



UKRAINE REGIONAL DISTRIBUTION CENTERS ASSESSMENT REPORT

September 2021

SAFEMed

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ACRONYMS

GDP	Good Distribution Practices
GSP	Good Storage Practices
HCF	health care facility
HIV	human immunodeficiency virus
MOH	Ministry of Health
NME	Non-profit municipal enterprise
PEPFAR	US President's Emergency Plan for AIDS Relief
PLHIV	people living with HIV
PPP	public-private partnership
SAFEMed	Safe, Affordable, and Effective Medicines for Ukrainians
SDP	service delivery point
TB	tuberculosis
UNDP	United Nations Development Program
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development

EXECUTIVE SUMMARY

Access to safe essential medicines is a critical component of an effective health care system. The Ministry of Health (MOH) in Ukraine is directly responsible for the procurement of medicines for several priority health programs, including HIV/AIDS, tuberculosis (TB), and viral hepatitis. The delivery of HIV, TB, and hepatitis commodities, procured by central government programs, are transported from national warehouses to regional distribution centers where they are stored until last mile distribution to public health facilities.

In November 2020, the MOH requested the Safe, Affordable, and Effective Medicines for Ukrainians (SAFEMed) Activity, funded by the US President's Emergency Plan for AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID), to conduct an independent assessment of compliance of regional-level distribution centers for storing medicines for HIV/AIDS, TB, and viral hepatitis treatment to Ukrainian legislation and Good Storage Practice (GSP). Analysis of the distribution centers' capacity was necessary to identify existing gaps and come up with recommendations for the MOH, Center for Public Health (CPH), and regional health administrations.

SAFEMed and CPH developed terms of reference for the assessment and determined the list of facilities to be inspected. It was decided to assess all 79 regional distribution centers across all regions of Ukraine. Through an open tender, SAFEMed selected a private firm to conduct the assessment. The winner was Kreston GCG, the Ukrainian branch of the leading international network Kreston International. The CPH, SAFEMed, and Kreston GCG developed a comprehensive checklist that was used during onsite visits. SAFEMed sought input on the checklist from Central Procurement Agency (CPA) to ensure the tool reflected their needs as well.

During April-May 2021, Kreston's auditors successfully conducted site visits to all regional distribution centers across Ukraine. Once visits were completed, Kreston submitted a report summarizing findings and recommendations for improvement. According to the findings, there were significant discrepancies in some of the distribution centers to the requirements of current Ukrainian regulations, in particular:

1. Some centers were not set up for drug storage and were sometimes overloaded.
2. The appearance of surfaces and auxiliary equipment (wiring, etc.) and covering of walls and ceilings of the premises for drug storage did not meet the established requirements. As a result, these locations could not be properly cleaned.
3. In conditions of limited funding, distribution centers were forced to adapt to the use of obsolete and worn-out equipment (household refrigerators, hygrometers, etc.).
4. The systems for tracking the shelf life of drugs during storage and shipment according to the FEFO (First expired, First out) principle were imperfect.

The assessment recommendations to MOH, CPH, CPA, and regional health administrations will be instrumental in reinforcing a more robust comprehensive national logistics system for Ukraine and will include identification of opportunities for private sector engagement in the warehousing field. SAFEMed will share assessment findings and recommendations with key stakeholders for collaborative action planning to address identified gaps.

BACKGROUND

Access to essential medicines is a critical component of an effective health care system. The MOH in Ukraine is directly responsible for the management of 19 national programs, including HIV/AIDS, TB, and viral hepatitis. The delivery of HIV, TB, and hepatitis commodities, procured by central government programs, are transported from national warehouses to regional distribution centers where they are stored until last mile distribution to public health facilities.

As part of its efforts to improve the medicines supply chain, SAFEMed conducted an assessment of the existing regional distribution centers that store ARV, TB and viral hepatitis therapies. Such an assessment has never been conducted at this complexity and scale, and previous inspections, conducted by CPH, showed poor results.

Regional distribution centers occupy an important place in the medicines supply chain. The procurement of antiretroviral (ARV) and TB drugs purchased centrally with state funds is managed by CPA. Upon arrival, goods are located at national level in central warehouses. Then medicines are delivered to the regions of Ukraine and stored in the regional distribution center's warehouses with further distribution to service delivery points on district-level where patients can get their medicines.



Picture 1. Pathway of drugs to the patient

Distribution centers have the responsibility of quality storage of drugs on the regional level and they are obliged to compliance the requirements of Ukrainian regulations. Distribution centers are based within medical health care facilities that have special premises (warehouses) where they store and handle medicines and supplies. Distribution centers have status of non-profit municipal enterprise, funded by the state budget and charitable organizations They also receive funds for paid medical services and rental services. Regional distribution centers receive information about stock of medicines from service delivery points and distribute goods to them in accordance with needs and available stock.

Analysis of distribution centers' capacity and compliance is necessary to identify existing gaps and come up with recommendations for the MOH, CPH, and other stakeholders to create a more comprehensive logistics model for Ukraine. Understanding the current situation can facilitate recommendations around the optimal transportation routes and delivery frequency (e.g., monthly deliveries instead of quarterly deliveries) and the potential role of private sector in warehousing and distribution.

APPROACH

In November 2020, the MOH requested SAFEMed to conduct an independent assessment of compliance of regional distribution centers to Ukrainian legislation. According to agreement with CPH it was decided to check all 79 regional distribution centers storing medicines for treatment of HIV, TB, and viral hepatitis in all the regions of Ukraine.

SAFEMed and CPH developed terms of reference for the assessment and determined the list of facilities to be inspected. It was decided to assess all 79 regional distribution centers across all regions of Ukraine. Through an open and competitive tender, SAFEMed selected a private firm to conduct the assessment. In March 2021 the contract was signed with the tender winner - Kreston GCG, the Ukrainian branch of the leading international network Kreston International. Kreston GCG has extensive experience performing comprehensive audits on compliance with the Good Practices of leading pharmaceutical companies and regulatory authorities in Eastern Europe and Central Asia.

The CPH, SAFEMed, and Kreston GCG worked together on developing a comprehensive checklist that was used during onsite monitoring visits and includes various aspects of storing medicines such as temperature control, quality, security, and the condition of the storage room. The checklist was based on the standards outlined in several regulations:

- “On approval of the Rules for storage and quality control of medicines in Health Care institutions”, approved by the Order of the Ministry of Health of Ukraine dated 16.12.2003 # 584 in the current version;
- Guidelines ST-N MOH 42-5.1: 2011 Medicines. Good storage practice;
- “On Approval of Instructions on Sanitary-Epidemiological mode of Pharmacy Establishments”, approved by the Order of the Ministry of Health of Ukraine dated 15.05.2006 # 275;
- “On Approval of the Rules for the Utilization and Destruction of medicines”, approved by the Order of the Ministry of Health of Ukraine dated 24.04.2015 # 242.
- as well as standards within the internationally recognized Good Storage Practices (GSP).

The task was to confirm if each of the requirements is strictly fulfilled in the assessed distribution center. In case the requirement is not met, it is considered a discrepancy and comments outlined in the related field of checklist.

SAFEMed sought input on the checklist from CPA to ensure the tool reflected their needs as well. The standard approved checklist used by auditors included 8 criterions in the following categories:

1. Room for drugs storage
2. Temperature control
3. Safety
4. Sanitary requirements
5. Storage
6. Control of pots and narcotic drugs
7. Quality
8. Computer and software

Each criterion has subcriteria with detailed description of the requirements indicated. In total check list consists of 30 subcriteria. The full checklist is presented in Appendix 1.

The example of first page of filled-in checklist is presented in picture 2.

Чек-лист для оцінки відповідності складських приміщень для зберігання лікарських засобів (ЛЗ) вимогам чинного законодавства № 1

Назва ЛПЗ:	Комунальне некомерційне підприємство «Вінницької обласної ради «Клінічний центр інфекційних хвороб».
Адреса ЛПЗ:	Вінницький р-н, селище Березина, вул. 5 км Барського шосе
Дата оцінки складського приміщення для зберігання ЛЗ:	12.04.2021
Візит здійснював (ПІБ, посада)	Коваленко О.М., ревізор
в присутності (ПІБ, посада):	Рудик Катерина Василівна, зав. складом, уповноважена особа (Наказ № 95К від 01.04.2021 фото - 9035), тел. (+380)96-045-88-64

Технічні характеристики складу

№		Коментарі	Фото №
1	Загальна площа складського приміщення (квадратні метри) (відповідно до документів)	Загальна площа 12,26 кв.м. (складське приміщення 1 кімната, 2 поверх амбулаторно-поліклінічного відділення) + холодильна камера 9,8 кв.м. + частина медпрепаратів денної потреби в кімнаті видачі ліків у шафі (фото 9023)	9027 (№49)
2	Загальна площа зберігання (квадратні метри) (відповідно до документів)	12,26 кв.м.	9019, 9015
3	Кількість дверей для відвантаження/для приймання	1 приміщення, 1двері	
4	Можливість зберігання в палетах	Так, однак не зберігається та немає такої необхідності.	9015
5	Загальна кількість палето-місць (стелажі та підлога)	Приблизно до 10 палет.	

Критерій	№	Підкритерій	Нормативні документи	Коментарі	Фото №
ПРИМІЩЕННЯ ДЛЯ ЗБЕРІГАННЯ ЛЗ	1	Кількість площі і приміщень для зберігання достатня та визначається кількістю ЛЗ, які в них зберігаються, з урахуванням їх токсикологічних, фармакологічних груп та фізико-хімічних властивостей.	Наказ МОЗ від 16.12.2003 №584 з змінами, розділ II, пункт 1.	На момент моніторингового візиту достатньо. - у наявності Калетра (дитячий сироп) з умовами зберігання у холодильнику, інші лікарські засоби не потребують зберігання в холодильниках, розміщені на стелажах в складському приміщенні.	
	2	Цілісність складських приміщень (відсутність протікання даху, трубопроводів, дір і проломів у дверях, стінах, інших пошкоджень які впливають на збільшення вологості, запиленості і збільшують ризик проникнення в приміщення комах/гризунів) та захист ЛЗ від коливань температури повітря.	Наказ МОЗ від 16.12.2003 №584 з змінами, розділ II, пункт 3.	Візуальних пошкоджень виявлено не було, – офісне приміщення, переобладнане під складське, розташоване на 2-му поверсі будівлі.	
	3	Забезпечення складських приміщень необхідною кількістю стелажів, шаф, холодильників, піддонів для зберігання ЛЗ.	Належна практика зберігання, Наказ МОЗ від 16.12.2003 №584 з змінами, розділ II, пункт 6.	На момент моніторингового візиту достатньо. У складському приміщенні та у холодильній камері металеві стелажі, в кімнаті для видачі ліків – 1 шафа.	

