Beyond COVID-19: Ukraine Legal Guide

As the world grapples with the COVID-19 pandemic and its profound impact, companies are looking for ways to safeguard their people and the long-term future of their businesses.

The Baker McKenzie team is pleased to provide you with regular updates in this legal guide on common questions that business will be considering in these unprecedented and uncertain times. We will help you navigate through these critical challenges and prepare for a changing world.

The comments above do not constitute legal or other advice and should not be regarded as a substitute for specific advice in individual cases.
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EMPLOYEES AND BUSINESSES
Is it possible to suspend employment agreements and/or reduce the employees’ working hours? If so, what procedure must be followed?

- No, it is not possible to suspend employment agreements in Ukraine. However, if the operation is being temporarily shut down, the employees may be sent on labor idle, as long as the employer does not have the required organizational or technical conditions to perform any work. The labor idle will become effective from the date indicated in the internal order issued by the director of the Ukrainian entity.

- It is possible to reduce employees’ working hours, but this will be considered as a change in the substantial terms of employment of the employees, which requires two months’ prior notice to the employees. The reduction of work hours will become effective upon expiration of the two-month notice, unless the employees sign amendments to their employment agreements indicating an earlier date.

Can employees refuse to come to work?

- Generally, no. Employees can refuse to come to work due to an illness of the employee or his/her family member confirmed by a sick leave paper, extract from the medical card and other evidence. Employees subject to mandatory observation or self-isolation can also refuse to come to work.

- The employer may adopt a flexible policy allowing employees not to come to work and work from home if they are feeling unwell or if the employee’s place of work is in close proximity to where an infected employee was located (i.e., the same open space office). Moreover, the Ministry of Health of Ukraine generally recommends that the employers provide remote working arrangements to employees.

Can employees refuse to attend meetings or to travel?

- Generally, no. However, travel and meetings are prohibited due to government restrictions.

- The Ukrainian state authorities have announced prohibitions on holding public events (with some exceptions). Therefore, employers should refrain from holding public or even internal meetings, and hold all meetings by means of videoconferences if possible.

- In addition, all passenger transport across Ukrainian international borders (except by personal automobile) has been stopped. Moreover, some restrictions have been introduced on travelling within Ukraine from 18 March. We recommend that employers consider this when planning business travel.
Can the employer suspend employees from work?

- The employer may suspend the employee from work under certain circumstances, in particular if:
  1. the employee has a confirmed disease qualifying as “especially dangerous” or “dangerous” (the current list of such diseases does expressly include COVID-19); or
  2. the employee provides a public service and has contacted patients with infectious diseases (including COVID-19), and he/she may not be temporarily transferred to another position.

- As of 11 March 2020, the Kyiv authorities have imposed some restrictions to prevent the spread of COVID-19. In particular, the employer must suspend an employee from work who has symptoms of the disease. In addition, the Ministry of Health of Ukraine has published general recommendations, according to which an employer must not admit to work an employee who has symptoms of the viral infection.

- Moreover, employees who have been in contact with a confirmed case or have visited a high-risk area are subject to self-isolation or observation (isolation) in specialized institutions. For this purpose, the employer should not admit these employees to work.

If employees are suspended from work or if an operation is being shut down, do the employees still need to be paid?

- If the employee is suspended from work due to a confirmed infectious disease, the employee will be entitled to sick pay. The employee is also entitled to sick pay for the period of the isolation.

- If the operation is being temporarily shut down, the employees may be sent on labor idle, as long as the employer does not have the required organizational or technical conditions to perform any work. In such case, the employee is entitled to receive at least two-thirds of his/her monthly salary.
Employment
Status: 13 May 2020

When is the employer forced to shut down its operations?

- From 6 April 2020, restaurants, shopping and entertainment centers, fitness centers and similar establishments must be closed to the public for the quarantine period. From 11 May, businesses in some industries were allowed to operate (e.g. beauty salons, advocate and notary offices, companies operating in mass media sphere, etc.) provided that the relevant sanitary and anti-epidemic measures are followed.

- According to the decision of the Permanent Commission on Technogenic Environmental Safety and Emergencies of the Kyiv City State Administration dated 11 April 2020, companies with employees with COVID-19 are subject to anti-epidemic restrictive measures for 14 calendar days. No additional official clarifications were provided in this regard. However, arguably, companies operating in Kyiv may be forced to shut down their operations for 14 days.

Does the employer have the obligation to report infections occurring in the business to the health authorities?

- There is no blanket mandatory reporting requirement for employers in Ukraine.

- However, in Kyiv employers in certain industries (i.e., transportation, grocery stores, pharmacies, etc.) are required to immediately report cases of their employees displaying respiratory infection signs (even if it is not yet confirmed as COVID-19) to the healthcare institution in charge of the area.

Can the employer require an employee to see a doctor?

- Generally, only employees providing a public service and whose activities can lead to the spread of infectious diseases may be subject to additional medical checks (on top of compulsory ones) if the epidemic situation worsens.

- Persons who have been in contact with patients with particularly dangerous and dangerous infectious diseases or bacterial carriers of agents of these diseases are also subject to mandatory preventive medical examinations and further medical supervision.

- According to the recommendations of the Ministry for Development of Economy, Trade and Agriculture of Ukraine and the State Labor Service of Ukraine, employees with symptoms of the disease must be immediately referred for a medical examination.
Are there mandatory requirements in relation to the workplace?

- There are only general recommendations with regard to ensuring workplace safety. However, they are mandatory for companies operating in Kyiv.

- For any employee who comes to the office, the employer is generally recommended (i) not to admit to work any employee with symptoms of a respiratory infection, (ii) to place posters that encourage hand hygiene at the entrance to the workplace and in other workplace areas, (iii) to frequently wash floors and disinfect and ventilate workplaces and premises, (iv) to ensure the availability of hygiene products (soap, antiseptic, etc.) and masks for employees and visitors, and (v) minimize the number of employees who are in contact with visitors.

- Moreover, Kyiv authorities imposed certain obligations on businesses that cannot operate remotely: (i) providing entrance sanitary control for visitors (if their reception cannot be stopped) by visual inspection and temperature screening (if necessary); (ii) providing employees contacting visitors with personal protective equipment (medical masks and antiseptic); (iii) conducting daily temperature screenings of all employees before and after working shifts; (iv) not permitting people with signs of acute respiratory infectious disease, etc., to come to work; and (v) disinfecting workplaces every three hours.

