SAFEMed
Technical Brief

SEPTEMBER 2025

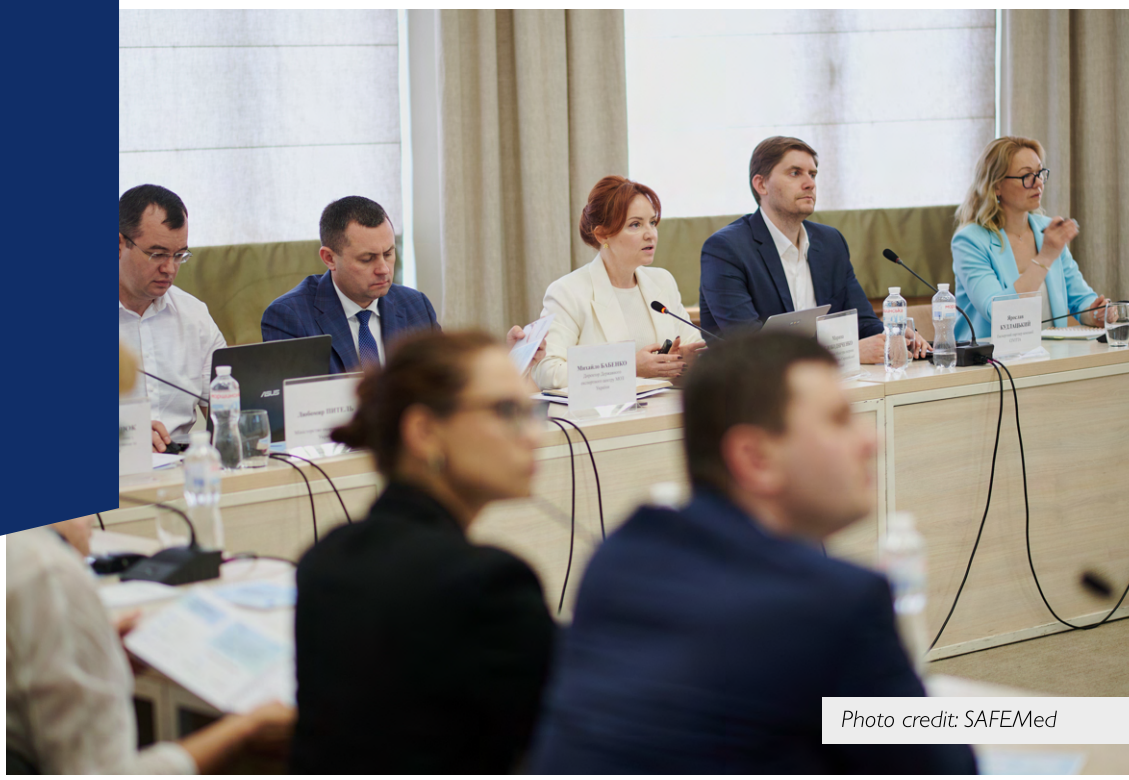


Photo credit: SAFEMed

ESTABLISHMENT AND OPERATIONALIZATION OF THE STATE CONTROL AUTHORITY IN UKRAINE

About SAFEMed

Improving access to safe and affordable medicines for the Ukrainian population through ongoing, ambitious health reforms is one of the Government of Ukraine's top priorities. The Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed) project (2017-2025) funded by the US Government is supporting this effort by applying health system strengthening best practices and evidence-based interventions. SAFEMed works to institutionalize rational medicine selection; systematize public procurement of pharmaceuticals and commodities; support sustainable public-sector pharmaceutical financing; and strengthen the pharmaceutical supply chain in collaboration with the government, civil society, and the private sector.

BACKGROUND

The pharmaceutical regulatory system is a framework of laws, policies, and institutions responsible for overseeing the development, manufacturing, distribution, and safety of medicines and healthcare products. Its primary goal is to ensure the quality, efficacy, and safety of pharmaceutical products, protecting public health and ensuring trust in the healthcare system.

