

≥ Patient health

Innovation

Product quality and safety

**Sustainability initiatives** 

# Patient health

We commit to placing patient health and independence at the heart of our operations, striving to continuously enhance the patient experience through intuitive, safe, and user-centric medical devices.



 $\odot$  These efforts support the target to empower more than 8 million patients to live more independently by 2030.

#### **Impacts**

Putting patients' needs at the forefront of everything we do enables them to manage their health more independently, helping improve outcomes and supporting their overall wellbeing.

Addressing patients' practical, physical and emotional needs related to injections directly supports their independence and quality of life.

#### **Key impact areas:**

- ≥ Treatment adherence and persistency
- ≥ Health outcomes and quality of life
- ≥ Independence
- □ Accessibility

#### **Approach**

We employ a patient-centric design approach, integrating insights from usability experts, engineers, and patients themselves.

Metrics and disclosures

Technologies such as the Molly® Connected Cap autoinjector add-on and the Needle Isolation Technology (NIT®) are specifically developed to help improve patient adherence and overcome common barriers, such as needle fear.



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#### **Progress**

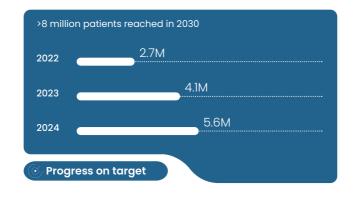
In 2024, we continued to contribute to patient health by supporting pharmaceutical and biotech partners in launching combination products across a range of therapeutic areas.

From endocrine disorders to oncology, these collaborations enabled the development of selfadministered solutions that help improve treatment adherence, promote patient independence, and enhance quality of life.

In 2024 alone, SHL Medical enabled 5.6 million patients to live more independently lives using SHL Medical devices, up from 4.1 million in 2023.

This growth is primarily driven by the rapid expansion of the cardiometabolic therapy area, particularly treatments related to obesity and cardiovascular diseases, where demand for autoinjectors has sharply increased.

Obesity, now affecting more than one billion people globally, has come to be regarded as the "single greatest threat to public health for this century", and has increasingly been recognized as a chronic condition requiring long-term pharmacological treatment.



Metrics and disclosures

#### Methodological note on patients reached KPI

Considering the significant contribution of cardiometabolic treatments to our overall growth, we have refined the methodology used to estimate the number of patients reached within a given year through our device used in the treatment of obesity. As a result, data for 2022 and 2023 have been recalculated using the updated methodology to ensure consistency and comparability across reporting years. The updated approach leverages real-world data and average treatment duration to provide a more accurate and representative estimate. This targeted recalibration achieves significantly greater consistency and precision in our patient impact reporting. See page 59 for further details.

Access to reliable, high-quality healthcare remains a global challenge – particularly for patients living with chronic or complex conditions.

Through our device platforms, SHL Medical contributes to addressing conditions such as:

- ≥ Inflammatory bowel diseases
- ∠ Cardiovascular diseases
- ≥ Migraine
- и Multiple sclerosis
- **Rheumatoid** arthritis
- ע Weight management
- ≥ Postmenopausal osteoporosis

## What's next: roadmap



Scalability



Ensuring scalability to address diverse therapeutic needs, from prevalent conditions to rare diseases, through the development of sustainable devices and the expansion of regional manufacturing to reduce CO<sub>2</sub> emissions and enhance regional manufacturing capacities

#### Insights

Our devices are used across all 12 **IQVIA-defined therapeutic areas** covering 40+ indications.





Aligned with UN Global Compact Principle 1, we are committed to respecting and supporting internationally proclaimed human rights, including the right to health. Our approach aims to contribute to SDG 3 (Good Health and Well-being) by placing patient health and independence at the core of our operations.

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# **Innovation**

We commit to driving innovation through patient-centric drug delivery solutions.

Our focus is to continually develop novel, patient-centric solutions that facilitate self-administration, address emerging therapeutic advancements, and support sustainable healthcare practices.