Стр. 1 / 5

Picture 2. First page of filled-in checklist

During April-May 2021, Kreston’s auditors successfully conducted monitoring visits to all regional distribution centers across Ukraine. Monitoring visits included the following activities:

- inspection of locations used for storing the drugs and the tools and devices used while storage;
- analysis of the documentation related to accounting and control of relevant commodities; and
- interviewing the responsible employees of the facility.

During the monitoring visits, photos of the condition of physical premises, devices, and equipment, related documents, etc., were made to substantiate the conclusions recorded in the checklists. Photos were made only by having permission from the responsible persons.

List of all the inspected distribution centers within the respective health care facilities in included in Appendix 2, each Health Care Facility (HCF) has its number, which is used further in the report (for example HCF #43). The number of HCF and number of actually inspected warehouse facilities do not correspond as different HCF may store commodities in the same place. The results of the assessment of warehouses that belong to different health care facilities or different programs, but physically are in the same building, were recorded in one checklist, appear in the Report in such way HCF #17+44+67.

The schedule of visits was updated on a weekly basis, taking into consideration COVID-19 quarantine restrictions in Ukraine. Based on the schedule of visits CPH informed by official letter the heads of regional health care facilities and departments of health of regional state administrations about planned monitoring visits 3-6 days before such a visit.

Once visits were completed, Kreston submitted a report to SAFEMed summarizing findings and recommendations for improvement.

The results set out based on the analysis of the data obtained in accordance with the objectives of activity, taking into account the existing restrictions on access to information. Specific cases of non-provision of requested documents, explanations, access to premises, etc., as well as the impact of such restrictions on the results of monitoring visits are described in the relevant sections of the report.

Results of assessment rely on the information provided by the employees of health facilities in the form of oral or written explanations, without additional confirmation from independent or documentary sources. All data and information presented in the report are based on the data that were available to auditors as of the date of the visit to each warehouse. Any changes or adjustments made after that date may not have been taken into account. Lastly, the fact of advance notice about the visits should also be considered as a factor influenced to the assessment.

SUMMARY RESULTS

Summary results of assessments by regions, health care facilities and programs, criteria and sub-criteria are presented in this section. Only one of the warehouses visited (HCF #53) had no discrepancies. The total number of visited hospitals by the number of discrepancies (according to number of sub-criterion of check list) was distributed as follows at Figure 1.

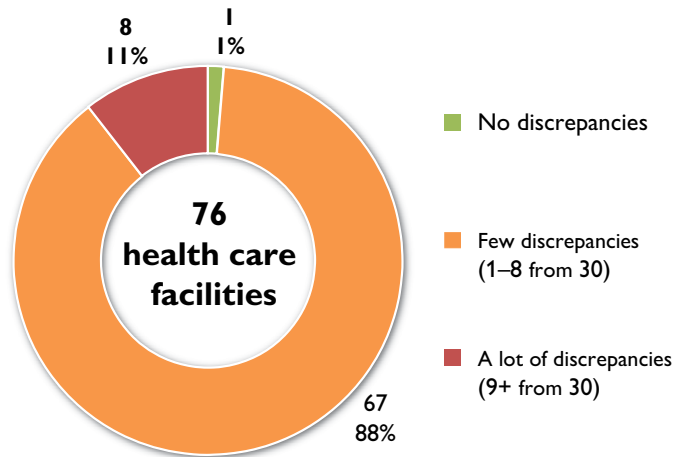


Figure 1. Groups of health care facilities by the number of discrepancies

All facilities storing HIV and Hepatitis commodities and all but one facility storing TB commodities had discrepancies. The number of discrepancies by programs (HIV, hepatitis, tuberculosis) is presented in Figure 2.

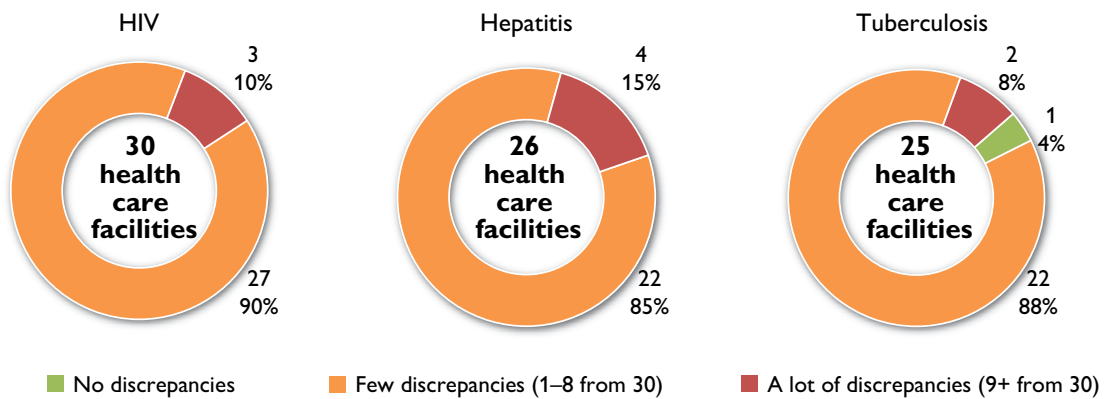


Figure 2. Groups of health care facilities by the number of discrepancies in terms of programs

No discrepancies were founded by one criterion “Control of potent and narcotic drugs”. The largest number of discrepancies (107 or 35% of the total) was recorded by the criterion “Safety”, the least number of discrepancies (1) - by the criterion “Computer and software”.

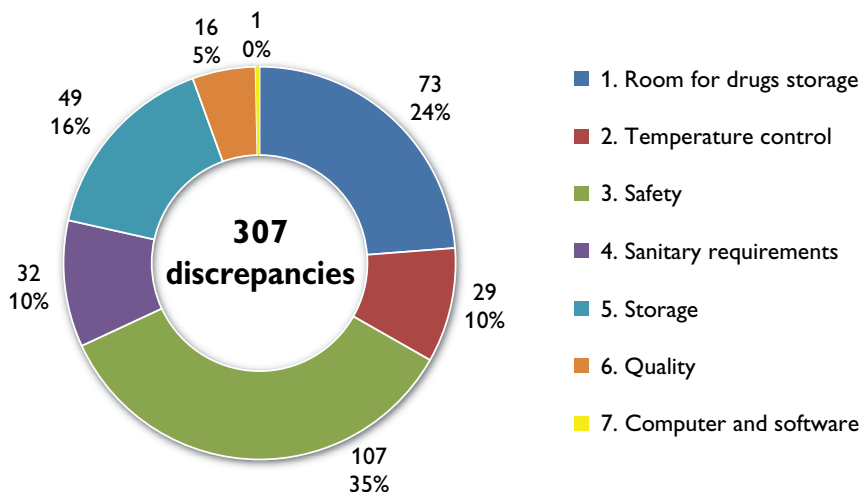


Figure 3. Distribution of comments by criteria

The distribution of all discovered discrepancies by programs and criteria is presented in Figure 4.

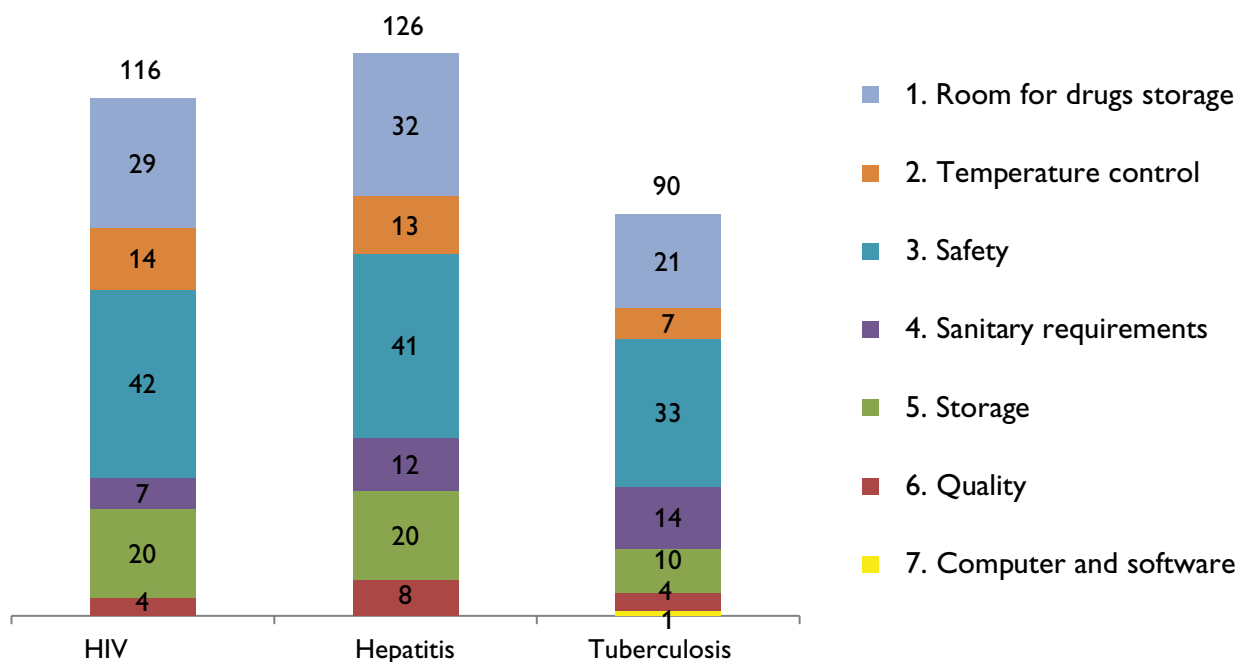


Figure 4. Distribution of discrepancies by criteria and program

The largest quantity of discrepancies was recorded in health care facilities of Rivne region (33 discrepancies per 3 hospitals monitored) and the city of Kyiv (28 discrepancies per 5 hospitals monitored).