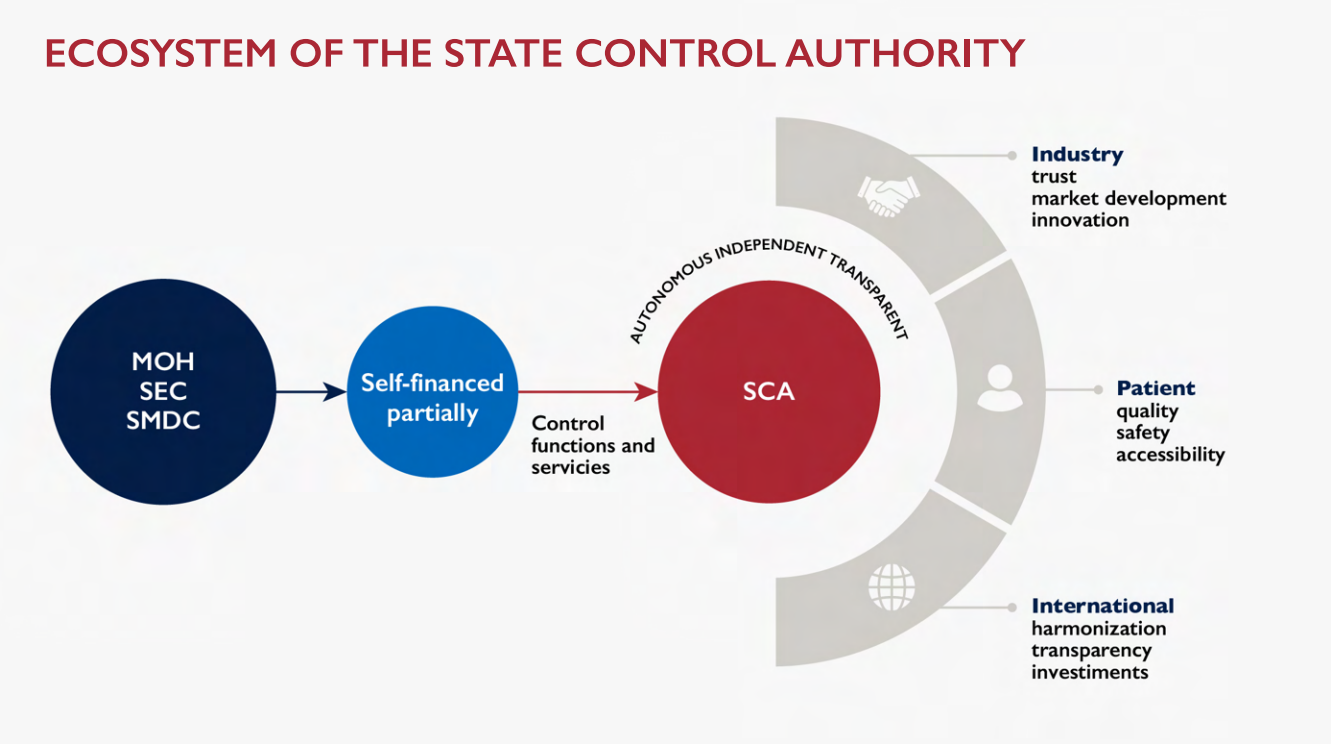
Ukraine's pharmaceutical regulatory system has long suffered from fragmentation, overlapping institutional mandates, and limited enforcement capacity. Regulatory responsibilities remain distributed across the Ministry of Health (MOH), the State Expert Center (SEC), and the State Medicines and Drug Control Service (SMDC), with uneven authority and chronic underfunding. These structural weaknesses undermine quality assurance, create public health risks, and diminish trust in the healthcare system. The implementation of the State Control Authority (SCA) as a unified regulatory body, an independent central executive body with special status, scheduled for January 2027, is declared by the Law of Ukraine "On Medicinal Products," enacted in July 2022[1], (hereinafter referred to as the 'Law on Medicines'), as the solution to address these issues.

The SCA is designed to consolidate regulatory functions currently fragmented across multiple institutions, and to operate in line with internationally recognized standards, including those of the WHO and U.S. FDA.

[1] *https://zakon.rada.gov.ua/laws/show/2469-20#Text*

It is envisioned in Law that after establishment the SCA will oversee the entire regulatory lifecycle - from market authorization to supervision across a wide range of health-related products, including medicines, medical devices, blood components, narcotics, and substances of human origin, as well as cosmetic products. The SCA will also be empowered to operate under a financially self-sustaining model, based on services and registration fees, ensuring its long-term autonomy and institutional resilience.