Can the employer force the employees to take a vacation?

- Employers cannot force employees to take a vacation. An employee’s written application is required to evidence their will to take a vacation.

- Employers can only discuss the option of taking vacation for the period of quarantine with employees.
Are there any special benefits/leave entitlement mandated during this period?

- For the quarantine period, terminated employees are entitled to unemployment payments from the first day of their registration as unemployed (generally, from the eighth day). Unemployment payments are made by the State Social Unemployment Insurance Fund of Ukraine (“Fund”).
- If the employees’ working time has been reduced due to suspension of the company’s work in response to quarantine measures, the employees are entitled to partial unemployment payments. Partial unemployment payments are made by the employer at the expense of the Fund from the first day of the working time reduction. However, it can only be applied to small and medium-sized companies. If the average number of employees is up to 50 individuals and the annual revenue of the Ukrainian company is up to the equivalent of EUR 10 million, the company will qualify as small. If the average number of employees is up to 250 and the annual revenue is up to the equivalent of EUR 50 million, the company will qualify as medium.
- Employees are entitled to sick leave allowance for the period of their stay in specialized healthcare facilities (in a mandatory observation facility), as well as for the period of self-isolation at home.

What are the penalties/sanctions for violating quarantine restrictions?

- A violation of any of the quarantine restrictions (e.g., not wearing a mask in a public place) may trigger the imposition of an administrative fine on the person amounting to up to UAH 34,000 (or USD 1,269).
- A violation of the sanitary rules and norms on the prevention of infectious diseases may lead to criminal liability in the form of a fine of up to UAH 51,000 (or USD 1,903), arrest for up to six months or imprisonment for up to three years (if such actions caused or could have resulted in spreading the disease). Actions that caused death or other grave consequences are punishable by imprisonment for up to eight years.
What is “personal data”? Under Law of Ukraine “On Personal Data Protection” No. 2297-VI dated 1 June 2010 (‘Data Protection Law’), "personal data" is any information about an individual who is identified or can be specifically identified.

Health information, including body temperature, travel information and device location data fall within the category of “special categories of personal data that constitute special risks to rights and freedoms of data subjects” (‘Sensitive Personal Data’).

Are companies required to report COVID-19 cases? Companies are not legally required to report COVID-19 cases. However, in Kyiv, employers are required to immediately report to medical institutions their employees displaying respiratory infection signs.

Moreover, according to Law of Ukraine “On Protection of the People from Infectious Diseases” No. 1645-III dated 6 April 2000, companies have to assist medical professionals in carrying out measures to protect the population from infectious diseases.
Data Protection
Status: 13 May 2020

How should personal data be processed when reporting COVID-19 cases?

- The purpose of personal data processing is the prevention of COVID-19.
- The most appropriate legal basis for processing would be a legitimate interest, in particular, the need to fulfill the obligation of a company as required by law. The data subject’s consent, protection of a vital interest of a data subject and processing for the purposes of the execution of a contract could also be used for processing in some cases.
- The scope of the collected personal data should be limited to the personal data that is required for the selected processing purpose.

The collected personal data should be deleted when it is no longer necessary for the prevention of COVID-19.

The amendments to the Law of Ukraine “On protection of the population from infectious diseases” on prevention of the spread of Coronavirus Disease (COVID-19) allow the processing of personal data without obtaining the consents of people who have tested positive for COVID-19.

Health information, place of hospitalization or self-isolation, full name of a patient with COVID-19, date of birth, place of residence, work or study are subject to processing. This data is also used to identify the contact persons.

The collected data of a person with COVID-19 can be used for the purpose of the implementation of anti-epidemic measures, which are defined in the Law of Ukraine “On protection of the population from infectious diseases”. The list of anti-epidemic measures is non-exhaustive and, in particular, includes urgent hospitalization, examination and treatment of patients, medical supervision (isolation and examination) of persons who have communicated with patients, etc.

These amendments will be valid for the period of quarantine and within 30 days from the date of its cancellation or during other restrictive measures (if they do not coincide with the quarantine period).

At the same time, within 30 days after the end of quarantine, personal data that have been processed without the consent of individuals will be subject to depersonalization, and in case of impossibility of depersonalization – destruction.
Are companies permitted to process personal data in connection with the COVID-19 pandemic (e.g., by requiring employees/visitors to fill out a questionnaire including questions on travel to high-risk areas and on whether they have been in close contact with someone who has positively tested for COVID-19, or by conducting temperature checks of employees and visitors in its premises)?

Yes, but if this information is considered Sensitive Personal Data, it can only be processed after:

- obtaining valid explicit consent from data subjects
- filing a respective notification to the Ukrainian Parliamentary Commissioner for Human Rights (“Commissioner”)
- appointing a personal data officer or establishing a specific division responsible for personal data protection

In particular, the temperature screening of employees or visitors is subject to their explicit consent.

The Data Protection Law provides a limited number of grounds for the processing of personal data without consent, including when:

- the personal data processing is necessary to protect the vital interests of the data subject
- the processing is performed for employment purposes

In practice, companies often use the above grounds for the processing of an employee’s personal data during the COVID-19 period. However, the Commissioner has not provided any practical guidance in relation to whether it is appropriate to use these grounds in connection with the COVID-19 pandemic.

Mandatory temperature screening may be introduced by the decision of the state authorities, e.g., such mandatory screening is applicable at the Ukrainian border points with respect to people entering Ukraine.

What personal data may be processed by companies?

Companies may process personal data related to:

- the fact that the employee has an illness or is feeling unhealthy, without specifying symptoms
- information on the last “close contact” with infected/potentially infected persons, without specifying the names of such persons and their relationships
- travel information to COVID-19 affected areas, without specifying any other details of the trip
- geolocation data
### Data Protection
**Status:** 13 May 2020

| **What data is processed by medical professionals?** | **Medical professionals may process:**  
- any symptoms of COVID-19 (including fever)  
- other necessary data |

| **Is it required to inform the data subjects of the respective processing?** | Yes. Under the Data Protection Law, when the personal data is collected, the data subject shall be informed of the data controllers, the composition and content of the personal data collected, the data subject’s rights, the purpose of personal data collecting and the personal data recipients, etc. |

| **Are companies permitted to disclose COVID-19 infection information?** | Yes. Companies are allowed to disclose COVID-19 infection information regarding people who have tested positive for COVID-19.  
Furthermore, companies operating in Kyiv are required to immediately report to medical institutions their employees displaying respiratory infection signs even if it is not yet confirmed as COVID-19. |

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Data Protection
Status: 13 May 2020

### How long can the respective personal data be stored?

The relevant personal data must be deleted as soon as it is no longer required for the purpose of personal data processing. This must be assessed on a case-by-case basis. The latest point in time will be the end of the pandemic. However, certain personal data such as visitor lists should be deleted earlier (generally after 4–6 weeks).