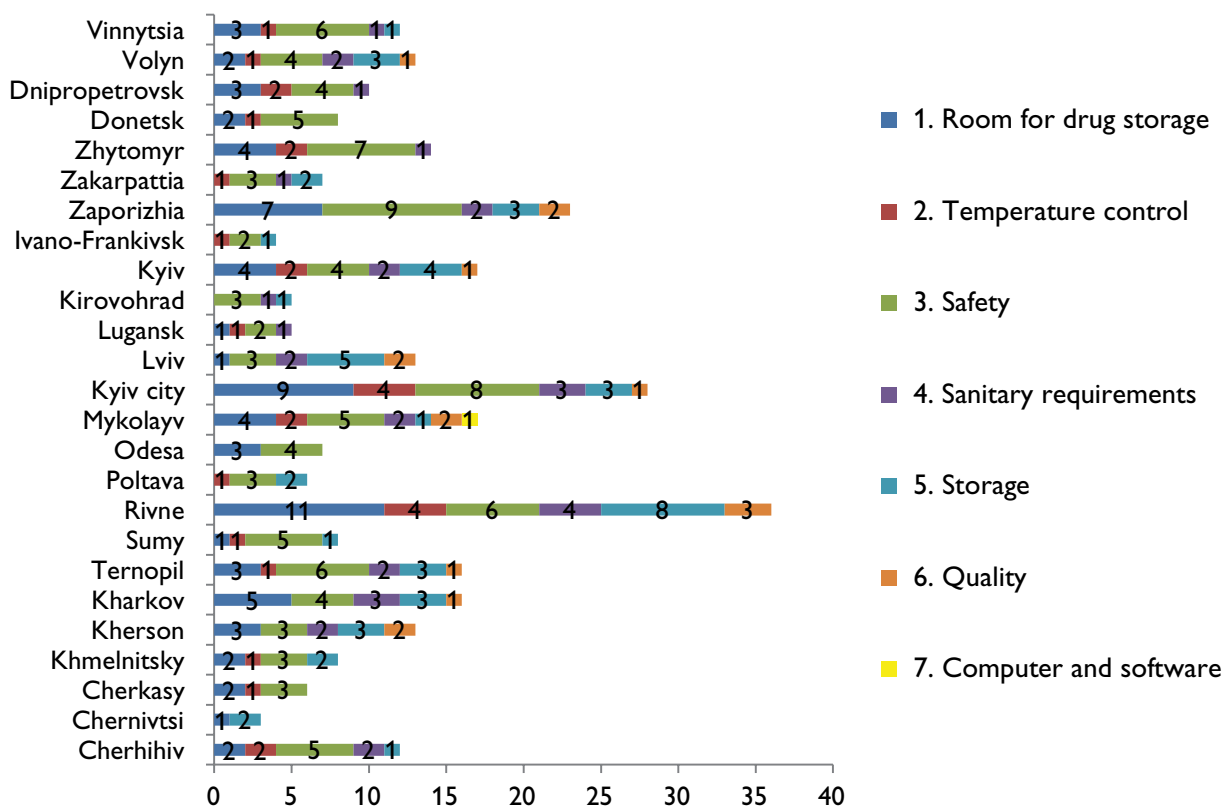


Figure 5. Distribution of discrepancies by criteria and region

Across the 12 PEPFAR priority regions, the largest quantity of discrepancies was observed in Kyiv city (28 discrepancies per 5 hospitals monitored) and Zaporizhia regions (23 discrepancies per 3 hospitals monitored). (Figure 6)

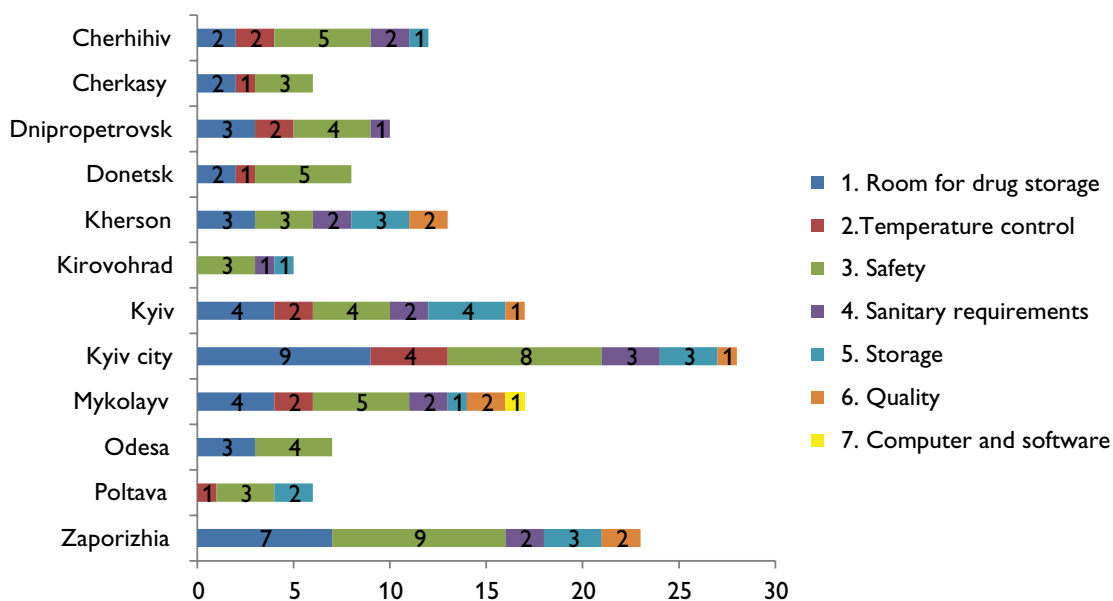


Figure 6. Distribution of discrepancies by criteria and PEPFAR region

Each criterion has subcriteria, in total the check list consists of 30 subcriteria. The largest number of discrepancies (57) was recorded by subcriterion 13, which included into the criterion “Safety”. No discrepancies were discovered by subcriterion 4, 18, 19, 24, 25, 26, 29 (refer to appendix 1 for the names of subcriteria).

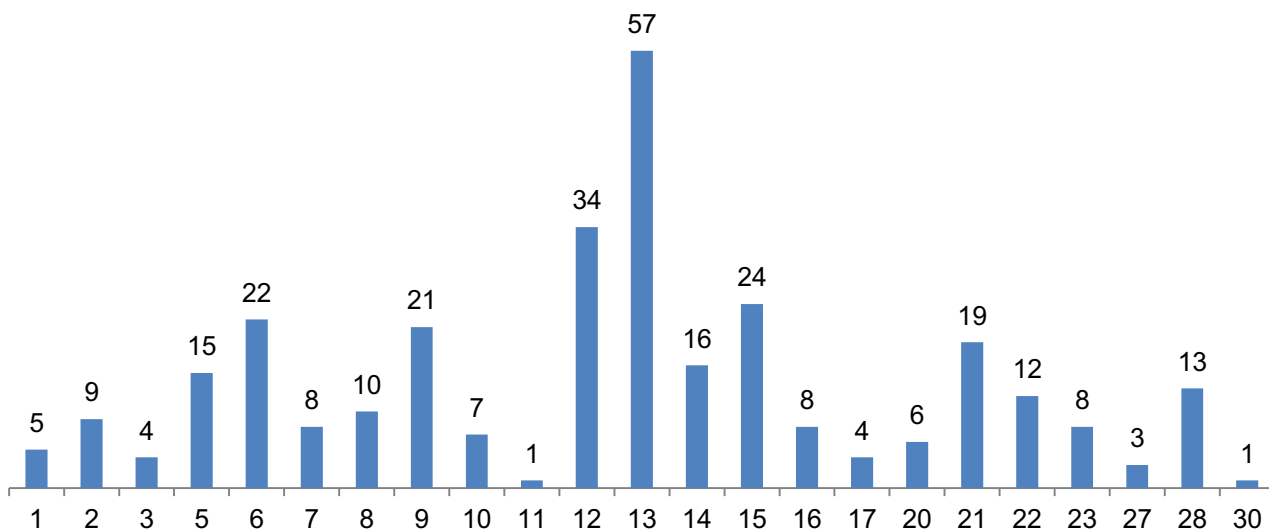


Figure 7. Distribution of discrepancies by subcriteria

WAREHOUSES CHARACTERISTICS

During the monitoring visits, the key parameters of the distribution centers for drugs storage were assessed, in particular:

- the total area of the warehouse premises (based on plans and/or passports of the relevant warehouse);
- total storage area;
- quantity of doors for loading/reception;
- ability to store on pallets; and
- total number of pallet space.

The total storage area was not documented in any of the hospitals visited. Storage on pallets was available in 71 warehouses, pallets were placed only on the floor (no pallet racks). The following table 1 presents the generalized parameters of the distribution centers, which were identified, as well as comments on the detected deviations.

#	Parameter	Value	Comments
1	The total area of the warehouse space	3–399 square meters	There is no documentary evidence HCF# 20, 25, 30, 38, 42, 43, 50, 54, 61, 66, 69, 73
2	Total storage area	—	There is no documentary evidence
3	Quantity of doors for loading/reception	1 for each room	—
4	Ability to store on pallets	Presented in 71 HCF	Missing in whole or in part in five HCF #25, 30, 65, 72, 79
5	Total number of pallet space	3–75 pallet spaces	On floor only

Table 1. Generalized parameters of the warehouses

DETAILED ASSESSMENT FINDINGS

This section summarizes the most significant and common violations for each item of the standard checklist, the total number and percentage of health care facilities with discrepancies to regulatory requirements and GSP, as well as references to specific HCF with particular discrepancies (Annex 2 contains the numbering of HCF).

CRITERION “ROOM FOR DRUGS STORAGE”

#	Subcriterion	Health care facilities with discrepancy
1	The area of storage facilities is sufficient and is determined by the quantity of drugs stored there, taking into account their toxicological, pharmacological groups and physicochemical properties.	5 6,6%

By this subcriterion, a discrepancy from the requirements of current regulations were found in 5 visited hospitals, the areas of storage facilities were insufficient, as a result:

- some drugs were stored in the corridor (HCF #17 + 44 + 67);
- warehouses are loaded to the maximum, racking equipment is not enough, as a result - free movement and access to the necessary drugs is difficult (HCF # 31, 46);
- medicines were located in a disorderly manner, access to certain surfaces, equipment and materials in warehouse was impossible (HCF # 60);
- according to the explanations of the responsible employees, when big volume of cargo intended for a significant period of use, is received at the same time, the available storage space becomes insufficient (HCF # 29).

HCF # 46



HCF # 46



HCF # 17+44+67



HCF # 69



#	Subcriterion	Health care facilities with discrepancy
2	The integrity of warehouses (the absence of leakage of roofs, pipelines, holes and breaches in doors, walls, other damages that affect the increase in humidity, dustiness and increase the risk of penetration into the premises of insects / rodents) and protection of drugs from fluctuations in air temperature.	9 11,8%

In 9 visited hospitals, the warehouses were in poor condition and in need of repair, in particular:

- marks on ceiling after leak, consequences of flooding (HCF# 20, 22, 24, 29, 38, 49, 69, 72);
- cracks and other damage on the walls (HCF# 24, 29, 38, 66);
- dirty, with breakthroughs on the floor (HCF# 38).