By improving transparency and consistency, the SCA is expected to positively impact key stakeholder groups: industry (through a predictable regulatory environment), patients (via strengthened product quality and safety), and the international community (through alignment with global frameworks and enhanced credibility).



In late 2023, SAFEMed was requested to expand its mandate and serve as a key technical partner to the MOH in preparing for this new priority for the country. As part of this support over the last two years, SAFEMed has supported the legal and policy groundwork for the SCA's establishment, contributing to improved accountability, regulatory clarity, and future operational readiness.

This brief summarizes the rationale for establishing the SCA, highlights key design components, and documents SAFEMed's contributions to one of the most transformative pharmaceutical governance reforms in Ukraine to date.

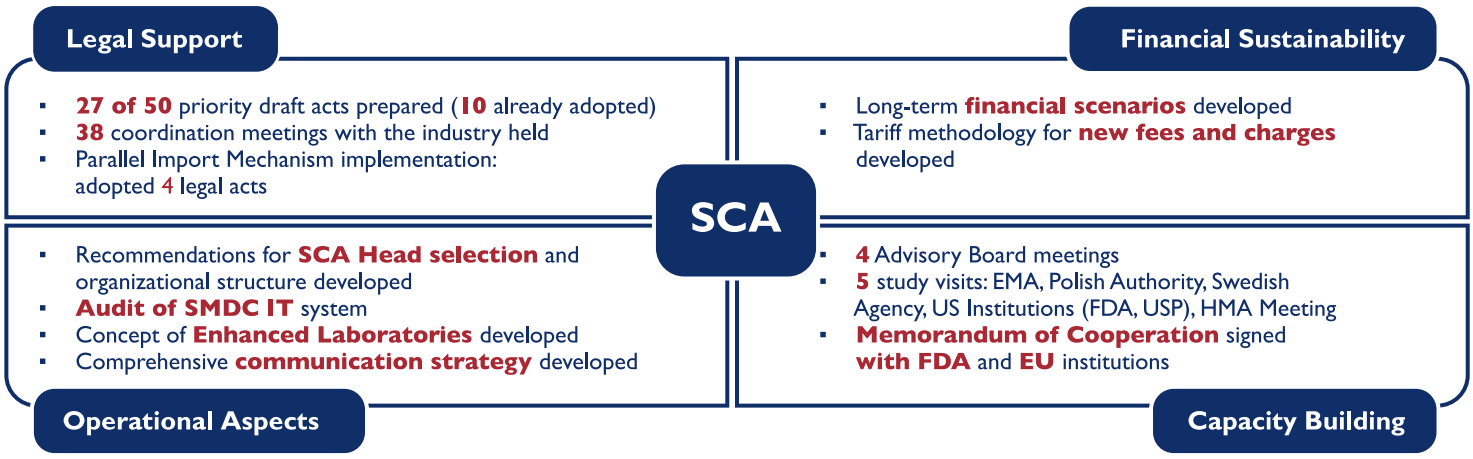
SAFEMED'S ROLE IN ADVANCING THE REFORM

The establishment of a new regulatory authority is not only legislative change. It requires a multi-dimensional transformation of the entire pharmaceutical oversight system. For the SCA to function as an effective, trustworthy and independent institution, its legal mandate, organization structure, financial model, and relationships with key stakeholders must be aligned with global best practices.

In close collaboration with the MOH, SAFEMed has served as the primary technical partner in laying the foundation for this transformation. The project's support was focused on the following core areas:

- Legal support
- Financial sustainability
- Organizational management
- Capacity building

KEY PILLARS OF SCA DEVELOPMENT



LEGISLATIVE FRAMEWORK

A strong legal foundation is essential to empower the SCA as Ukraine's future independent pharmaceutical regulator. From the very beginning, SAFEMed has supported the MOH in developing the legislative and regulatory framework necessary to establish the SCA's authority, functions, and compliance with international standards.

To coordinate this complex process, the MOH established a high-level working group in September 2023 formed by MOH Order[2] and included representatives of the MOH, SEC, SMDC, and SAFEMed. The WG is chaired by the Deputy Minister of Health. While this body served as a coordination platform, the core technical and legal work was supported by SAFEMed in close partnership with the MOH, SEC, and SMDC. SAFEMed embedded legal experts within the MOH and engaged LA law firm to support end-to-end drafting, review, and stakeholder validation of the required legislative instruments.

