# Preventing Shortages of Donated Blood and Blood Components: Administrative Law Instruments in the EU and Ukraine

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**Abstract.** The article examines administrative law instruments for preventing shortages of donated blood and blood components intended for transfusion in the European Union and Ukraine. Its purpose is to clarify the duties arising from supply risks and substantiate improvements to Ukrainian regulation. Doctrinal analysis, systematic interpretation and functional comparison cover legislation and publications available by 31 May 2026. The study distinguishes the applicable European blood directives from the prospective supply-continuity requirements of Regulation (EU) 2024/1938. Hungarian legislation illustrates how stock information, strategic planning and logistics can be assigned to an identifiable organisational unit. Ukrainian law already provides for forecasting, reserve requirements, daily reporting, redistribution, notification of contractual supply failures and humanitarian imports. The analysis identifies a narrower issue: how these mechanisms should address an imminent shortage of a particular component before a contractual failure occurs or national stock indicators deteriorate. The article proposes supplementing existing notification rules with an urgent preventive trigger, specifying assessment and referral duties, and recording the grounds, measures and outcome of the response. It also proposes clarifying the relationship between urgent requests for external assistance and the national stock indicators used in the humanitarian import procedure. These recommendations build on existing powers and distinguish operational coordination, regulatory supervision and clinical allocation. Donor consent, blood safety, proportionality, data minimisation and judicial protection delimit the permissible response. The contribution is a legal model connecting a defined supply risk, the responsible actor, an authorised measure and a reviewable record. Its operational effectiveness requires subsequent assessment through exercises, administrative records and evidence of timely access to transfusion care.

**Key words:** blood donation; blood shortages; blood components; administrative law; continuity of supply; SoHO Regulation; emergency preparedness; public authorities; Ukraine.

## INTRODUCTION

Effective blood shortage prevention requires stock reports to inform timely action by an authorised body. The legal framework must identify who assesses a supply risk, arranges assistance and records the response. The connection between information and public responsibility is therefore a distinct problem of administrative law.

World Health Organization (WHO) guidance identifies reduced donor availability and shortages of essential materials and equipment among the threats to blood supply during emergencies [20]. Preparedness and response responsibilities must remain identifiable when several organisations contribute to transfusion care. Shortage prevention therefore concerns routine administration as well as exceptional measures.

The European reform offers a timely comparative setting. In explaining the adoption of the new framework for substances of human origin (SoHO), the Council of the European Union highlighted the need to address supply sufficiency and differences in national oversight [5]. Pupella connects the reform with weaknesses in emergency supply continuity and the development of more consistent oversight arrangements [12, p. 462]. These contributions support examining how a continuity objective becomes an actionable legal duty.

Ukrainian scholarship provides complementary perspectives. Teremetskyi and his co-authors associate socially significant medical services with coordinated organisational, financial and legal measures [14, p. 5]. Teremetskyi identifies legality, legitimate purpose, necessity and proportionality as criteria governing interference with protected rights [13, p. 343]. Applied here, these approaches direct attention to both the capacity to respond and the limits of intervention. A specific procedure linking blood-stock information to shortage responses requires further analysis.

The purpose of this article is to identify administrative law instruments for preventing shortages of donated blood and blood components in the EU and Ukraine and to substantiate improvements to the connection between monitoring, notification, planning and response. The research question is which legal elements establish an identifiable and reviewable duty to act when a supply risk is reported. The analysis concerns blood and components intended for transfusion; industrial plasma fractionation and plasma-derived medicinal products fall outside its substantive scope.

## METHODS

The study applies doctrinal legal analysis and systematic interpretation to legislation in force on 31 May 2026. Adopted provisions with deferred application are examined separately. The source set comprises Ukrainian primary and secondary legislation, EU acts, Hungarian Government Decree No. 323/2006, guidance from WHO and the European Directorate for the Quality of Medicines & HealthCare (EDQM), and relevant scholarship published by the same date. Institutional explanations are used to establish the documented purpose of reforms, without treating those explanations as binding rules.

Functional comparison follows four questions: what circumstance activates a duty; which actor bears it;

what response is legally available; and what record permits subsequent scrutiny. Hungary illustrates the connection established by law between information and operational coordination. The analysis distinguishes existing requirements from the author's proposals. It does not examine confidential stock data, patient records or internal emergency plans; conclusions are consequently limited to normative design and do not establish institutional non-compliance or comparative clinical outcomes.