HCF # 29



HCF # 29



HCF # 38



HCF # 24



HCF # 49



HCF # 66



See also comments and photos to subcriteria 5 and 15.

#	Subcriterion	Health care facilities with discrepancy
3	Provision of warehouses with the necessary number of racks, cabinets, refrigerators, trays for storage of drugs.	4 5,3%

Four visited hospitals (HCF#17 + 44 + 67, 31, 46, 69) had an insufficient number of racks, cabinets and other storage equipment (also due to not enough space, see comments and photos to sub-criterion 1).

HCF # 31



HCF # 17+44+67



#	Subcriterion	Health care facilities with discrepancy
4	In case of the presence of thermolabile drugs in the warehouse, the total volume of refrigeration equipment is sufficient for the proper storage of such drugs.	0 0,0%

By this subcriterion no discrepancies to the current regulatory requirements were detected. Visited warehouses had sufficient refrigeration equipment, in particular, industrial and domestic refrigerators, refrigerator showcases, and a horizontal fridge camera were used. There were fridge rooms in two HCF.

#	Subcriterion	Health care facilities with discrepancy
5	Arrangement of surfaces and auxiliary equipment (wiring, etc.), covering the walls and ceiling of the premises for storing drugs allow for wet cleaning using detergents and disinfectants.	15 19,7%

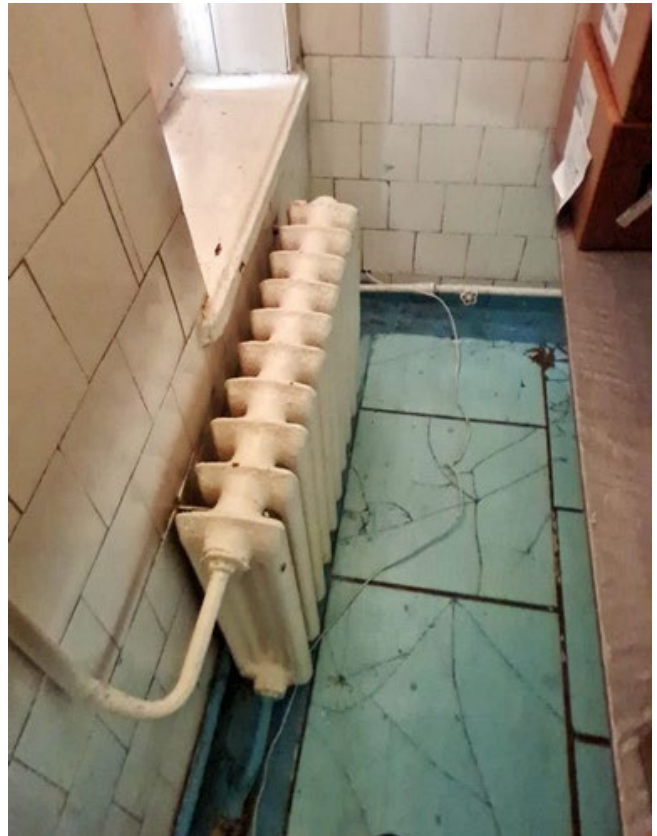
By this subcriterion, deviations were identified in fifteen HCF, in particular:

- wall and ceiling coverings (wallpaper, whitewash, chipboard) did not allow for wet cleaning with detergents and disinfectants (HCF# 1, 8, 12, 20, 29, 38, 43, 46, 48, 56, 61, 62, 66 , 69); in particular, in HCF# 12 office premises were temporarily adapted for storage;
- arrangement of surfaces and auxiliary equipment, in general, allows for wet cleaning with detergents and disinfectants, but such cleaning can be difficult due to peeling/cracks on painted surfaces (HCF# 20, 38);
- arrangement of electrical wiring and lighting makes it difficult to clean (HCF# 20, 43, 61, 62, 66, 69, 75);
- the floor covering is cracked and dirty (HCF# 20);
- drugs on pallets are located close to the walls in several tiers, thus proper cleaning is impossible (HCF# 38).

HCF # 20



HCF # 20

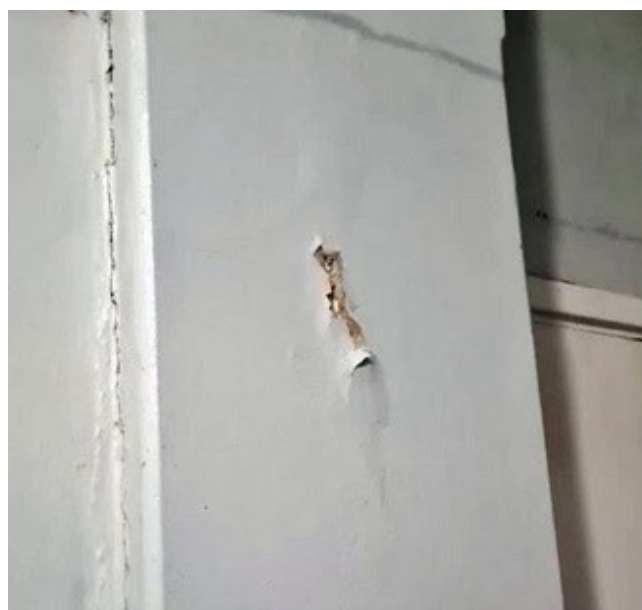


HCF # 38



HCF # 66



HCF # 62**HCF # 20**

In addition, the lack of storage space and the arrangement of separate storage areas (see subcriterion 1, 2) makes it difficult or impossible to access surfaces and equipment, as well as stored drugs, which are located in a disorderly manner. See also comments on sub-criterion 15.

#	Subcriterion	Health care facilities with discrepancy
6	The existing design of warehouses protects the drugs from direct sunlight. The lighting level allows safe handling with drugs and the ability to read markings.	22 28,9%

By this subcriterion discrepancies were detected in 22 hospitals, in particular:

- insufficient protection from the sun, the windows do not protect from direct sunlight (HCF# 18, 34, 59, 64, 76);
- protection of drugs from direct sunlight is provided in part, in particular, the windows are equipped with fabric/office vertical blinds, partially covered with a mirror film (“foil”) and fabric, etc. (HCF# 2, 5, 7, 10, 12, 15, 24, 28, 30, 43, 51, 52, 57, 71, 72, 74);
- pallets are placed too close to each other and in some places the opportunity to see the marking on the packaging is almost absent (HCF# 31).

HCF # 34



HCF # 59



HCF# 16, 22 show examples of best practice for protecting drugs from direct sunlight - the windows were equipped with sunshade.

#	Subcriterion	Health care facilities with discrepancy
7	There is a zone of loading/reception of drugs, which protects the drugs from the influence of weather conditions.	8 10,5%

In the eight hospitals visited (12, 29, 34, 36, 46, 49, 59, 61) the loading/reception area was not adequately (fully or partially) protected from the effects of weather phenomena.

#	Subcriterion	Health care facilities with discrepancy
8	Warehouses are equipped with exhaust ventilation of air to provide the necessary storage conditions, in the case when it is impossible - vents.	10 13,2%

In the nine hospitals visited (7, 25, 29, 38, 46, 56, 61, 70, 73) the warehouses were not equipped with exhaust ventilation or other means of ventilation, in particular, they were absent:

- air conditioners;
- exhaust ventilation;
- windows (or they did not open).

In addition, HCF# 49 was equipped with “natural” ventilation, which did not meet the requirements of current regulations - installed pipes for air inlet and outlet: one on the floor, the other under the ceiling.

HCF # 49



Instead, two hospitals identified examples of best practice in organizing ventilation. In particular, conditions for supply and exhaust ventilation were created in the premises of HCF# 48, an industrial air conditioner was installed at the entrance to the warehouse and in addition a domestic air conditioner was installed in the room. In HCF# 28 a supply and exhaust ventilation system with mechanical motivation was organized.

CRITERION “ TEMPERATURE CONTROL”

#	Subcriterion	Health care facilities with discrepancy
9	A measuring equipment (thermometers and hygrometers) must be provided at warehouses and refrigerators*, where medicines are stored	21 27,6%

According to this subcriterion, discrepancies were detected in 23 hospitals, in particular:

- verification and/or testing of equipment was not carried out, or documents confirming their implementation were not provided (HCF# 1, 8, 28, 29, 30, 31, 37, 43, 45, 46, 62, 77);
- deadlines for verification are overdue, the last verifications were dated 2019 (HCF# 11, 21, 58, 69, 74, 78 + 3);
- there are no passports for thermometers and hygrometers (HCF# 14, 62);
- there are no separate thermometers and hygrometers for measuring air parameters. In HCF# 1 the thermometers of the refrigerator were not shown (in the log with temperature fixation there are no name/position and signature of the executor, and also no signature of the authorized person for control), in HCF# 20 thermometers and hygrometers are absent (in room 2);
- although the last verification of thermometers and hygrometers in HCF# 48 was in the IV quarter 2020, the condition of the hygrometers is improper (rust, violation of the protective circuit).

HCF # 69

ПАСПОРТ на засіб виміральної техніки
Термометр медичний фармацевти

- Назва ЗВТ: *Термометр*
- Тип ЗВТ: *Вим-1*
- Заводський номер: *С.338*
- Діапазон вимірювань: *0 - 25 °C*
- Клас точності: _____
- Завод виробник: *ПАО «Смексвін»*
- Дата введення в експлуатацію: _____
- Дата випуску: *13.06.14р (побірка) кв. 2019*

РЕЗУЛЬТАТИ ПОВІРКИ

Дата повірки	Висновки	Дата повірки	Висновки
<i>14.05.13</i>	<i>придатний</i>		
<i>11.04.14р</i>	<i>придатний</i>		
<i>14.04.14р</i>	<i>придатний</i>		
<i>05.03.2018р</i>	<i>придатний</i>		
<i>27.03.13</i>	<i>придатний</i>		

HCF # 78

ПАСПОРТ НА СРЕДСТВО ИЗМЕРИТЕЛЬНОЙ ТЕХНИКИ
 Наименование предприятия: *КП «ВОЛСІТ БЗФачі Вал»* Наименование СИТ: *Термометр «Смексвін»*

Заводской номер	Тип	Диапазон измерения	Класс точности, разряд, допуст. погреш.
<i>№ 8464312</i>	<i>ТС-7 М1</i>	<i>1-20 + 20</i>	

РЕЗУЛЬТАТЫ ПОВЕРКИ

Дата	Заключение (годен-негоден)	Оттиск клейма поверителя	Дата	Заключение (годен-негоден)	Оттиск клейма поверителя
<i>18.12.19</i>	<i>годен</i>	<i>(Signature)</i>			

Дата составления паспорта « 03 » 12 2019 г.