Key areas of SAFEMed support included:

- Mapping and prioritization of regulatory acts that are essential for operationalizing the SCA in line with Law on Medicines. A total of 50 legal acts were identified, of which 35 are directly related to the SCA's functions.
- Legal drafting of high-priority regulations. SAFEMed's legal partners led or supported the preparation of nine key acts, including those on import procedures, licensing conditions, and parallel import.
- Facilitating cross-sector dialogue with industry and stakeholders. More than 35 consultation sessions were organized, each accompanied by technical facilitation and feedback collection to align legal provisions with implementation realities.
- Supporting adoption and advancement. As of mid-2025, over 40% of the required legal acts have been either adopted or are under formal review, with the remainder in various stages of drafting and validation.

As of now, all the draft legislation is at different stages of approval. Please see the table for details below:

Legislation (legal acts)	Number of acts	% of total
Already adopted	10	20%
Drafts already prepared and waiting GOU passage	11	22%
Prepared for submission to the MOH for approval	6	12%
In progress	3	6%
Yet to be developed	8	16%
Technical acts/no amendments required/non-urgent/minor changes	9	18%
Outside the scope of SCA	3	6%
TOTAL	**50**	**100%**

[2] *by order of the Ministry of Health of Ukraine № 1650 dated September 20, 2023*

Through this multi-dimensional legal support, SAFEMed has helped build the regulatory infrastructure needed to operationalize the SCA and enable future enforcement mechanisms aligned with global good regulatory practices.

FINANCIAL SUSTAINABILITY AND MODELING

Ensuring the long-term financial autonomy of the future SCA is a core element of the institutional reform. The SCA is envisioned as a self-sustaining regulator with the authority to generate revenue through fees and service charges - an approach aligned with international best practices and essential to overcoming the chronic underfunding of the previous institutions.

This is made possible by a separate provision in the new Law on Medicines granting the SCA a special status that will allow it to charge fees for services provided - a mechanism that is relatively uncommon among other state bodies.

To support this approach, SAFEMed worked closely with MOH, SEC, and SMDC to develop an interactive financial modeling tool. This instrument enables simulation of budget scenarios for the SCA, including projections of operating costs (e.g., staffing, laboratory infrastructure) and income generation based on different services and fee structures. It serves as a decision-support tool for effective policy planning and financial oversight.

Building on the modeling tool, SAFEMed engaged a local consulting firm Civitta to develop a fee calculation methodology based on global benchmarks. This methodology outlines the structure and rationale for the newly introduced fees and contributions by the Law on Medicines:

- Annual contributions from marketing authorization holders, manufacturers, importers, and distributors.
- Pharmacovigilance-related fees.
- Service-based charges across different market actors.

Civitta also provided recommendations disaggregating fees across segments of the pharmaceutical industry, including pharmacies, manufacturers, marketing authorization holders, importers, and wholesale distributors.

These efforts help ensure that the SCA can operate with predictable, diversified, and transparent funding mechanisms, reducing reliance on state budget and strengthening its independence and accountability. The methodology of process for calculation fees and charges is described below.

PROCESSING OF INFORMATION	CONDUCTING INTERVIEWS	SUMMARIZING AND CLARIFYING INFORMATION	FORMING METHODOLOGY AND CALCULATION TARIFF
The procedure for performing functions To define: ■ tasks/ steps ■ characteristics of each step of the process ■ list of questions for interviews/ inquiries	With representative of the MOH/SEC/SMDC ■ responsible for the functions ■ familiar with the organization's vision of new function	■ summarizing information from interviews ■ requesting additional information ■ analysis of historical data	Creating a tariff calculating model (Excel tool): ■ Calculation ■ Presentation and approval Formation of a document with a methodology

CAPACITY BUILDING AND INTERNATIONAL ENGAGEMENT

Building a competent, globally-aligned regulatory authority requires more than structural reform - it demands an investment in institutional capacity, knowledge transfer, and stakeholder alignment. SAFEMed has played a essential role in enabling the MOH and its key institutions to engage with leading regulatory agencies, adopt global best practices, and enhance their strategic vision.