## RESULTS

### The legal significance of a shortage

For this study, shortage prevention means the organisation of legally assigned monitoring, preparedness and response duties directed at maintaining timely access to suitable blood and components. This analytical definition concerns obligations to take appropriate measures and does not imply an absolute guarantee of supply.

Three situations should be distinguished: a stock reduction manageable through routine replenishment; a forecast shortfall requiring coordination; and an actual or imminent inability to meet a necessary transfusion need. Each may require a different response. An urgent local shortage of a particular component can arise while aggregate national stocks remain stable. National stock indicators and notifications of individual supply risks therefore perform complementary functions.

Supply reporting also differs from haemovigilance. Directive 2002/98/EC establishes the European blood quality and safety framework, including competent authorities and oversight [8]. Articles 5 and 6 of Commission Directive 2005/61/EC address notification of serious adverse reactions and events [6]. A shortage can arise without a reportable safety event; a safety event can also necessitate withdrawal of components and cause a shortage. Where both occur, supply coordination and safety investigation require identifiable responsibilities and exchange of relevant information.

### The prospective EU framework for supply continuity

Regulation (EU) 2024/1938 is in force, but its Chapter VIII supply-continuity requirements apply from 7 August 2027 under Article 87. Directive 2002/98/EC remains applicable at the study's cut-off. Article 3(34) defines a critical SoHO entity by a contribution whose loss cannot be compensated by other entities or alternative substances or products for recipients [9]. The Regulation provides a prospective comparative benchmark; Ukrainian authorities require powers conferred by Ukrainian law.

Article 62 distinguishes Member States' efforts towards sufficiency from critical entities' continuous stock monitoring. Articles 63 and 67 require national and entity emergency plans. Under Article 64, critical entities must notify significant shortages without undue delay. In the transfusion context, this covers cancellation or postponement, or a significant risk of either, caused by unavailability and posing a serious risk to human health. Competent authorities must forward alerts to national authorities, take mitigation measures where possible and use the information in reviews of national emergency plans [9].

This allocation of responsibility distinguishes a sufficiency objective from specific monitoring, planning and notification duties. Performance of those duties can be assessed even where circumstances beyond an organisation's control affect the outcome. A legal evaluation should therefore examine both the steps required of each actor and the reasons for the chosen response.

Pupella describes the prospective combination of activity reporting, emergency planning and information exchange [12, p. 463]. These mechanisms serve different time horizons. Periodic data inform preparation and resource allocation; urgent alerts allow assessment of a particular supply threat. Their relationship must be specified in the response procedure.

EDQM's Blood Supply Contingency and Emergency Plan materials offer an operational method for identifying risks, stakeholders and expected actions [7]. A Ukrainian plan should additionally specify the legal power supporting each action, the instrument required and any dependency on another body's decision. Planning documents cannot independently create coercive powers or alter competence established by law.

### Existing Ukrainian instruments and their interaction

Law No. 931-IX establishes a foundation for sufficiency. Articles 4 and 6 address meeting national needs and Cabinet powers concerning supply norms and reserves; Article 11 structures the system at national, regional and hospital levels. Article 23(3) requires Cabinet approval of mandatory annual supply volumes and reserves, while Article 24 addresses donation during emergencies [19]. These provisions require implementation through specific planning and response mechanisms.

The Procedure approved by Cabinet Resolution No. 254 of 7 March 2025 links several mechanisms. Paragraph 9 requires state and municipal blood system entities to calculate minimum stocks and report daily to the National Transfusion Centre. Paragraph 10 requires stocks covering state and municipal transfusion providers' weekly needs plus 25 per cent; the additional percentage rises to at least 50 per cent during the specified emergencies and martial law. Paragraph 11 links needs with national planning, while paragraph 12 requires contractual provision for round-the-clock supply and order-fulfilment deadlines [4].

Paragraph 17 provides for distribution between state and municipal blood system entities on the National Transfusion Centre's demand, without a distribution contract or cost reimbursement, to meet the specified security and defence needs or supply public providers treating victims of the listed emergencies and martial law. Paragraph 18 requires a state or municipal transfusion provider to notify that Centre in writing within one working day of a contractual supply failure by a state or municipal blood system entity; it also provides an alternative procurement mechanism [4]. These provisions already establish an event-related notification duty and a defined basis for exceptional redistribution.

The Ukrainian Transplant Coordination Centre's

explanation of the reform confirms its emphasis on common calculations of needs and minimum stocks [15]. Existing channels also include daily operational stock reporting through MedData by 10:00 under paragraph 2(6) of Ministry of Health Order No. 424 of 7 March 2022; paragraph 2(4) addresses mutual supply between state and municipal blood system entities during shortages [11]. The improvement proposed here concerns anticipatory notification of a threat to transfusion availability, including before a contractual supply failure occurs. It should complement these channels without duplicating routine reports.