### Have data privacy regulators issued any guidance either permitting or restricting the collection of personal data for the purposes of identifying COVID-19 cases?

The Commissioner has not issued any specific guidance on how to comply with data protection requirements and data subject rights during the COVID-19 pandemic.

On 2 April 2020, the Commissioner released a statement about the mass spamming of citizens via online social messaging services with information on the exact addresses of persons infected with COVID-19. The Commissioner emphasized that personal data and confidential information must only be processed in compliance with the law and any violation of this rule may be a ground for administrative or criminal liability.

On 14 April 2020, the Commissioner released a statement on its website regarding the application of international standards for the protection of personal data in the context of the COVID-19 pandemic (European vector):

Furthermore, by its Resolution No. 255 the Cabinet of Ministers of Ukraine (CMU) instructed the Ministry of Digital Transformation of Ukraine (MDT) to create an app to monitor compliance with the self-isolation regime (“App”). Starting on 6 April 2020, all Ukrainian citizens who returned from abroad received a text message with an invitation to install the App. When the App is being installed, the person starts receiving push notifications during the 14 days of self-isolation with a request to take pictures. The App then analyzes the GPS location data and, in the case of any non-compliance, sends a notification to the police.

According to the MDT, the data collected by the App includes the telephone number, the address of the person and the GPS location processed only when taking pictures. The processing of the aforementioned personal data is conducted by the MDT based on the consent the App users give when installing the App.

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Could the parties claim that the COVID-19 pandemic is a force majeure event, which excuses the parties from performing the lease obligations?

On 17 March 2020, the Ukrainian Parliament passed Law No. 530-IX “On amendments to certain legislative acts of Ukraine aimed at the prevention of occurrence and spread of coronavirus (COVID-19)” and officially included the quarantines imposed by the government (such as the COVID-19 quarantine) in a list of force majeure events.

This does not entail the automatic enforcement of force majeure provisions in the relevant leases and does not allow for non-performance under such leases. It only grants any interested party an opportunity to obtain a certificate confirming that the COVID-19 quarantine qualifies as a force majeure event.

The COVID-19 quarantine and pandemic, as a force majeure event, does not release from liability the failure to properly perform the affected obligation, such as late payment interests or other penalties (for tenants) and penalties for the failure to provide premises suitable for the purpose of a lease (for landlords).

If the tenant cannot use its leased premises, does it have to continue paying rent?

The tenant may not have to continue to pay, but this depends on the terms of the lease and negotiations with the landlord. Some leases may contain a rent suspension clause, entitling the tenant to cease the payment of rent if the premises are damaged, destroyed or inaccessible.

Statutory remedies are also available. Under art. 762 (6) of the Civil Code of Ukraine, a tenant is relieved of its obligation to pay rent for the period during which the tenant could not use the leased property, where this is due to circumstances for which the tenant is not responsible.

Further, on 13 April 2020, the Ukrainian Parliament passed Law No. 553-IX “On amendments to the Law of Ukraine On State Budget of Ukraine for 2020,” which allows any tenant who is unable to use or access the premises due to the existing prohibitions on carrying out certain business activities, or access certain premises during the COVID-19 quarantine, to request a reduction of the rent. The tenant has to make the connection between the inability to use or access the premises and the COVID-19 quarantine and pandemic sufficiently plausible. For example, in the case of commercial leases, tenants may point out that the operation of their business was prohibited by the decisions of state and local authorities.
Real Estate
Status: 13 May 2020

If the tenant cannot use its leased premises, does it have to continue paying for utilities, service charges or operational expenses?

This depends on the terms of the lease and negotiations with the landlord. Statutory remedies (art. 762 (6) of the Civil Code of Ukraine and Law No. 553-IX “On amendments to the Law of Ukraine On State Budget of Ukraine for 2020”) do not address the payment of utilities and operational expenses.

If the government imposes additional public health requirements, can the landlord compel the tenant to comply with these?

Leases in Ukraine often contain a tenant’s covenant to comply with all legal obligations or statutory requirements that are related to their business within the leased premises. So, if the government imposes additional public health requirements in respect of the business activities that the tenant carries out in the leased premises (e.g., minimum distance and maximum numbers of persons in the leased premises), the landlord can request the tenant to comply with these rules in order to fulfil its contractual obligations.

If compliance with public health requirements falls to the landlord, who pays for items such as an enhanced cleaning regime, additional cleaning of common areas, any deep cleaning and the provision of additional refuse removal, for example?

The landlord may have to pay. The list of services (maintenance services, operational services) provided by the landlord is usually exhaustive and expressly defined in the lease. As such, it may be difficult to recover unexpected costs from the tenant via the service charge.

Is it possible to terminate a lease due to COVID-19?

Under Ukrainian law, the failure of a tenant or landlord to perform their respective obligations due to events beyond their reasonable control does not automatically lead to the termination of a lease agreement. It should be possible, however, to initiate the procedure of lease termination due to material adverse change.

Could the parties argue that the lease contract has been frustrated by the impact of COVID-19?

This is theoretically possible, but a statutory provision covering frustration is very rarely enforced.
CORPORATE GOVERNANCE
Implications for Limited Liability Companies
Status: 13 May 2020

Have any changes been made to the procedure of holding general participants’ meetings of limited liability companies?

No. The only changes that have been made are related to limited liability companies (LLCs) that are issuers of securities. Please see the section below for a description of such changes. Nevertheless, taking into account the general limitations imposed during the quarantine (in particular, holding any kind of mass event), holding a meeting of participants of an LLC where all participants are present in one place may be difficult. The meetings of participants in LLCs can still be held remotely via videoconference, by absentee voting or by voting by poll (unless the latter is forbidden under the company’s charter) under the general procedure provided for by Ukrainian law. At the moment, this is especially useful given the legislative requirement for LLCs to hold their annual meetings of participants by 30 June 2020, where they have to approve the results of the 2019 financial year, decisions on distribution of profits, etc.