To support this process, SAFEMed organized a series of international study visits and knowledge exchanges with regulators in the United States, the Netherlands, Belgium, Poland, Sweden, and Malta. These visits facilitated experience with advanced regulatory frameworks, including Good Regulatory Practices (GRP), pharmacovigilance systems, and operational models for independent agencies. Through these engagements, Ukrainian institutions established long-term dialogue with counterparts such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Swedish Medical Products Agency and the European Commission.

In parallel, SAFEMed supported the design and launch of an Advisory Board on SCA formation, chaired by the Deputy Minister of Health. The Board serves as a platform for high-level consultation with international and national stakeholders. Beyond its technical function, the Board reinforces the political visibility and legitimacy of the SCA reform in the eyes of global partners.

Additionally, SAFEMed provided technical assistance in drafting and submitting the European Union (EU) Twinning Fiche[3]. This was a critical milestone that led to the formal approval of the EU Twinning Project focused on aligning the SCA with the EU regulatory framework. This long-term institutional partnership between Ukrainian and EU regulatory bodies will further strengthen the capacity and credibility of the SCA as it moves toward operationalization. Since then, on 22 September 2025, EU announced the results for Twinning project for Ukraine "Support the establishment of the State Control Authority (SCA) for medicines and medical devices," with the contract expected to be signed soon, marking a significant milestone toward creating a strong, EU-aligned regulator operational from January 2027. The project will be implemented by a consortium of Lithuania, Poland, and Germany, leveraging their regulatory expertise and EU integration experience.

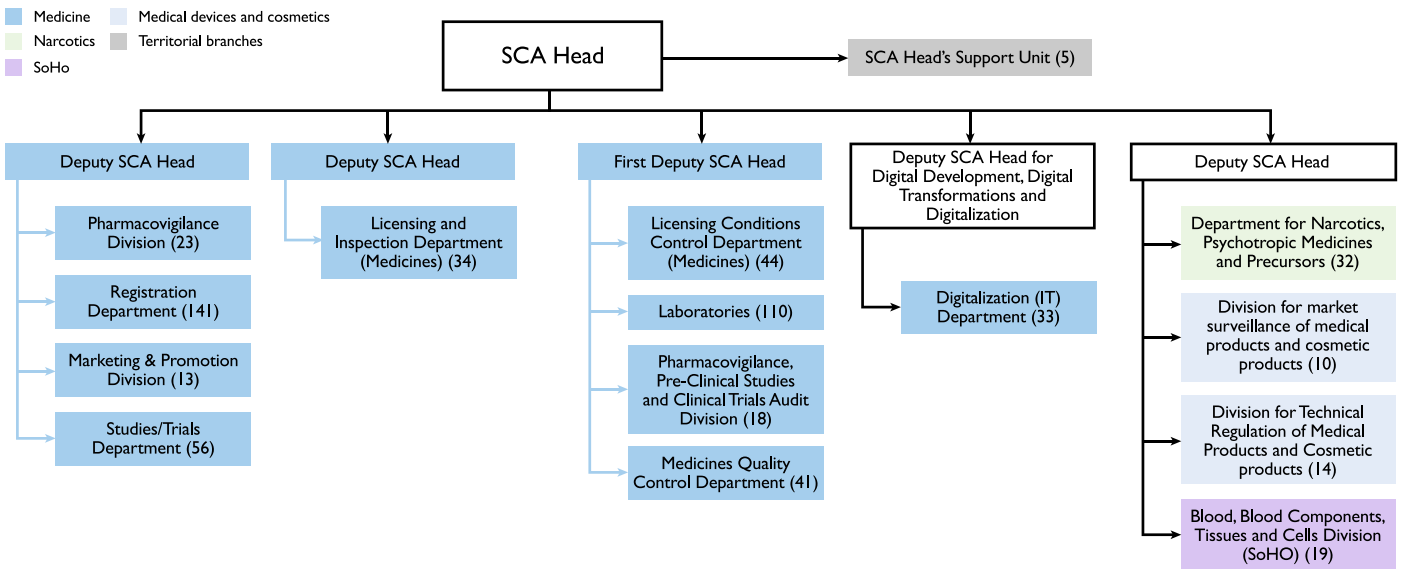
ORGANIZATIONAL MANAGEMENT AND COMMUNICATION

To ensure the future SCA is equipped for effective and independent operation, SAFEMed supported the MOH in strengthening key operational foundations, including:

- Preparation of a proposed organizational structure.
- Detailed recommendations for the transparent selection of the SCA's leadership.
- An audit of the SMDC IT system to assess infrastructure readiness and future digital solutions.
- Development of a comprehensive communication strategy to raise awareness among stakeholders.