ПАСПОРТ НА СРЕДСТВО ИЗМЕРИТЕЛЬНОЙ ТЕХНИКИ
 Наименование предприятия: *КП «ВОЛСІТ БЗФачі Вал»* Наименование СИТ: *Термометр «Смексвін»*

Заводской номер	Тип	Диапазон измерения	Класс точности, разряд, допуст. погреш.
<i>№ 18455</i>	<i>Т.Р. 7 М1</i>	<i>1-20 + 20</i>	

РЕЗУЛЬТАТЫ ПОВЕРКИ

Дата	Заключение (годен-негоден)	Оттиск клейма поверителя	Дата	Заключение (годен-негоден)	Оттиск клейма поверителя
<i>18.12.19</i>	<i>годен</i>	<i>(Signature)</i>			

Instead, HCF# 16 identified an example of best practice for thermometers and hygrometers provision - a digital logger was used.

#	Subcriterion	Health care facilities with discrepancy
10	A log or a card for recording the temperature and relative humidity of the air is present in the warehouse, the actual indicators are entered daily. Records of temperature and relative humidity are regularly checked by the authorized person.	7 9,2%

Deviations to this subcriterion were found in seven visited hospitals, in particular:

- logs of temperature and/or relative humidity are missing or have not been shown (HCF# 28, 62, 66), in particular, in HCF# 62 logs of relative humidity are not kept due to the lack of hygrometers;
- for refrigerators, where there are 2 thermometers, only one temperature value is recorded (HCF# 29, 36);
- records of temperature and relative humidity are checked by an authorized person irregularly (HCF# 69);
- logs are kept, but according to the log, the temperature in the lower segment of the refrigerator was +9...+10°C, i.e., exceeded the set temperature limit (+2...+8°C), specified in the instructions of the drug (HCF# 57).

HCF # 57

Хімія

Дата	№ холодильника	Час зняття показників	Температура повітря		Відповідальна особа
			верх	низ	
01.04.21		9 ⁰⁰ -16 ⁰⁰	4c°-5c°	9c°-10c°	<i>Вmf</i>
02.04.21		9 ⁰⁰ -16 ⁰⁰	4c°-5c°	9c°-10c°	<i>Вmf</i>
03.04.21		—			
04.04.21		—			
05.04.21		9 ⁰⁰ -16 ⁰⁰	4c°-5c°	9c°-10c°	<i>Вmf</i>
06.04.21		9 ⁰⁰ -16 ⁰⁰	4c°-5c°	9c°-10c°	
07.04.21		9 ⁰⁰ -16 ⁰⁰	4c°-5c°	9c°-10c°	
08.04.21		9 ⁰⁰ -16 ⁰⁰	4c°-5c°	9c°-10c°	
09.04.21		9 ⁰⁰ -16 ⁰⁰	4c°-5c°	9c°-10c°	
10.04.21		—			
11.04.21		—			
12.04.21		9 ⁰⁰ -16 ⁰⁰	4c°	9c°	

#	Subcriterion	Health care facilities with discrepancy
11	Medicines that required storage at a controlled temperature should be transported under the same conditions using appropriately adapted technical means. Obtaining medicines that require the “cold chain” should be confirmed by acceptance certificate and transfer, accompanying documents with the records of storage conditions during transportation shall be received and stored.	1 1,3%

There were no acts of acceptance-transfer in HCF# 79 (warehouse 2).

CRITERION “SAFETY”

#	Subcriterion	Health care facilities with discrepancy
12	Room for drugs storage is equipped with security and fire-fighting means (fire extinguishers, fire detectors, etc.) in working condition.	34 44,7%

34 of the visited hospitals had discrepancies by this sub-criterion, in particular:

- storage facilities (fully or partially) were not equipped with fire alarm, or it was obsolete/inoperable (HCF# 2, 7, 10, 11, 12, 25, 29, 30, 32, 33, 38, 43, 46, 48, 49, 59, 61, 62, 69, 70, 71, 72, 76); however, almost all warehouses were equipped with at least fire extinguishers;
- warehouses (fully or partially) were not equipped with burglar alarms, or it was obsolete/inoperable (HCF# 1, 2, 8, 11, 14, 17 + 44 + 67, 21, 23, 25, 29, 31, 32, 33, 38, 43, 45, 46, 49, 51, 54, 56, 59, 62, 70).

#	Subcriterion	Health care facilities with discrepancy
13	The design of warehouses is durable and provides protection against unauthorized penetration (durable reinforced doors, locks, grids, etc.). The windows of the first floor are closed (if any).	57 75,0%

Two thirds of the analyzed HCF had the following discrepancies from the requirements listed in this subcriterion:

- there are no bars on the doors (HCF# 1, 4, 5, 6, 9, 13, 15, 19, 20, 21, 24, 26, 29, 31, 33, 35, 37, 41, 42, 47, 50, 52, 55, 57, 59, 60, 63, 65, 68, 70, 72, 73, 74, 76, 77, 78 + 3);
- there are no bars on the windows (HCF# 1, 4, 24, 29, 37, 72);
- wooden doors were used (HCF# 8, 9, 10, 12, 21, 25, 30, 31, 32, 33, 38, 46, 47, 48, 56, 61, 62, 64, 65, 66, 69, 70, 71);
- plastic doors were used (HCF# 7, 17 + 44 + 67, 18, 20, 22, 36, 37, 46, 57, 60, 71);
- locks were installed only in the front door (HCF# 7).

HCF # 38



HCF # 66



#	Subcriterion	Health care facilities with discrepancy
14	Warehouse zones are not used as pass-through areas for unauthorized personnel. Measures for controlled access to the warehouse are determined and taken.	16 21,1%

In 14 visited hospitals (HCF# 7, 10, 16, 18, 30, 36, 38, 39, 43, 48, 54, 61, 66, 69) controlled access to warehouses was provided, but the relevant documents on its implementation were not provided. In one case (HCF# 76) the warehouse premises were publicly available, measures for controlled access to the warehouse premises were not defined (see photo below).

HCF # 76



Also, an approved list of staff authorized for access to the premises was not provided in HCF# 59.

CRITERION “SANITARY REQUIREMENTS”

#	Subcriterion	Health care facilities with discrepancy
15	The premises are clean and in good sanitary condition. In the room for storage of drugs the floor is cleaned in a wet way with the use of detergents and disinfectants - at least once a day, general cleaning of walls and equipment at least once a month.	24 31,6%

Discrepancies by subcriterion were found in 24 visited hospitals, in particular:

- the premises were in improper sanitary condition - dirty surfaces, covered with dust, etc. (HCF# 22, 38, 46, 48, 49, 62, 66, 69);
- the premises were partially in a state of disrepair, in need of repair (HCF# 20 - general warehouse, 38, 43); see also comments on subcriterion 5;
- covering of walls and ceilings (wallpaper, whitewashing), as well as in some places the installation of electrical wiring, did not allow for wet cleaning with detergents and disinfectants (HCF# 29, 61, 62); see also comments on subcriterion 5;
- cleaning schedule and/or cleaning protocols, logs of current and general cleaning were not provided (HCF# 1, 28, 29, 30, 33, 36, 43, 46, 48, 50, 54, 57, 62, 63, 65, 66, 69, 72, 73).

HCF # 46



HCF # 66



HCF # 46



HCF # 62



#	Subcriterion	Health care facilities with discrepancy
16	Marked cleaning equipment is stored in specially designated places and kept clean.	8 10,5%

In the eight hospitals visited (HCF# 31, 34, 37, 42, 46, 49, 62, 64) the cleaning equipment was not fully or partially marked.

HCF # 34



HCF # 37



In addition, HCF# 62 had no designated place for storage of inventory.

CRITERION “STORAGE”

#	Subcriterion	Health care facilities with discrepancy
17	Drugs are stored separately by pharmacological groups depending on the route of administration, taking into account the physicochemical properties of drugs and in accordance with the requirements specified in the instructions for medical use.	4 5,3%

In some cases (HCF# 46, 57, 62, 69) ensuring the storage of drugs separately by pharmacological groups was impossible due to insufficient storage space and/or shortcomings in the organization of storage methods. See more comments on subcriteria 1, 22.

#	Subcriterion	Health care facilities with discrepancy
18	Dangerous and other harmful materials, food products, foreign objects, etc. (except drugs) are stored separately from pharmaceutical products.	0 0,0%

By this subcriterion, no discrepancies to the current regulatory requirements were detected.

#	Subcriterion	Health care facilities with discrepancy
19	Medicines are located on racks, in cabinets or refrigerators, and if necessary — on pallets; poisonous drugs are stored in a locked metal cabinet. Medicines purchased at budget funds are stored on a separate shelf/cabinet, with appropriate labeling.	0 0,0%

By this subcriterion, no discrepancies to the current regulatory requirements were detected.

#	Subcriterion	Health care facilities with discrepancy
20	Drugs are located at a sufficient distance from heating devices / air conditioners (effect on the physical and chemical properties of drugs is excluded).	6 7,9%

Placement of drugs at an insufficient distance from the heaters were recorded in the six HCFs visited (23, 25, 31, 42, 46, 79) (see also the photo of HCF# 46 to subcriterion 15).

HCF # 23



HCF # 42



#	Subcriterion	Health care facilities with discrepancy
21	Warehouses have a separate clearly designated quarantine zone for drugs, marked "QUARANTINE".	19 25,0%

In the 19 hospitals visited, the warehouses did not have a separate, clearly defined quarantine zone for drugs (HCF# 9, 10, 11, 13, 19, 20, 21, 22, 24, 28, 30, 37, 49, 61, 62, 65, 66, 68, 75). In some cases, according to the explanations of the responsible persons, the quarantine zone is allocated and marked only when necessary (HCF# 9, 13, 19, 21, 24, 37, 65, 68, 75). In other cases, the responsible employees noted that the need for such an area has not arisen for at least the last 2-3 years (HCF# 10, 20, 61, 66), according to the explanations of the head nurse of HCF# 22, all drugs are controlled upon delivery, in case of non-compliance - returned immediately to supplier. In addition, there were third-party safe boxes in the HCF# 62 in the unmarked area, which was declared to us as quarantine, (see photo below).