What changes have been introduced in relation to LLCs that are issuers of securities?

If an LLC is an issuer of securities, the requirement to hold the company’s annual meeting of participants within six months following the end of the reporting year (by 30 June 2020) does not apply in 2020. This meeting may be held within three months after the end of the quarantine period established by the Cabinet of Ministers of Ukraine.

If the convocation and holding of the general meeting of participants of LLCs that are issuers of securities under the general procedure provided for by the law is not possible due to the current COVID-19 restrictions, such meetings can be held under the temporary procedure, which will be developed and approved by the National Commission on the Securities and Stock Market. This procedure has not been approved as of the date of this guide.

In addition, the deadlines for disclosing annual financial information for LLCs that are issuers of securities have been extended. If the annual participants’ meeting is held after 30 April 2020, such information can be disclosed within five business days after holding the meeting as described above.
Implications for Joint Stock Companies
Status: 13 May 2020

Are there any amendments to the deadline for holding the 2020 annual meeting of shareholders in joint stock companies?

Yes. Similarly to LLCs that are issuers of securities, joint stock companies (JSCs) and corporate investment funds can postpone their annual meeting of shareholders (which shall be held no later than 30 April 2020). In 2020, such meetings can be held within three months after the end of the quarantine period established by the Cabinet of Ministers of Ukraine.

Have any changes been made to the procedure of holding general shareholders’ meetings in JSCs?

Yes. General shareholders’ meetings in JSCs, as well as in corporate investment funds and credit unions, may be held remotely under a temporary procedure. This procedure was adopted by the National Securities and Stock Market Commission in relation to JSCs and corporate investment funds on 16 April 2020.

The temporary procedure applies to annual meetings of shareholders, which have to be held to approve the results of the 2019 financial year, as well as to any extraordinary meetings to maintain companies’ business. The remote meetings will be available with the help of a new electronic service, which was developed by the National Depository of Ukraine and made available for public use on 13 May 2020. To use the service, companies will be required to conclude a special services agreement with the National Depository of Ukraine and the shareholders — with their respective depositary institutions. General shareholders’ meetings that were convened before 16 April 2020, but have not yet been held, can be postponed and held remotely by the decision of the companies’ supervisory board.

What if the powers of members of the company’s supervisory board expire in 2020?

The recent legislative amendments state that if powers of members of supervisory boards of joint stock companies, supervisory boards and audit committees of credit unions expire in 2020, they will be automatically extended in full until the date of the next general shareholders’ meeting, which may be held remotely within the term described above.
Implications for Joint Stock Companies
Status: 13 May 2020

Have the deadlines for submitting financial information been extended?

Yes, such deadlines have been extended. In particular, the annual financial information of JSCs can now be disclosed within five business days after holding the annual general meeting of shareholders. The annual report on the activity of funds can be disclosed within five business days after holding the corporate fund’s annual meeting as described above and approval of the equity fund’s annual report by the authorized body of its asset management company.

The persons responsible for filing and disclosing financial statements will not be liable for breaches of disclosure deadlines for financial statements of 2019, provided that such statements are disclosed during the quarantine period or within five business days after holding the annual general meeting of shareholders as described above (or, for companies that are not issuers of securities, within 90 calendar days following the day of the end of the quarantine), but in any event no later than 31 December 2020.
LENDING AND SECURITY ARRANGEMENTS
Can a Ukrainian bank-lender increase the interest rate under an existing loan agreement?

No. In March, the Ukrainian parliament prohibited the increase of interest rates (except for floating rates) under consumer loans until 31 May 2020. Later in March, the Verkhovna Rada of Ukraine passed Law No. 540-IX, which established a temporary prohibition for Ukrainian financial institutions to increase interest rates under loan agreements with Ukrainian borrowers. The prohibition will remain in effect for the duration of the restrictive measures introduced by the Government of Ukraine in response to the COVID-19 pandemic.

Are borrowers permitted to suspend discharging payment obligations under loan agreements for the duration of the quarantine period?

Generally, no. The exception is consumer loans. Law No. 533-IX explicitly prohibited lenders from applying negative measures, including fines and penalties, for failure to perform payment obligations under consumer loans between 1 March and 30 April.

In addition, pursuant to the Law No. 530-IX, the Cabinet of Ministers of Ukraine was obliged by the Verkhovna Rada of Ukraine to prepare legal acts and undertake necessary measures aimed at the deferral of payments under financial agreements secured by a mortgage. As of today, no such legal acts have been adopted. By its Letter dated 22 March 2020, the National Bank of Ukraine (NBU) obliged banks to notify borrowers that, pursuant to Law No. 530-IX, payments under loans secured by mortgages would be deferred for the duration of the quarantine period. However, neither Law No. 530-IX nor other Ukrainian legislation requires such a deferral as of the date of this Guide.

Another initiative on payment holidays was launched by the NBU by passing regulation No. 39, dated 26 March 2020 ("Restructuring Regulation"). The Restructuring Regulation liberalized certain regulatory requirements related to the credit risk assessment, purporting to stimulate Ukrainian banks to enter into debt restructurings arrangements ("Restrurings") with their clients suffering from the consequences of the pandemic.

Do Restrurings launch automatically? Who may enter into a Restrurings?

The Restructuring may be initiated by either a borrower or lender Ukrainian bank. The Restructuring Regulation does not apply to loans with the lenders such as Ukrainian non-bank financial institutions or foreign financial institutions.
Lending Arrangements

Status: 13 May 2020

When is a borrower eligible for a Restructuring?

The NBU clarified that the credit risk regulatory easement and the Restructurings should be made available with respect to debtors that were not in default as of 1 March 2020. The implementation of the Restructuring is also subject to the following conditions:

- The loan agreement should be restructured by September 2020.
- The restructuring is necessary in view of financial difficulties caused by the quarantine and restrictive measures introduced by Ukrainian government.
- The bank is able to justify the launch of either a short-term or long-term perspective Restructuring based on the evaluation of debtor.

Debtors - legal entities applying for the Restructuring should provide banks with evidence of a significant decrease in their income level or termination of their business activity.

The Restructuring Regulation does not prohibit banks from entering into restructuring arrangements of other loans and debtors that do not fall under the above-listed conditions (including loans defaulted as of 1 March 2020), provided that such arrangements will not cause failure to comply with relevant regulatory limits applicable to banks.