Resolution No. 681 of 30 June 2023 establishes a specialised wartime mechanism for the security and defence forces. Paragraphs 9 and 10 of its Procedure assign monitoring of needs to the Ministry and coordination of participating entities, logistics and stocks to the Ukrainian Transplant Coordination Centre [1]. These functions operate within the mechanism's defined scope and must be distinguished from general regulatory supervision.

Resolution No. 921 of 29 August 2023 provides a route for humanitarian imports and assigns, for its purposes, the National Transfusion Centre's functions to the Ukrainian Transplant Coordination Centre. Paragraph 5 of its Procedure links a fall in national average stocks, assessed against the preceding 180 calendar days, to domestic coordination and redistribution. The Centre informs the Ministry if those measures cannot be implemented or the specified improvement is absent within ten calendar days of the decrease. The Ministry prepares the proposed decision; paragraph 4 requires a Cabinet decision for imports under this Procedure [2].

The mechanism thus connects monitoring, domestic assistance and possible external supply. The ten-day provision is not a general waiting period for domestic action; the inability to implement measures is a separate ground for referral. The remaining issue is how an urgent local shortage of a particular component should be assessed when the national indicator does not adequately reflect the threat. An express urgent-referral provision would clarify this relationship.

Resolution No. 1294 of 12 December 2023 provides for phased implementation of the eBlood information and communication system according to technical readiness. Paragraphs 5–7 of its Procedure distinguish the state, represented by the Ministry, as owner; the Ukrainian Transplant Coordination Centre as holder of the right of operational management; and the State Enterprise 'Electronic Health' as administrator [3]. The property-law right of operational management must not be confused with technical administration or authority to direct blood distribution. The legal establishment of the system does not establish that every function was operational by the cut-off date.

**The Hungarian institutional example**

Hungarian Government Decree No. 323/2006 offers a functional comparison. Sections 1 and 3 place the Hungarian National Blood Transfusion Service (OVSZ) under the health minister and provide for central and regional units. Section 5(2)(b), (d) and (f) specifically assigns to its central organisational unit (OVSzK) strategic planning, the national logistics and information network, a blood-stock register and dispatch service, and continuing data collection and analysis [10]. The allocation connects stock information with the organisational means to coordinate supply.

The comparative lesson concerns the completeness of assigned functions. A monitoring body needs an express route to initiate action or refer the matter to another competent institution. These operational functions do not establish the service's designation as a future SoHO competent authority. Operational delivery and regulatory oversight require separate legal analysis.

For Ukraine, the functional test is whether providers, the coordinating centre and the Ministry can identify who assesses a notification, commits resources, arranges delivery and reviews the response. This test supports clarification of existing responsibilities; organisational restructuring would require additional evidence of deficiencies that cannot be resolved within the current arrangement.

**Safeguards and review of shortage responses**

Shortage prevention must preserve donor protection and blood safety. Article 14 of Law No. 931-IX requires donor examination, information and written consent; Article 23(4) subjects imports to safety and quality requirements [19]. Under the future EU framework, Article 66 excludes voluntary and unpaid donation and donor consent from emergency derogations [9]. Supply urgency therefore cannot justify compulsory donor participation, and humanitarian assistance must meet the applicable safety requirements.

Article 19 of the Ukrainian Constitution confines public action to its lawful basis, competence and prescribed manner; Article 55 guarantees judicial protection against public decisions, actions and omissions [16]. A claim that redistribution is necessary therefore needs to identify the available legal instrument. Coordination, contractual supply, an internal instruction and an externally binding administrative decision may have different legal effects.

Article 2(2) of the Code of Administrative Justice requires examination of legality, justification, proportionality and timeliness, among other criteria. Articles 5 and 19 connect administrative judicial protection with the relevant rights or interests and a public-law dispute [17]. Not every clinical or contractual disagreement falls within administrative jurisdiction. For an alleged failure to respond, the analysis should identify the duty, its trigger, the responsible actor and when performance became due.

Teremetskyi's proportionality analysis supports examining the justification and burden of intervention [13, pp. 343–344]. Applied to redistribution, this requires assessment of the consequences for both the requesting provider and the institution releasing stock. The response should document whether the transfer can address the reported need without creating an unjustified threat to transfusion availability elsewhere.