HCF # 62



#	Subcriterion	Health care facilities with discrepancy
22	Medicines of the same name and dosage are placed taking into account the remaining shelf life in such a way as to ensure the priority use of medicines with a shorter shelf life.	12 15,8%

By this subcriterion, a discrepancy from the requirements of current regulations were found in 12 visited hospitals, namely:

- the requirements of the subcriterion were not met or confirmation of its fulfillment was not provided (HCF# 12, 20, 22, 31, 40, 42, 57, 73), in particular, in some cases it is impossible to organize such an arrangement due to the characteristics of warehouses (HCF#12, 31, 40);
- the requirements of the subcriterion were partially met (HCF# 32, 38, 69, 76), in particular, drugs are sometimes located close to the wall in several tiers.

See also comments and photos to sub-criteria 1, 23.

#	Subcriterion	Health care facilities with discrepancy
23	The FEFO (first expired first out) principle is clearly observed during storage and shipment.	8 10,5%

In the seven hospitals visited (HCF# 20, 22, 42, 57, 65, 72, 73) confirmation of compliance with the requirements of this sub-criterion was not received. In particular:

- in the provided documents and reports only the fixation of balances was reflected, there was no information on the movement of drugs according to the FEFO principle (HCF# 42, 57, 72, 73);
- according to the explanations of the responsible employees, special software is used for accounting according to the FEFO principle, but its work has not been demonstrated (HCF# 22);
- employees of HCF# 20 demonstrated accounting registers in MS Excel software; these registers do not allow tracking the movement of the drug by batch number and/or expiration date.

In addition, HCF# 69 violated the requirements of this subcriterion in terms of storage organization (see comments on sub-criteria 17, 22).

#	Subcriterion	Health care facilities with discrepancy
24	Transfer, transfusion into another container, packaging or entertaining of medicines, replacement of labels in health facility is prohibited (on all open packages of drugs the date of their opening is indicated, it is forbidden to cut blisters)	0 0,0%

By this subcriterion, no discrepancies to the current regulatory requirements were detected.

#	Subcriterion	Health care facilities with discrepancy
25	When shipped drugs that require special storage conditions (controlled temperature, “cold chain”) proper packaging in thermal bags is ensured, taking into account the type of vehicle. Thermal bags, refrigerants are available in the warehouse.	0 0,0%

By this subcriterion, no discrepancies to the current regulatory requirements were detected.

CRITERION “CONTROL OF POTENT AND NARCOTIC DRUGS”

#	Subcriterion	Health care facilities with discrepancy
26	Conditions for storage and use of pots, narcotic drugs and precursors shall comply with the requirements of the legislation of Ukraine	0 0,0%

By this subcriterion, no discrepancies to the current regulatory requirements were detected.

CRITERION “QUALITY”

#	Subcriterion	Health care facilities with discrepancy
27	Drugs with doubts about the quality or expired, removed and placed in “Quarantine” with the designation “Application is prohibited to an appropriate order” with indication of name of drug, quantity, reasons for withdrawal from circulation and the date of movement. The journal of records of orders / decisions / prescriptions from the State Service of Ukraine on Medicines and Drugs Control is available and of proper maintenance.	3 3,9%

HCF# 46 did not keep a log of orders/decisions/prescriptions from the State Service of Ukraine for Medicines and Drug Control. In two other hospitals (HCF# 30, 62) the responsible employees assured that this log is kept, but could not provide it for acquaintance.

#	Subcriterion	Health care facilities with discrepancy
28	There is a system for tracking the shelf life of drugs.	13 17,1%

13 analyzed HCF had deviations according to this subcriterion, namely:

- the expiration date tracking system was not demonstrated (HCF# 20, 22, 42, 57, 65, 73);
- the system operates using paper media that do not provide reliable control (HCF# 38, 43, 61, 66, 69);
- the implemented software does not work properly (HCF# 24, 72), see comments on sub-criterion 23.

#	Subcriterion	Health care facilities with discrepancy
29	Disposal is carried out in accordance with the current legislation.	0 0,0%

By this subcriterion, no discrepancies to the current regulatory requirements were detected.

CRITERION “COMPUTER AND SOFTWARE”

#	Subcriterion	Health care facilities with discrepancy
30	The presence of computer equipment with access to the Internet and software for working on the Internet.	1 1,3%

HCF# 43 does not have computer equipment with Internet access and appropriate software.

CONCLUSIONS AND RECOMMENDATIONS

Regional warehouses for storing medicines for HIV/AIDS, TB, and viral hepatitis treatment are organized and operate in the structure of the respective health care facilities. Due to lack of appropriate warehousing space, most HCFs were forced to adapt available premises to serve as a location for the storage of medicines aimed for further distribution through the regions.

According to the results of monitoring visits, was found that 8 HCF (11% from 76 HCF) had a significant number of discrepancies (9+ from 30), 67 HCF (88% from 76 HCF) had few discrepancies (1-8 from 30) and only one HCF had no discrepancies to the requirements of current legislation. Mostly discrepancies were as follows:

1. Some warehouses were not adapted for drug storage and were sometimes overloaded (did not correspond to the volume of goods). As a result, it was impossible to meet certain regulatory requirements:
 - organization of proper ventilation of all premises;
 - location of drugs by forms and methods of application, expiration date for compliance with the FEFO principle;
 - ensuring accessibility to all areas of the warehouse, including for cleaning purpose; and
 - ensuring sufficient distance from heating appliances.
2. Arrangement of surfaces and auxiliary equipment (wiring, etc.), covering of walls and ceilings of adapted premises for drug storage did not meet the established requirements. As a result, such warehouses could not be fully cleaned using detergents and disinfectants.
3. Due to limited funding, hospitals were forced to adapt to the use of obsolete and worn-out equipment in warehouses, the suitability of which was in doubt (household refrigerators, obsolete hygrometers, etc.).
4. The systems for tracking the shelf life of drugs during storage and shipment according to the FEFO principle were imperfect. Monitoring visits showed that almost every HCF tried to adapt the usual methods that were effective for small volumes of goods, but not for drugs intended for further distribution through the region. As a result, a significant part of the employees keeps records of stocks and try to track their circulation “manually” - in logs, on sheets, boards, etc., even having technical means. In other cases, existing software is used (usually accounting software “1C: Enterprise”, or MS Excel spreadsheet), which is not adapted for accounting of the warehouses in compliance with the principle of FEFO.

During the monitoring visits and interviewing the responsible employees was concluded that the staff of the warehouses of the HCFs is not sufficiently aware of the requirements of the GSP, although its compliance is necessary for the proper performance of the functions of warehouses for storing medicines for HIV/AIDS, TB, and viral hepatitis treatment. According to comments from staff, most hospitals have limited financial resources thus, presumably, not able to spend them on staff development in adequate amounts. This may lead to a decrease in their professional level and, in the medium term, negatively affect the quality of stored drugs.

According to the results of the analysis, the following recommendations are provided. These recommendations can be addressed both to the PHC itself and to public authorities responsible for the formulation and implementation of health policy, in accordance with their competencies and powers:

1. To oblige the managers of the HCF to eliminate the discrepancies recorded in the relevant checklists. Facilitate organizationally and consultatively.
2. Facilitate the proper financing of HCFs in terms of organization, reconstruction, proper maintenance of existing drug storage areas and the creation of an appropriate system for monitoring the circulation of drugs with the use of software capabilities.
3. To organize comprehensive trainings for warehouse employees on the topic “Organization of the warehousing of the health care facility in accordance with the current regulatory requirements of Ukraine” using the results of monitoring visits as practical cases. The training can be organized both in the format of a workshop and in the format of a webinar, with the provision of training materials to participants. Such materials should be used to organize the proper implementation of procedures for drug storing in accordance with Ukrainian legislation and GSP.

APPENDIX 1. CHECKLIST

CHECKLIST FOR ASSESSING THE COMPLIANCE OF WAREHOUSES FOR STORAGE OF MEDICINES WITH THE REQUIREMENTS OF CURRENT LEGISLATION

Health care facility name:

Health care facility address:

Date of assessment:

Visit carried out by (full name, position):

in presence of (full name, position):

Technical characteristics of the warehouse

- 1 The total area of the warehouse space (square meters) (according to the documents)
- 2 Total storage area (square meters) (according to documents)
- 3 Quantity of doors for loading / reception
- 4 Ability to store on pallets
- 5 Total number of pallet space (shelves and floors)

Критерій	№	Subcriteria	Normative documents	Comments
Room for drugs storage	1	The area of storage facilities is sufficient and is determined by the quantity of drugs stored there, taking into account their toxicological, pharmacological groups and physicochemical properties.	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 2, p. 1	
Room for drugs storage	2	The integrity of warehouses (the absence of leakage of roofs, pipelines, holes and breaches in doors, walls, other damages that affect the increase in humidity, dustiness and increase the risk of penetration into the premises of insects / rodents) and protection of drugs from fluctuations in air temperature.	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 2, p. 3	
Room for drugs storage	3	Provision of warehouses with the necessary number of racks, cabinets, refrigerators, trays for storage of drugs.	Good storage practice ¹ , Order of the Ministry of Health of December 16, 2003 No. 584 as amended, Section 2, p. 6 (Instruction ST-N MOH 42-5.1:2011 Medicines. Good storage practice” – Order of the Ministry of Health of Ukraine dd. 03.10.2011 № 634)	
Room for drugs storage	4	In case of the presence of thermolabile drugs in the warehouse, the total volume of refrigeration equipment is sufficient for the proper storage of such drugs.	Good storage practice, Order of the Ministry of Health of December 16, 2003 No. 584 as amended, Section 2, p. 6	
Room for drugs storage	5	Arrangement of surfaces and auxiliary equipment (wiring, etc.), covering the walls and ceiling of the premises for storing drugs allow for wet cleaning using detergents and disinfectants.	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 2, p. 7	

¹ “Guidelines ST-N MOH 42-5.1: 2011 Medicines. Good storage practice”- order of the Ministry of Health of 03.10.2011 No 634. <https://www.dls.gov.ua/wp-content/uploads/2019/02/%D0%9D%D0%B0%D1%81%D1%82%D0%B0%D0%BD%D0%BE%D0%B2%D0%B0-%D0%9B%D0%97%D0%9D%D0%9F%D0%97.pdf>