Are Restructurings equally accessible by small, medium and large businesses?

The NBU recommended banks to elaborate special programs on the Restructuring of loans with small businesses and individuals and to automatize the restructuring processes to the extent possible. Certain banks already introduced such programs, establishing a standardized set of conditions for the restructurings.

The Restructurings of debts of medium and large businesses are considered by banks in each case individually. Before taking the decision on Restructuring, the banks should assess, among other things, whether a debtor will be able to restore its sound financial standing in future.
What measures may be implemented pursuant to the Restructuring Regulation?

There is no exhaustive list of Restructuring measures; the set of such measures may be negotiated by bank and its client in each particular case. However, the NBU recommended that banks utilize the measures provided for in the NBU regulations, including the following:

- deferral of principal instalments repayment and extension of maturity dates (payment holidays)
- introduction of PIK interest option (accrued interest is capitalized and added to the principal amount)
- decrease of installments and other payments amounts

Do the payment holidays under Restructurings and consumer loans mean that the payment obligations accruing during the quarantine period will be written off?

No. Payment obligations will be postponed for the period negotiated with the bank.

Can the introduction of the quarantine be treated as a force majeure event that allows a deferral of payments under loan agreements and an exemption of borrowers from liability for the respective non-performance of payment obligations?

Generally, no. Unless otherwise expressly provided in the loan agreement (which would customarily not be the case), force majeure events (except those directly affecting the banking or payment systems) do not entitle the borrower to defer payments under the loan agreement and, accordingly, do not enable exemption from liability for the non-performance of such obligations.
Which provisions of loan documentation should be verified?

Although some of your loan arrangements may not be subject to the Restructurings (including loans provided by non-residents), we recommend undertaking necessary measures in a timely manner. Review your loan and related documentation to determine the extent to which the pandemic and the related measures imposed by the authorities may affect the discharge of the borrower’s, guarantor’s/surety’s and security providers’ obligations both in the short term and in the long run. Pay attention to the following issues in the first place:

- payment schedule
- drawdown provisions
- repeated representations
- financial covenants
- project completion covenants
- material adverse effect
- events of default (EOD)

You should also investigate the provisions of related security documents and material (project) contracts. In particular, review what effect disruptions or defaults in the performance of the underlying contracts (e.g., sale of products, delivery of raw materials or spare parts, performance of construction works, etc.) may affect the existence and value of the security, verify provisions on contractual liability and force-majeure events in all project-related contracts to assess whether your counterparties may claim force majeure and how this would affect your project.
Which preventive measures can be used to avoid the occurrence of a default under loan documents?

Based upon the above referenced review, you may decide to take the following risk mitigation or remedial actions:

- **Waiver requests**: If you need a small number of obligations to be waived to avoid negative consequences in a short-term perspective.

- **Amendments**: If you wish your loan documentation to provide for carve-outs to material adverse effect and material adverse change clauses or if you need to extend maturity dates, introduce interest holidays, adjust financial covenants, etc.

- **Restructuring**: If long-term perspective changes are required, such as the restructuring of key financial terms.

Timely and careful drafting and effective negotiation is the key to success.

More information on recommended loan documentation checks and preventive measures may be found [here](#).
What state financial support measures are available for Ukrainian businesses to overcome the consequences of the pandemic?

To support Ukrainian businesses in maintaining their operation during the quarantine period, the Verkhovna Rada introduced a number of measures including exemptions from certain tax liabilities and the postponement of deadlines for certain mandatory filing. However, no comprehensive scheme aimed at financial support of business suffering from the introduction of restrictive measures has been elaborated by authorities so far.

That said, earlier in April, the Cabinet of Ministers of Ukraine tailored the existing “5-7-9% affordable loans” program (loans to micro and small businesses at decreased rates supported by the state) to address the needs of certain businesses in light of negative impact of the pandemic. Now the “5-7-9% loan” may be obtained specifically to prevent and/or overcome negative consequences of the pandemic and to refinance existing indebtedness before Ukrainian banks. Such loans are provided through the banks approved by the Entrepreneurship Development Fund. The Entrepreneurship Development Fund may support such loans, particularly by financing a part of interest payments. The businesses willing to overcome negative pandemic impact can apply for “5-7-9% loan” within the duration of the quarantine period and 90 days thereafter.

Are “5-7-9% loans” available to all types of businesses? What are the principal terms of such loans?

The “5-7-9% loan” are available to micro and small businesses only. The maximum limit of such loans is UAH 3 million, while the maximum tenor is five years.
Can a lender enforce a pledge during the quarantine period? Currently, there exists no express prohibition on enforcement of pledges/mortgages during the quarantine period. However, in respect of consumer loans, Law No. 530-IX permits deferral of payment obligations and prohibits the imposition of fines, penalties or other monetary sanctions for the failure to perform payment obligations during the quarantine period. Although there is no express indication that such prohibition should also apply to enforcement of pledges/mortgages (to the extent they secure consumer loans), it can be argued that such enforcement should not be permissible if it is triggered by a payment default occurring during the quarantine period.

Is a lender allowed to enforce a mortgage during the quarantine period? Law No. 530-IX strictly prohibits the enforcement of the residential property mortgages that secure payments for utility services. The same law obliged the Cabinet of Ministers of Ukraine to develop legislation imposing a broader prohibition on the enforcement of residential mortgages. However, such legislation has not yet been developed.
Has the NBU introduced any additional currency control restrictions in view of the pandemic and the related quarantine?

No. The NBU does not plan to introduce any such restrictions within the duration of the quarantine period, as long as the situation on financial and currency markets does not deteriorate significantly.

Is lender allowed to enforce a mortgage during the quarantine period?

Law No. 530-IX strictly prohibits the enforcement of the residential property mortgages that secure payments for utility services. The same law obliged the Cabinet of Ministers of Ukraine to develop legislation imposing a broader prohibition on the enforcement of residential mortgages. However, such legislation has not yet been developed.
STATE SUPPORT OF BUSINESSES
## Tax Reliefs
**Status:** 13 May 2020

### Which tax reliefs are available in Ukraine?

**Corporate income tax.** In 2020, funds (value of goods) voluntarily transferred to combat COVID-19 would not fall under the tax adjustment, increasing financial result by an amount that exceeds 4% of the profit for the previous reporting year.