A shortage notification should normally communicate component categories, usable quantities,

anticipated needs and delivery constraints without identifying individual donors or patients. Article 6(3) of the Law on Personal Data Protection requires data to be appropriate, adequate and non-excessive for the specified purpose [18]. A separate justified need for identifiable information must be assessed under the applicable rules. The suggested notification process should also preserve a functioning alternative channel during a digital outage.

## DISCUSSION

Ukraine already combines planning, reserves, stock reporting, redistribution and notification of contractual supply failures. The principal opportunity for improvement lies in responding earlier to a specific threat to transfusion availability and connecting that assessment to existing assistance powers. The following proposals address that connection while preserving the responsibilities of providers, coordinators and regulatory authorities.

First, the notification duty in paragraph 18 of the Procedure approved by Resolution No. 254 should be supplemented by a preventive trigger: a documented actual or imminent inability to meet necessary transfusion needs within the clinically available time. The trigger should specify the component and affected service and should not depend solely on contractual non-performance or deteriorating national stocks. An urgent warning should be required without undue delay; the existing one-working-day period for reporting contractual failure should not substitute for an earlier warning where delay threatens care. Technical thresholds and assessment deadlines require validation with transfusion specialists.

Second, the procedure should identify who receives and assesses the warning, when referral to another competent body is required and which measure is available. Assessment should lead, where its legal conditions are met, to redistribution under paragraph 17, contractual assistance or referral for external supply. A preliminary warning should permit a verified update. The record should capture receipt and assessment times, the legal basis and reasons for the measure, the implementing actor and the outcome, including reasons for declining or modifying assistance.

Third, paragraph 5 of the Procedure approved by Resolution No. 921 should expressly address a documented urgent shortage of a particular component that cannot be resolved domestically within the necessary time. The amendment should specify evidence for urgent referral, its relationship with the average-stock indicator and ten-day provision, and the Ministry's assessment duties. The Cabinet of Ministers of Ukraine would retain its decision-making role under paragraph 4. The proposed provision would supplement, rather than displace, the existing import procedure.

Fourth, the amendments should coordinate the mechanisms under Resolutions Nos. 254 and 681 and preserve their defined scope. Extension of public reporting or response duties to additional providers, including private entities, requires an adequatestatutory basis; Law No. 931-IX should be amended where existing powers are insufficient. Internal forms and coordination agreements cannot impose new public duties or sanctions on third parties.

Fifth, the procedure should be tested against operational capacity. WHO links risk assessment, emergency planning, response and recovery [20], while EDQM identifies stakeholders and actions before disruption [7]. Exercises should test whether a warning reaches the responsible actor, alternative supply can be assessed and assistance can be delivered. Administrative readiness requires evidence beyond the existence of a plan or successful electronic submission.

Two hypothetical examples illustrate the proposal. An anticipated platelet shortfall at a hospital should prompt assessment of suitable stocks and delivery time even if national aggregate stocks are stable. A reporting-platform failure should permit the same warning through an authorised alternative channel, with later reconciliation of the record. These examples test procedural design and do not substitute for clinical decisions.

Evaluation should distinguish procedural performance from service outcomes. Notification and assessment times, documented authority and implementation of measures concern administration; fulfilment of clinically justified requests concerns availability. Wastage, burdens on assisting providers and donor protection should also be assessed. Empirical work is needed before attributing supply improvements to a reporting mechanism, particularly given the influence of personnel, transport, funding and suitable stocks.

## CONCLUSIONS

Administrative law supports shortage prevention by connecting a defined risk with an identifiable duty, an authorised response and a reviewable record. This model distinguishes routine stock information, notification of contractual supply failures and preventive warnings about threatened transfusion availability. It also separates supply coordination, regulatory supervision and clinical decision-making.

The prospective EU SoHO provisions differentiate sufficiency objectives, monitoring, notification and preparedness duties. Ukrainian legislation already provides concrete response instruments, including exceptional redistribution and mandatory notification of contractual supply failures under Resolution No. 254. Hungary illustrates the express assignment of stock information and coordination functions to a central organisational unit; its experience supplies a functional comparison without proving the superiority of one institutional structure.

For Ukraine, the priority is to supplement existing notification duties with an urgent preventive trigger, define assessment and referral responsibilities, and clarify access to humanitarian imports where a local component shortage threatens timely care. These changes require an adequate legal basis and safeguards for donor consent, blood safety, proportionality, personal data and judicial protection. Their operational value should be tested through exercises, administrative records and evidence of timely access to transfusion care.

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