INSTITUTIONAL STRUCTURE

SAFEMed supported the MOH in developing the draft organizational structure for the SCA, modeled on best practices from mature regulatory agencies such as the Swedish Medical Products Agency. The proposed structure reflects the SCA's core functions, ensures clear lines of accountability, minimizes duplication of roles, and enables evidence-based resource planning, including for staffing and financing.



[3] *Document that outlines the objectives, activities, and expected results of a technical assistance or partnership project aimed at capacity building and institutional strengthening, often within the framework of EU programs.*

SCA LEADERSHIP SELECTION

Recognizing that the credibility of the SCA depends on strong and independent leadership, the MOH turned to SAFEMed as a trusted technical partner to provide guidance on the selection of the institution's future Head. This request reflects a high level of confidence in SAFEMed's neutrality and international expertise, particularly given the corruption risks that often accompany appointments to public regulatory bodies in transition contexts.

SAFEMed responded by developing a set of detailed recommendations grounded in global best practices, including models used by agencies such as the U.S. FDA and the European Medicines Agency. These recommendations emphasized the need for transparent and depoliticized appointment process, with clear eligibility criteria, a structured evaluation framework, and oversight by an independent Selection Committee comprised of representatives from the Cabinet of Ministers, Verkhovna Rada, and MOH.

The proposed approach aims to protect the independence and integrity of the future SCA leadership, mitigate conflict-of-interest risks, and promote institutional resilience. It is also aligned with Ukraine's anti-corruption legislation and includes provisions to ensure public accountability and long-term trust in the new regulator.

DIGITAL INFRASTRUCTURE AND READINESS

To inform future digital planning, SAFEMed conducted an assessment of the existing IT infrastructure at SMDC. The audit helped identify system gaps and guided early planning for digital tools that will support regulatory workflows in the future SCA, including licensing, inspections, and data-driven decision-making.

SCA STRATEGIC COMMUNICATION

Given the sensitive and highly visible nature of regulatory reform, effective communication has been an important element of SAFEMed's support to the MOH. Acknowledging the risks of public misunderstanding and potential misinformation, SAFEMed led the design and implementation of a comprehensive communication campaign aimed at building stakeholder trust, managing expectations, and reinforcing the legitimacy of the future SCA.

The campaign was one of the most significant SAFEMed investments within the SCA support package and was designed to promote awareness, transparency, and coordinated messaging across all levels, from government stakeholders to patients, industry, the general public and international partners.

Key elements of the campaign included:

- Targeted communication products: SAFEMed, in cooperation with a professional marketing firm, produced a series of multimedia materials, such as animated videos, infographics, interviews, and social media content tailored to different stakeholder groups. See photo below.
- Content strategy and stakeholder coordination: An embedded communications consultant worked alongside the MOH, SEC, and SMDC to align messaging, anticipate communication risks, and facilitate responsive engagement with key audiences.
- Media outreach: Articles and press releases were strategically placed in specialized online sources and broader media to inform public around the reform.
- International positioning: Communication materials were also prepared to align with international expectations and signal Ukraine's commitment to global standards in pharmaceutical regulation.
- Based on the experience research of over 30 organizations operating in other countries, proposed a unified brand identity for the future regulator, including proposals for naming, logo, and visual standards, to build a recognizable and credible institutional image.

Photo credit: SAFEMed

Through targeted, strategic, and sustained support, SAFEMed has played a critical role in shaping the future of pharmaceutical regulation in Ukraine. By aligning legislation with international standards, laying the groundwork for a financially sustainable model, strengthening institutional capacity, and advancing organizational and communication strategies, the project has helped establish the foundation for a transparent, professional, independent SCA.

Brochure on SCA prepared for meeting with industry, June 6, 2025.

TRANSITION PERIOD AND FURTHER STEPS

The successful establishment of SCA requires a carefully planned transition process to ensure regulatory continuity and institutional stability. In coordination with MOH, SEC initiated the development of a transitional procedure that will govern the interaction between MOH, SEC, and the future SCA. This transitional arrangement is intended to keep the integrity of regulatory functions, particularly around the assessment of registration dossiers, as responsibilities shift from existing institutions to the newly created authority.