**Value added tax.** Until the last calendar day of the month in which the quarantine is terminated, import and supply on the territory of Ukraine of goods purpose to combat COVID-19 are subject to VAT exemption.

**Land tax.** From 1 March 2020 until 31 March 2020, land tax (rent) should not be levied on individuals and legal entities with respect to their land plots used in commercial activities.

**PIT.** Ukraine has postponed the deadline for filing the annual PIT Return from 1 May 2020 to 1 August 2020. The deadline for the payment of the relevant PIT liabilities are pushed back from 1 August 2020 to 1 October 2020.

### Other obligatory payments (fees) subject to legislative reliefs

**Import duty.** Until 30 June 2020, goods purposed to combat COVID-19 are subject to import duty exemption.

**Unified Social Contribution.** From 1 March 2020 through to 30 April 2020, individual entrepreneurs are exempt from the obligation to pay the Unified Social Contribution for themselves.

### How can I apply for the reliefs?

There is no need to apply for the above tax reliefs — they were enacted automatically.

### Filing of tax returns

The deadline for filing the annual tax returns for 2019 by individuals was extended until 1 July 2020 (previously 1 May 2020). Respective tax liabilities should be paid until 1 October 2020 (previously 1 August 2020).
Tax audits

Ukraine also introduced special procedural rules for tax audits for the period of the COVID-19 quarantine:

- freeze on new on-site tax audits and suspension of current ones until 31 May 2020; chamber tax audits, tax audits related to VAT refund as well as excise duties may continue
- extension of deadlines for tax audits

The deadlines for challenging the tax assessments and other tax decisions with the higher-level tax office or the court were extended.

Liability

Fines for the violation of tax legislation will not apply to violations taking place during the period from 1 March to 31 May 2020, with the exception of violations in the following areas: VAT; excise tax; royalty tax; tax on production of ethanol and fuel; and alienation of pledged property.

Fines for late registration of VAT or excise duty invoices will not apply until 31 May.

No late payment interest will be charged from 1 March to 31 May 2020. Late payment interest accrued during this period must be written-off.
SUPPLY CHAIN
Are there any export restrictions adopted in response to the COVID-19 pandemic?

Yes, in response to the COVID-19 outbreak Ukraine introduced an export ban on personal protective equipment, including respirators, masks and gloves until 1 June 2020.


Are there any import relaxation measures adopted in response to the COVID-19 pandemic?

Yes, Ukraine introduced import relaxation measures to the extensive list of items, among other things, medicines, disinfectors, medical devices, personal protective equipment, laboratory equipment and ambulance cars. The following import relaxation measures apply:

- import duty exemption
- VAT exemption
- priority customs clearance
- simplified conformity assessment procedure


The list of goods subject to the above import relaxation measures is specified in the Resolution of the Cabinet of Ministers of Ukraine No. 224 dated 20 March 2020 amended as of 8 April 2020.
Has Ukraine restricted cross-border cargo transportations?

Yes, the Order of the Cabinet of Ministers of Ukraine No. 288-p dated 13 March 2020 specified a list of border checkpoints temporary closed for cargo and passenger transportation, which may, in certain cases, slow down the customs clearance of goods. The interactive map of open checkpoints is available here.
Can the COVID-19 pandemic serve as a ground for release from liability for failure to perform contract obligations?

The COVID-19 pandemic does not, by itself, release the parties from their contractual obligations or from the liability for the failure to properly perform their contractual obligations.

At the same time, in case a party was directly prevented from performing under the contract by the COVID-19 pandemic-related restriction (e.g., export ban, suspension of work of an enterprise etc.), the affected party might be released from liability for non-performance, invoking a force majeure event.

However, force majeure circumstances do not release the parties from liability for their payment obligations.

Can a party claim a force majeure event if the contract does not provide for a force majeure clause?

For Ukrainian law-governed contracts, a force majeure event can be claimed as a matter of Ukrainian law even if not directly provided for in a contract.

Considerations if the contract provides for a force majeure clause

If the contract provides for a force majeure clause, the definition of the force majeure event and the requirements for invoking a force majeure event should be analyzed to assess whether a party can rely on a force majeure clause. In particular, Ukrainian law-governed contracts often provide for a very short time period for giving a force majeure notice (same or next day). Failure to serve such a notice in accordance with the contractual requirements may deprive the affected party from a release from liability under the force majeure clause.
Can parties claim that the COVID-19 pandemic is a valid reason for contract amendment or termination?

Ukrainian legislation allows amending or terminating a contract as an exceptional measure in case of material changes in circumstances compared to those that were in place when the parties entered into a contract (material adverse effect). In particular, when due to the changes in the circumstances, a party is deprived of the benefits it expected to receive under the contract, and if it was aware of such changes in the circumstances it would not have entered into the contract. Therefore, depending on the actual circumstances of a particular transaction, effects of the COVID-19 pandemic and related government measures may serve as a ground to initiate contract amendment or termination by parties on the basis of a material change in circumstances (material adverse effect) either by mutual agreement of the parties or in court.

Recommended actions

Taken that the COVID-19 pandemic measures vary in different parts of the world and change at a different pace, the risk of disruption of the supply chain may last significantly longer that the actual lockdown in Ukraine. Therefore, to prevent the unexpected negative consequences and losses, we recommend carrying out due diligence of the supply chain sustainability and take the following steps to mitigate COVID-19 related risks:

1. To review the terms of all existing contracts to determine what force majeure provisions they contain and whether the parties may rely on them due to the COVID-19 pandemic, including assessing whether any changes to amendment, termination and liability clauses might be required to take into account potential COVID-19 related implications.

2. To review contracts through the whole supply chains to assess whether they provide for consistent allocation of risks related to COVID-19 and what changes might be required to ensure consistent allocation of risk.

3. When entering into new commercial agreements, to consider potential COVID-19 disruptions and clearly draft the relevant clauses on obligations, risk allocation, liability, force majeure, suspension of performance and termination.
Are there any exemptions for procuring goods and services to combat the COVID-19 pandemic?

Yes, Ukrainian legislation exempts from public procurement procedures goods, works and services aimed at combating the COVID-19 pandemic including such goods as medicines, disinfectors, medical devices, personal protective equipment, laboratory equipment, ambulance cars etc.
WORK OF STATE COURTS AND ARBITRATION TRIBUNALS
What does this mean for my health-related patents?