Критерій	№	Subcriteria	Normative documents	Comments
Room for drugs storage	6	The existing design of warehouses protects the drugs from direct sunlight. The lighting level allows safe handling with drugs and the ability to read markings.	Good storage practices	
Room for drugs storage	7	There is a zone of reception / shipment of drugs, which protects the drugs from the influence of weather conditions	Good storage practices	
Room for drugs storage	8	Warehouses are equipped with exhaust ventilation of air to provide the necessary storage conditions, in the case when it is impossible - vents.	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 2, p. 5	
Temperature control	9	<p>A measuring equipment (thermometers and hygrometers) must be provided at warehouses and refrigerators*, where medicines are stored</p> <p>All the measuring equipment is serviceable and regular metrological verification is carried out, in particular, should be available:</p> <ul style="list-style-type: none"> • passports for thermometers and hygrometers (the number in the passport and on the measuring device corresponds); • schedule of measuring equipment verification in health facility; • certificates of verification of devices and acceptance certificate performed, confirming the verification. <p><i>*In case of presence of a refrigeration room, its annual testing is carried out, confirmed by the acceptance certificate performed.</i></p>	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 2, p. 4	
Temperature control	10	<p>A journal or a card for recording the temperature and relative humidity of the air is present in the warehouse, the actual indicators are entered daily:</p> <ul style="list-style-type: none"> • temperature and relative humidity in the premises; • temperature in each unit of refrigeration equipment (from each thermometer used for the equipment). <p>Records of temperature and relative humidity are regularly checked by the authorized person.</p>	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 2, p. 4	
Temperature control	11	Medicines that required storage at a controlled temperature should be transported under the same conditions using appropriately adapted technical means. Obtaining medicines that require the “cold chain” should be confirmed by acceptance certificate and transfer, accompanying documents with the records of storage conditions during transportation shall be received and stored.	Good storage practices	
Safety	12	Room for drugs storage is equipped with security and fire-fighting means (fire extinguishers, fire detectors, etc.) in working condition.	Order of the Ministry of Health of December 16, 2003 No 584 as amended, Section 2, part 2	

Критерій	№	Subcriteria	Normative documents	Comments
Safety	13	The design of warehouses is durable and provides protection against unauthorized penetration (durable reinforced doors, locks, grids, etc.). The windows of the first floor are closed (if any).	Good storage practices	
Safety	14	Warehouse zones are not used as pass-through areas for unauthorized personnel. Measures for controlled access to the warehouse are determined and taken.	Good storage practices	
Sanitary requirements	15	The premises are clean and in proper sanitary condition. In the room for drug storage the following actions are carried out: <ul style="list-style-type: none"> • cleaning the floor in a wet way using detergents and disinfectants — at least 1 time per day; • general cleaning of walls and equipment (racks, shelves, etc.) — at least 1 time per month. 	Good storage practice, order of the Ministry of Health of December 16, 2003 No. 584 as amended, Section 2, p. 7; Order of the Ministry of Health of Ukraine dd. 15.05.2006 No 275	
Sanitary requirements	16	Marked cleaning equipment is stored in specially designated places and kept clean.	Good storage practice, order of the Ministry of Health of Ukraine dd. 15.05.2006 No 275	
Storage	17	Drugs are stored separately according to pharmacological groups depending on the route of administration, taking into account the physical and chemical properties of drugs and in accordance with the requirements specified in the instructions on medical use.	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 3, p. 1	
Storage	18	Dangerous and other harmful materials, food products, foreign objects, etc. (except drugs) are stored separately from pharmaceutical products.	Good storage practices	
Storage	19	Medicines are located on racks, in cabinets or refrigerators, and if necessary — on pallets; poisonous drugs are stored in a locked metal cabinet. Medicines purchased at budget funds are stored on a separate shelf/cabinet, with appropriate labeling.	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 3, p. 3	
Storage	20	Drugs are located at a sufficient distance from heating devices / air conditioners (effect on the physical and chemical properties of drugs is excluded).	Good storage practices	
Storage	21	Warehouses have a separate clearly designated quarantine zone for drugs, marked “QUARANTINE”.	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 3, p. 8	
Storage	22	Medicines of the same name and dosage are placed taking into account the remaining shelf life in such a way as to ensure the priority use of medicines with a shorter shelf life.	Order of the Ministry of Health of December 16, 2003 No 584 as amended, Section 3, p. 4	
Storage	23	The FEFO (first expired first out) principle is clearly observed during storage and shipment.	Order of the Ministry of Health of December 16, 2003 No 584 as amended, Section 3, p. 4	

Критерій	№	Subcriteria	Normative documents	Comments
Storage	24	Transfer, transfusion into another container, packaging or entertaining of medicines, replacement of labels in health facility is prohibited (on all open packages of drugs the date of their opening is indicated, it is forbidden to cut blisters)	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 3, p. 6	
Storage	25	When shipped drugs that require special storage conditions (controlled temperature, “cold chain”) proper packaging in thermal bags is ensured, taking into account the type of vehicle. Thermal bags, refrigerants are available in the warehouse.	Good storage practices	
Control of pots and narcotic drugs	26	Conditions for storage and use of pots, narcotic drugs and precursors shall comply with the requirements of the legislation of Ukraine	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 3, p. 2	
Quality	27	Drugs with doubts about the quality or expired, removed and placed in “Quarantine” with the designation “Application is prohibited to an appropriate order” with indication of name of drug, quantity, reasons for withdrawal from circulation and the date of movement. The journal of records of orders / decisions / prescriptions from the State Service of Ukraine on Medicines and Drugs Control is available and of proper maintenance.	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section V, p. 2.2, 2.3, p. 3, abstract. 4 (regarding Appendix 2 to the order)	
Quality	28	There is a system for tracking the shelf life of drugs.	Good storage practices	
Quality	29	Disposal is carried out in accordance with the current legislation.	Order of the Ministry of Health of 16.12.2003 No 584 as amended, Section 3, p. 10 , Order of the Ministry of Health of 24.04.2015 No 242	
Computer and software	30	The presence of computer equipment with access to the Internet and software for working on the Internet.	Good storage practices	

APPENDIX 2. LIST OF HEALTH CARE FACILITIES COVERED BY MONITORING VISITS

Program	Region	#	Full name of the health care facility	Actual address
HIV/AIDS	Vinnitsia	1	Non-profit municipal enterprise (NME) “Vinnitsia Regional Clinical Aids Center”	Vinnitsa district, berezina village
HIV/AIDS	Volyn	2	NME “Volyn Regional Infectious Diseases Hospital “Structural unit” center for prevention and control of AIDS”	Lutsk, str. Voli, 1A
HIV/AIDS	Dnipropetrovsk	4	NME “City clinical hospital No 21 named after Prof. E.G. Popkov» of Dnipropetrovsk City Council	Dnipro, str. Rope, 17
HIV/AIDS	Dnipropetrovsk	5	NME “Kryvyi Rih AIDS Center” of Dnipropetrovsk Regional Council	Kryvyi Rih, str. Nikopol highway, 4-g
HIV/AIDS	Donetsk	6	NME “Donetsk regional center for prevention and control of AIDS”	Raihorodok village, str. Kuybysheva, 2-G
HIV/AIDS	Donetsk	7	NME “Mariupol city hospital No 4 named after Matsuk	Mariupol, str. Pashkovsky, 4
HIV/AIDS	Zhytomyr	8	NME “Regional medical specialized center” of Zhytomyr regional Council	Zhytomyr, str. Pokrovska, 28
HIV/AIDS	Zakarpattia	9	NME “Transcarpathian regional center of public health”	Uzhhorod, str. Second, 72
HIV/AIDS	Zaporizhia	10	NME “Regional infectious clinical hospital” of Zaporizhzhya regional Council	Zaporizhzhya, str. Dobrolyubova, 23
HIV/AIDS	Ivano-Frankivsk	11	NME “Ivano-Frankivsk Regional Clinical Infectious Diseases Hospital of Ivano-Frankivsk Regional Council”	Ivano-Frankivsk, str. Hetman Sagaidachnogo, 66
HIV/AIDS	Kyiv	12	NME “Kyiv regional center of public health” of the Kiev regional Council	Kyiv, str. Baggovutivska, 1 room № 332
HIV/AIDS	Kirovohrad	13	NME “Kirovohrad regional center for prevention and control of AIDS of Kirovohrad regional Council	Kropyvnytskyi, str. Komarova, 1
HIV/AIDS	Lugansk	14	NME «Lugansk regional medical center of socially dangerous infectious diseases» of Lugansk regional Council	Severodonetsk, str. Smetanina, 5
HIV/AIDS	Lviv	15	NME “Lviv regional center of public health” of Lviv regional Council	Lviv, str. Lysenko, 45
HIV/AIDS	Mykolayiv	16	“Mykolayiv Regional Center for Palliative Care and Integrated Services” of Mykolayiv Regional Council	Nikolaev, str. PotemkinSkaya, 138-B

Program	Region	#	Full name of the health care facility	Actual address
HIV/AIDS	Odesa	17	NME “Odesa regional center of socially significant diseases” of the Odesa regional Council	Odesa, str. Sergiy Yadov, 4
HIV/AIDS	Odesa	18	NME “Center for HIV/AIDS prevention” of Odesa city Council	Odesa, str. Mechnikov, 132/7
HIV/AIDS	Poltava	19	NME “Regional center for HIV/AIDS prevention and control” of Poltava regional Council	Poltava, str. Hospital, 5
HIV/AIDS	Rivne	20	NME “Regional center of public health” of Rivne regional Council	Rivne, str. Joliot Curie, 19
HIV/AIDS	Sumy	21	NME “Regional clinical medical center of socially dangerous diseases” of Sumy regional Council	Sumy, str. Bilopilsky Way, 22
HIV/AIDS	Ternopil	22	NME “Ternopil regional medical center of social and dangerous diseases” of Ternopil regional Council	Ternopil, str. Kupchinsky, 14
HIV/AIDS	Kharkiv	23	NME “Regional clinical center for prevention and control of AIDS” of Kharkiv regional Council	Kharkiv, str. Wrestling, 6
HIV/AIDS	Kherson	24	NME “Kherson Regional Infectious Diseases Hospital named after. G.I. Horbachevsky» of Kherson Regional Council	Kherson, Berehove passage, 3
HIV/AIDS	Cherkasy	26	NME “Cherkasy regional center of public health” of Cherkasy regional Council	Cherkassy, str. Nechuya-Levitsky, 22
HIV/AIDS	Chernivtsi	27	NME “Chernivtsi Regional AIDS Center”	Chernivtsi, str. Mussorgskogo, 2
HIV/AIDS	Chernihiv	28	NME “Chernihiv regional medical center of socially significant and dangerous diseases”	Chernihiv, str. Ivan Mazepa, 3
HIV/AIDS	Kyiv city	29	NME “Kyiv city clinical hospital No 5”	Kyiv, str. Recreation, 11
HIV/AIDS	Kyiv city	30	National Children’s Specialized Hospital “OKHMATDYT” of the Ministry of Health of Ukraine	Kyiv, str. Chornovola, 28/1
HIV/AIDS	Kyiv city	31	State Institution «Institute of Epidemiology and Infectious Diseases. Named after L.V. Gromashevskiy»	Kyiv, str. Amosova, 5
HIV/AIDS	Dnipropetrovsk	78	NME “Dnipropetrovsk regional center of socially significant diseases” of Dnipropetrovsk regional Council	Dnipro, str. Bekhtereva, 1