The transition period is set to begin in January 2027 and is expected to last for one year. Key transitional arrangements include:

- Completion of all registration assessments initiated by SEC before December 31, 2026.
- Transfer of decision-making authority for new registrations to the SCA starting in 2027.
- Gradual transfer of expert personnel from SEC to SCA across three phases (Q1: 30%, Q2: 30%, Q3: 40%).
- Handover of regulatory archives and case files to ensure data continuity.

Looking ahead, Ukraine's continued progress toward an effective and internationally aligned pharmaceutical regulator will depend on the successful implementation of several critical next steps:

- Finalization and approval of the remaining legal acts and regulatory methodologies, including fee calculation mechanisms.
- Launch of a transparent and competitive process for appointing the Head of the SCA.
- Deployment of the financial model to ensure SCA's operational autonomy.
- Endorsement of the organizational structure and initiation of staff recruitment and onboarding.
- Operationalization of the transitional framework for full transfer of responsibilities by January 2028.
- Implementation of the EU Twinning Project to strengthen institutional capacity.
- Availability of the sufficient IT infrastructure to fulfill envisioned SCA functions.
- Continued delivery of targeted training and technical assistance aligned with international regulatory models.
- Sustained stakeholder engagement and proactive communication to build awareness, support, and legitimacy for the reform.

LESSONS LEARNED

Alignment with national priorities accelerates impact

SAFEMed's ensured that establishing the SCA complemented Ukraine's efforts to integrate EU standards, improve transparency, and strengthen the pharmaceutical sector, demonstrating how institutional reforms can reinforce overarching strategic objectives.

Stakeholder engagement is critical for legitimacy and support

Engaging a broad range of stakeholders from government agencies to industry representatives and international partners helped foster a shared understanding of reform benefits. Regular consultations, open dialogue, and inclusive participation built transparency and trust, which facilitated implementation of complex processes like legislative development, organizational restructuring, and system integration.

Leadership as the foundation of sustainable reform

Effective reform relies heavily on mature, committed leadership that can embed change into daily practices and foster a shared vision. Building a resilient and evolving system takes time, patience, and the continuous engagement of sector professionals and leaders. Strong leadership ensures reform efforts are sustainable, adaptable, and capable of withstanding setbacks.

Institutional ownership ensures sustainability

Embedding reforms within the capacities and strategies of Ukrainian institutions fosters sustainability. SAFEMed developed clear organizational structures, leadership appointment recommendations, and capacity-building measures to ensure the future SCA remains operationally independent and accountable, with strong local ownership at its core.

Building on international best practices enhances effectiveness

Drawing on global regulatory models and expert advice provided a valuable reference point. SAFEMed's facilitation of international collaborations, Advisory Board consultations, and knowledge exchanges helped shape a credible, standards-based regulatory authority aligned with EU practices, supporting Ukraine's broader integration goals.

Holistic reform takes time and patience

Building a robust and effective regulatory authority requires careful planning, coordination, and sustained effort. Establishing legislative frameworks, organizational structures, and stakeholder requires long-term commitment and flexibility to adapt to evolving political and institutional landscapes, ensuring that reforms are resilient and sustainable.

Effective communication accelerates implementation

A broad, clear communication campaign that explains the meaning, processes, and benefits of reform serves as an effective tool to accelerate industry wide dialogue and community engagement. This approach helps bridge the gap between theory and practice, fostering consensus and supporting the timely implementation of socially important reforms.

SUMMARY

The successful transition to a fully operational SCA in Ukraine relies on a clear, coordinated plan, robust stakeholder engagement, and ongoing political and institutional commitment. Building on SAFEMed's experience and lessons learned, the next steps must be supported by continuous communication, capacity building, and alignment with international best practices. These elements will be essential to ensure that the reform is not only achievable but also sustainable, fostering long-term stability and credibility of Ukraine's pharmaceutical regulation system.

Learn more at msh.org/projects/safe-affordable-and-effective-medicines-for-ukrainians/

This publication is made possible by the support of the American people, under the terms of contract number AID-121-C-17-00004, funded by the US Government. The contents of this publication are the sole responsibility of Management Sciences for Health and do not necessarily reflect the views of the United States Government.

SAFEMed - UKRAINE
Email: ua-safemed@safemedua.org