#### **Impacts**

Innovative drug delivery systems directly impact patient health by supporting treatment adherence, facilitating home-based administration and enhancing the overall patient experience. The ability to enable home-based delivery of large-volume and high-viscosity biologics further expands access to personalized treatments, especially in chronic disease and oncology. Innovation also drives resource efficiency, reducing environmental footprint throughout production and distribution.

#### Key impact areas:

- User needs: support for self-administration and patient independence
- ≥ Adaptability to emerging therapeutic advancements
- ≥ Resource efficiency and product environmental footprint
- ≥ Digital health integration and innovation

#### **Approach**

Our structured approach to innovation integrates patient insights, sustainability objectives, and adaptive technological solutions.

Research and development activities continuously inform our product pipeline, addressing emerging healthcare demands.

We operate under a vertically integrated business model, with the majority of production processes managed in-house. This structure allows for greater control over quality, innovation, and resource efficiency, as SHL Medical designs and builds its own manufacturing and testing equipment. Vertical integration also facilitates alignment across the device development value chain, supporting operational consistency and process optimization.



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#### **Progress**

#### Elexy™

We introduced our first electromechanical autoinjector, designed to accommodate both prefilled syringes (1.0 mL and 2.25 mL) and cartridges (3.0 mL and 5.0 mL). Its versatility significantly accelerates combination product development timelines and allows for greater flexibility across varying injection profiles, responding effectively to diverse therapeutic dosing requirements.



#### Molly® Connected Cap

The Molly® Connected Cap is a compact, retrofittable connectivity solution designed for our Molly modular platform technology. In 2024, we advanced its capability to accurately record and transmit real-time data on patient device usage, facilitating improved monitoring and treatment adherence. This development underscores our continued focus on integrating digital health technologies within our existing product platforms.

Metrics and disclosures



### Large-volume/high-viscosity drug delivery systems

Throughout 2024, development on our drug delivery systems continued, addressing largevolume and high-viscosity therapeutics. These platforms are designed to meet the growing demand for personalized medicine, with potential application in therapeutic areas such as oncology, thereby enabling effective homebased self-administration of complex therapies.



#### What's next: roadmap

Areas

Innovations in many forms

Continue expanding our innovation efforts with a strong focus on digital integration, patient-centric design, and sustainable manufacturing ensuring that future product developments remain closely aligned with patient needs, environmental responsibility, and our strategic goal of empowering greater patient independence



Our approach contributes to SDG 9 (Industry, Innovation and Infrastructure) by advancing patient-centric drug delivery solutions that enable self-administration, support therapeutic innovation, and promote more sustainable healthcare practices.

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# Product quality and safety

We commit to ensuring the highest standards of product quality and patient safety. Quality and safety are non-negotiable cornerstones of our operations.

#### **Impacts**

Robust quality management and safety standards protect patients from risks associated with product use, ensure reliability, and maintain trust among healthcare providers, regulators, and patients.

#### Key impact areas:

- ≥ Patient safety and wellbeing
- ≥ Regulatory compliance
- ע Trust and confidence among stakeholders

#### Policies and approach

#### ISO 13485

Our quality system is certified to ISO 13485, ensuring consistent control over medical device design, production, and distribution in line with regulatory requirements.

Metrics and disclosures

#### ISO 14971

Device risk management complies with ISO 14971, supporting the identification and control of potential risks throughout the medical device lifecycle.

#### **FDA 21 CFR 820**

We comply with FDA 21 CFR Part 820, which outlines quality system requirements for medical devices marketed in the US, focusing on product safety and effectiveness.

#### **Progress**

In the reporting period we continued to strengthen the integration of quality and safety across all stages of our operations – from product development to large-scale manufacturing. Using a risk-based approach, ensuring that all materials, components, and sub-assemblies were tested with state-of-the-art inspection methods to meet stringent international standards.

We also successfully completed the ISO 13485 certification audit at our testing lab in Switzerland, expanding the scope of our quality management system to formally include this location in addition to the existing coverage of drug delivery system design and development.



Our approach supports UN Global Compact Principle 1, by respecting the right to health and safety, and contributes to SDG 3 (Good Health and Well-being).