(1) Changes to the Procedural Codes

On 2 April 2020, the changes to the Procedural Codes became effective, which provide for the following rules to be applied by the commercial, civil and administrative courts during the officially declared quarantine:

- The court may decide to restrict the access to the court hearing for a person without a mandate in case there is a threat to the life or health of a person.
- The parties may participate in the court hearing online using their personal video-conference equipment. Please note that the State Judicial Administration of Ukraine has defined the EasyCon system as the only possible video-conference tool.
- The procedural terms, established by the procedural law, are extended for the duration of the officially declared quarantine, i.e., the lapse of the procedural terms is suspended for the term of the officially declared quarantine.
- The procedural term, established by the court, shall not be shorter than the term of the officially declared quarantine.

(2) Functioning of the Ukrainian courts

On 17 March 2020, the Council of Judges of Ukraine adopted the recommendations, establishing a special regime of the courts’ operation during the officially declared quarantine. Considering these recommendations, most of the Ukrainian courts have decided the following:

- To cancel the court hearings, scheduled during the term of the officially declared quarantine.
- To restrict access to the court hearings for persons without a mandate.
- To stop personal appointments of citizens by the court’s management.
- To provide an online case materials’ review by means of e-correspondence with the court.

To limit acceptance of procedural documents to postal correspondence, e-correspondence and a post box in the court’s premises.
To what extent are arbitration proceedings affected by the COVID-19 pandemic?

The arbitration proceedings are also affected by the COVID-19 pandemic. At the same time, the International Commercial Arbitration Court at the Ukrainian Chamber of Commerce and Industry (ICAC) has announced that it continues to administer arbitration cases during the officially declared quarantine. Furthermore, the ICAC has published the following recommendations for the Arbitral Tribunals with regard to the arbitral proceedings:

- To submit the documents in electronic form.
- To hold the organizational meetings via video conference or telephone conference.

In cases where oral hearings are scheduled during the officially declared quarantine:
(1) to hold oral hearings via video conference; (2) to conduct arbitration proceedings on the basis of written materials; (3) to hold the hearing in the absence of a party; or (4) to postpone or suspend the arbitral proceedings.
FURTHER AREAS
### How has COVID-19 impacted the activities of the Antimonopoly Committee of Ukraine?

Notwithstanding the implementation of the quarantine in Ukraine aimed at prevention of spreading of COVID-19, the Antimonopoly Committee of Ukraine (the “AMC”) remains fully functional and continues to perform its functions in a regular way, save for adaption of certain health security measures, including:

- suspension of all events (e.g., round tables, workshops) involving more than 10 persons, except for those essentially important for the AMC’s work;
- limitation of the number of persons, which may be present in the AMC’s premises;
- participation of the parties in the hearings of the Permanent Administrative Board for Review of Complaints Regarding Violations of Public Procurement Law (the “Board”) either via videoconference tools or through submission of written arguments by the parties via electronic means;
- attendance of third parties at hearings is limited only to video broadcasts on the Board’s Facebook pages.

The above measures came into force since 18 March 2020 and will remain effective throughout the entire quarantine period.

The AMC continues to conduct investigations and to consider cases, as well as to accept merger control and concerted actions filings for review in the usual way. At the same time, although there was no official announcement about adjustments to the timelines of the filings review, some slight delays may happen (especially in relation to the filings submitted under the fast-track procedure) due to the remote work of some of the authority’s staff.
What should be taken into account when promoting and advertising medicinal products during the COVID-19 pandemic?

According to official information from the World Health Organization ("WHO"), there are currently no confirmed and effective medicinal products aimed at Coronavirus treatment. Therefore, the information distributed by pharmaceutical companies or other medicinal products market participants that refers to the ability of a medicine to prevent or cure the coronaviruses, in the absence of relevant and reliable scientific confirmations thereof, contains indications of unfair competition.

Under these circumstances, on 31 March 2020 the AMC issued the recommendations that are mandatory for consideration by medicinal products manufacturers, advertisement holdings and Ukrainian TV channels to refrain from creation and distribution of advertisements that may mislead a viewer as to the ability of a medicinal product to prevent or cure COVID-19 in the absence of a proper confirmation thereof, in particular, the official recommendations of the Ministry of Health of Ukraine.

According to the Ukrainian competition legislation, dissemination of misleading information is considered as unfair competition and potentially may lead to imposition of a fine in the amount of up to 5% of the global annual turnover of the respective company (on a group level) for the financial year preceding the year in which the fine is imposed. It should be noted that the AMC does not usually impose the maximum allowed fines but defines the amount of a fine individually on a case-by-case basis.
What should be taken into account when promoting and advertising products with antiseptic and disinfectant effects?

On 2 April 2020 the AMC published an alert for manufacturers to refrain from distribution of false, incomplete or inaccurate information regarding antiseptic or disinfectant properties of sprays, solutions, gels, napkins and other products, as well as their ability to kill viruses, including COVID-19 (i.e., Coronavirus), in order to attract consumers.

In particular, the information regarding a product entails a greater risk of being treated as misleading by the authority if, among other things:

- the information contains the wording derived from Coronavirus/COVID and/or visual representation of the virus in the absence of sufficient justification thereof;
- the information contains unconfirmed data on the ability of the product to affect viruses, including COVID-19, or to increase immunity;
- the information on the properties of the product does not correspond to the information from the technological documentation thereof;
- the mentioned product referred to does not contain or contain insufficient amount of the active ingredient;
- the information contains misleading data regarding the effective time, minimum required amount of the product, etc.;
- the information refers to the ability of the product to kill a specific percentage of bacteria (e.g., 95%, 99%, 99.9%, etc.) in the absence of relevant tests/trials;
- the mentioned product referred to has not received required approvals, permits or other authorization documents from the competent authorities yet.

The AMC stated that it will take all the measures prescribed by the Ukrainian competition law against companies distributing misleading information, including, in particular, imposition of fines.
What else is under the AMC’s radar due to COVID-19?

PHARMA MARKET

In order to prevent economically unreasonable price increases for medicinal products or artificial creation of a products deficit by the pharmaceutical markets participants the AMC, at the end of March, issued recommendations urging to refrain from any actions resulting in the price increase of for domestic or imported medicinal products at a rate higher than increase of the foreign exchange rate.