Program	Region	#	Full name of the health care facility	Actual address
HIV/AIDS	Khmelnitsky	79	NME “Khmelnitsky Regional AIDS Center”	1) Khmelnitsky, Skovoroda Str., 17 (main warehouse) 2) s. Scazhyntsi, Yarmolynets district
Hepatitis	Dnipropetrovsk	3	NME “Dnipropetrovsk Regional Center for Socially Significant Diseases” of Dnipropetrovsk Regional Council	Dnipro, str. Degtyareva, 1
Hepatitis	Ivano-Frankivsk	11	NME “Ivano-Frankivsk Regional Clinical Infectious Diseases Hospital” of Ivano-Frankivsk Regional Council	Ivano-Frankivsk, str. Hetman Sagaidachnogo, 66
Hepatitis	Khmelnitsky	25	NME “Khmelnitsky Infectious Diseases Hospital” of Khmelnitsky City Council	Khmelnitsky, str. Gregory Skovoroda, 17
Hepatitis	Kyiv city	29	NME “Kyiv city clinical hospital No 5”	Kyiv, str. Recreation, 11
Hepatitis	Vinnitsia	56	NME “Vinnitsa City Clinical Hospital No.1”	Vinnitsa, str. Khmelnitsky highway, 96
Hepatitis	Volyn region	57	NME “Volyn Regional Infectious Diseases Hospital”	Lutsk, str. Shevchenko, 30 (hospital pharmacy)
Hepatitis	Donetsk	58	NME “City Hospital No.1 Kramatorsk”	Kostiantynivka, str. European, 17 (hospital room)
Hepatitis	Zhytomyrska	59	NME “Regional clinical hospital named after. O.F. Herbachevskiy» of Zhytomyr Regional Council	Zhytomyr, Red Cross Str., 3,
Hepatitis	Zakarpattia	60	NME “Regional Clinical Infectious Diseases Hospital” of Zakarpattia Oblast Council	Uzhhorod, str. Griboyedova, 20-A
Hepatitis	Zaporizhia	61	NME “Regional Infectious Clinical Hospital” of Zaporizhia Regional Council	Zaporizhzhya, str. Hvardiys’kyi 142
Hepatitis	Kyiv	62	NME “Base of special medical supply” of Kyiv Regional Council	Kyiv region, Obukhiv, str. Kashtanova, 66A
Hepatitis	Kirovohrad	63	NME “Kirovohrad Regional Hospital” of Kirovohrad Regional Council	Kropyvnytskyi, ave. University, 2/5
Hepatitis	Lugansk	64	NME “Luhansk Regional Center for Socially Significant Diseases”	Luhansk region, Severodonetsk, str. Smetanina, 5
Hepatitis	Lviv	65	NME “Lviv Regional Infectious Diseases Clinical Hospital”	Lviv, str. Pekarska, 54
Hepatitis	Mykolaiv	66	NME “Mykolaiv Regional Center for Treatment of Infectious Diseases” of Mykolayiv Regional Council	Nikolaev, str. Astronauts, 43

Program	Region	#	Full name of the health care facility	Actual address
Hepatitis	Odesa	67	NME “Odesa regional center of socially significant diseases” of the Odesa regional Council	Odesa, str. Sergiy Yadov, 4
Hepatitis	Poltava	68	NME “Poltava Regional Clinical Infectious Diseases Hospital” of Poltava Regional Council	Poltava, str. May Day, 22
Hepatitis	Rivne	69	NME “Central City Hospital” of Rivne City Council	Rivne, str. Mykola Karnaukhov, 25-A
Hepatitis	Sumy	70	NME “Central City Clinical Hospital “ of Sumy City Council»	Sumy, str. 20th anniversary of Victory, 15
Hepatitis	Ternopil	71	NME “Ternopil City Municipal Emergency Hospital” Infectious Diseases Department	Ternopil, str. Clinical,1
Hepatitis	Kharkiv	72	NME “Regional Clinical Infectious Diseases Hospital” of Kharkiv Regional Council	Kharkiv, str. Heroes of Stalingrad, 160
Hepatitis	Kherson	73	NME “Kherson Regional Infectious Diseases Hospital named after. G.I. Horbachevsky» of Kherson Regional Council	Kherson, str. Mykola Hrynka, 1-A
Hepatitis	Cherkasy	74	NME “Cherkasy City Infectious Diseases Hospital” of Cherkasy City Council	Cherkassy, str. Samila Kishky, 210/1
Hepatitis	Chernivtsi	75	NME “Chernivtsi Regional Clinical Hospital”	Chernivtsi, str. Holovna, 137
Hepatitis	Chernihiv	76	NME “Chernihiv Regional Hospital” of Chernihiv Regional Council	Chernihiv, str. Volkovich, 25
Hepatitis	Dnipropetrovsk	77	NME “Dnipropetrovsk Oblast Children’s Clinical Hospital” of Dnipropetrovsk Oblast Council	Dnipro, str. Space, 13
Tuberculosis	Lugansk	14	NME “Lugansk regional medical center of socially dangerous infectious diseases” of Lugansk regional Council	Severodonetsk, str. Smetanina, 5k
Tuberculosis	Vinnytsia	32	NME “Vinnytsia regional specialized territorial medical association “Ftiziatriy” of Vinnytsia regional Council	Vinnitsa district, Bohoniki village, Complex of buildings and structures
Tuberculosis	Volyn	33	NME “ Volyn regional phthisiopulmonological medical center” of Volyn regional Council	Lutsk, str. Lviv, 50
Tuberculosis	Dnipropetrovsk	34	NME “ Dnipropetrovsk Regional Clinical Treatment and Prevention Association “Phthisiology” of Dnipropetrovsk Regional Council	Dnipro, str. Bekhtereva, 12
Tuberculosis	Donetsk	35	NME “Regional clinical anti-tuberculosis dispensary”	Raihorodok village, str. Jubilee, 2 g

Program	Region	#	Full name of the health care facility	Actual address
Tuberculosis	Zhytomyr	36	NME “Regional anti-tuberculosis Dispensary” of Zhytomyr Regional Council	Guyva village, str. Berdychivska, 64
Tuberculosis	Zakarpattia	37	NME “Regional clinical phthiopulmonological treatment and diagnostic center» of Zakarpattia regional Council	Uzhhorod, str. Nakhimova, 4
Tuberculosis	Zaporizhia	38	NME “Zaporizhzhya Regional Phthiopulmonology Clinical Medical and Diagnostic Center” of Zaporizhzhya Regional Council	Zaporizhzhya, str. Perspective, 2
Tuberculosis	Ivano-Frankivsk	39	NME “Ivano-Frankivsk Regional Phthiopulmonology Center” of Ivano-Frankivsk Regional Council	Ivano-Frankivsk, str. Matejka, 53
Tuberculosis	Kyiv	40	NME “Kyiv Regional Phthiologiical Center” of Kyiv regional Council	Kyiv-Svyatoshinsky district, Boyarka, str. M. Dlyakhove, 23
Tuberculosis	Kirovohrad	41	NME “Kirovohrad Regional anti-tuberculosis Dispensary” of Kirovohrad Regional Council	Kropyvnytskyi, str. Habdrachmanova, 18/29
Tuberculosis	Lviv	42	NME “Lviv regional phthiopulmonological clinical treatment and diagnostic center» of Lviv regional Council	Lviv, str. Zelena, 477
Tuberculosis	Mykolayv	43	NME “ Mykolayv regional phthiopulmonological medical center” of Mykolayv regional Council	Mykolaiv district, Nadbuzka village, str. Veselynivska, 4
Tuberculosis	Odesa	44	NME “Odesa regional center of socially significant diseases” of the Odesa regional Council	Odesa, str. Sergiy Yadov, 4
Tuberculosis	Poltava	45	NME “Poltava Regional Clinical anti-tuberculosis Dispensary” of Poltava Regional Council	Poltava district, Suprunivka village, str. Kiev Shosse, 1-V
Tuberculosis	Rivne	46	NME “Rivne regional phthiopulmonological medical center” of Rivne regional Council	Rivne, str. Butler, 108
Tuberculosis	Sumy	47	NME “Regional clinical phthiopulmonological medical center” of the Sumy regional Council	Sumy district, Stepanivka village, str. Toropylivska St., 6
Tuberculosis	Ternopil	48	NME “Ternopil regional phthiopulmonological medical center” of Ternopol regional Council	Ternopil district, Velyki Hai village, str. Pidlisna, 26-A
Tuberculosis	Kharkiv	49	NME “Regional anti-tuberculosis dispensary No1” of Kharkiv regional Council	Kharkiv, str. Newton, 145
Tuberculosis	Kherson	50	NME “Phisiopulmonological Medical Center” of Kherson Regional Council	Kherson, Mykolaiv highway, 82

Program	Region	#	Full name of the health care facility	Actual address
Tuberculosis	Khmelnitsky	51	NME “Khmelnitsky regional anti-tuberculosis dispensary” of Khmelnitsky regional Council	Khmelnitsky district, Ruzhychanka village, str. Liberators, 1
Tuberculosis	Cherkasy	52	NME “Cherkasy regional anti-tuberculosis dispensary” of Cherkasy regional Council	Cherkassy district, Geronymivka village, str. Dispensary, 1
Tuberculosis	Chernivtsi	53	NME “Chernivtsi Regional Clinical anti-tuberculosis Dispensary”	Chernivtsi, str. I.Bohuna, 18
Tuberculosis	Chernihiv	54	NME “Chernihiv regional medical center of socially significant and dangerous diseases” of Chernihiv regional Council	Chernihiv, ave. Peace
Tuberculosis	Kyiv city	55	NME “Ftiziatria” executive body of Kiev city Council (Kiev city state administration)	Kyiv, str. Vasylykivska, 35

