, and capacity building, the Swiss Health Alliance positions itself as a strategic partner for governments, international organizations, and the private sector to jointly shape robust, sustainable, and inclusive quality ecosystems in the health sector.

### Operationalization via SHA Health (PPP) Certification

The SHA Health (PPP) Certification serves as a binding regulatory and assessment framework for the structured implementation of the objectives and measures outlined above.

It combines the governance dimension with the impact dimension (environment and social) and translates political objectives, quality infrastructure, and regulatory requirements into verifiable, comprehensible, and internationally compatible assessment logic.

This ensures that quality and standards in the healthcare sector are not only promoted conceptually, but also systematically measured, evaluated, and further developed—in line with international sustainability principles and the Sustainable Development Goals.