The AMC also officially declared that the facts of unreasonable price increase for medicinal and hygiene products would be thoroughly and promptly investigated. The same goes for other potential abuses, such as creation of an artificial deficit.

TELECOM

At the end of the March, the AMC issued mandatory for consideration recommendations to three major mobile phone service providers in Ukraine urging them to refrain from committing concerted/similar actions (in order to receive excessive profits) that may lead to prevention, elimination or restriction of competition.

The authority emphasized that introduction of restrictive measures related to the spread of Coronavirus in Ukraine, isolation of citizens and need for remote work would lead to increased consumption of mobile services, which, consequently, may induce the mobile phone service providers to raise their prices.

Under these circumstances, in order to facilitate the ability of subscribers to promptly receive information (in particular, by means of communication tools) necessary for performance of their professional duties, as well as, to prevent extra financial expenses for mobile services, the AMC has recommended the mobile phone service providers to refrain from:

- raising their tariffs;
- terminating social, cheap or minimum tariffs;
- automatic (forced) transferring of subscribers to more expensive tariff;
- deteriorating the quality of their services.
In view of the foregoing, such simultaneous / similar actions of mobile phone service providers may be qualified by the authority as anti-competitive concerted actions.

RETAIL

The AMC made several public statements expressing its concerns regarding situation with a permanent growth of prices for food, medicinal and hygiene products during the period of nationwide restrictive measures caused by the spread of Coronavirus.

The price monitoring of the AMC has showed that various retail networks engaged in selling of food products in Kyiv and Kyiv region has rapidly increased the prices for certain long-lasting food products during the quarantine. According to the AMC, the synchronized nature of such behavior may serve as a signal of anticompetive concerted practices of the market participants, i.e., food products suppliers or retailers, or even both of them.

The same situation is observed in the market for medical products where the prices for disposable medical masks have grown as well.

Since the authority has not identified any objective factors that may potentially have caused such a rapid rise of the prices for the said products, it decided to launch an investigation against suppliers and retailers of food products and disposable medical mask assuming a violation of the Ukrainian competition law in their actions.

The other business industries, including socially sensitive, will be definitely closely monitored by the AMC.
Intellectual Property
Status: 13 May 2020

What does this mean for my health-related patents?
The government can, in the public’s interest or in the interest of protecting the state, request a compulsory license on inventions relevant to overcome a national epidemic. On 7 April 2020, the head of the Ukrainian parliament committee on national health, medical care and health insurance announced that a draft law on compulsory licensing of medical products for fighting the coronavirus infection should soon be submitted to the parliament for consideration.

Are there any trademark applications filed containing “COVID” or “CORONAVIRUS”?
As of 4 May 2020, there is an application for a *coviDEZ* trademark with respect to the goods of class 5 of the International Classification of Goods and Services (ICGS), filed by a private person in April, and an application for a "Коронавірус інфо" (Coronavirus info) trademark with respect to the services of class 38 of the ICGS, filed by a private person in March.

Are there any implications on pending patent, trademark and design registry proceedings in front of the Ukrainian Patent and Trademark Office (UPTO)?
No. The UPTO has not announced any ex officio extensions of currently pending time limits. The reinstatement of missed deadlines will be carried out in accordance with national and international legislation.

Is there any specific impact in the area of counterfeiting?
Some companies in the healthcare industry have noticed an increase in counterfeiting and fraudulent activities as a result of the COVID-19 pandemic. Due to the lack of urgently needed products such as respiratory masks and disinfectants, there is an increasing risk that fraudsters and counterfeiters will use brands of renowned manufacturers to fraudulently offer such products. Moreover, in the press there are already the first reports of seizures of counterfeit COVID-19 test kits (see the following article).

Trademark owners from potentially affected industries should monitor the market more closely and, for example, set up domain monitoring since fraudsters often register domains using the trademarks or corporate logos of the original manufacturers to make their offer appear legitimate.
INDUSTRY FOCUS: PHARMA & MEDICAL PRODUCTS
Have the pricing and reimbursement procedures for medicinal products and medical devices been affected?

Yes, the pricing and reimbursement procedures for medicinal products and medical devices have been affected as follows:

- Under Law No. 3539-IX “On Amending Certain Laws of Ukraine Aimed at Ensuring Treatment of Coronavirus Disease (COVID-19)” dated 30 March 2020, in addition to already existing powers to regulate prices, the government was additionally empowered to (i) set maximum wholesale and retail prices for anti-epidemic goods and socially significant products and (ii) prohibit mass buying and selling the same products at prices exceeding those set by the government during the quarantine. The list of anti-epidemic and socially significant products was established by the government on 22 April 2020. This list includes (i) certain food products, (ii) seven INNs of pharmaceuticals, including Paracetamol and Azithromycin, (ii) 11 antiseptics and disinfectants and (iii) 10 items of personal protective equipment, including medical masks, gloves etc. Change of retail prices for such products is subject to declaration.

- In addition, liability for violating pricing regulations was increased.

Are there any export bans applicable to medical or healthcare products?

Yes, the government prohibited the exportation of certain personal protective equipment, including respirators and medical masks, effective as of 22 March 2020. The list of goods that cannot be exported is set forth in Resolution of the Government No. 223 “On Preventing Export (Sending) of Certain Anti-Epidemic Goods outside the Customs Territory of Ukraine by Citizens” dated 16 March 2020.

Are there any tax incentives for suppliers of pharmaceuticals, medical devices or personal protective equipment?

Has the government adopted exceptional public procurement measures?

Yes, Law of Ukraine No. 530-IX and Resolution of the Government No. 226 “On Amending Certain Resolutions of the Government” dated 20 March 2020 envisaged an expedited and simplified procedure for the procurement of goods, works and services required to combat COVID-19. Under this procedure, public procurement entities may procure goods, works and services to combat COVID-19 outside the online Prozorro platform that is used under the standard procurement procedure. Under the simplified procedure, the procurement entity is authorized to establish its own criteria for selecting successful bidders. The procurement entity must only upload the procurement report, procurement agreement and performance report to the Prozorro platform.

Have procedural requirements been relaxed for COVID-19-related medicines and devices?

• No. At the same time, the Ministry of Health of Ukraine (MOH) is considering a draft order, whereby the legal timelines for approving MA/clinical trial applications may be extended due to quarantine. In addition, originals of MA certificates will not be issued until the end of the quarantine (the MA will be confirmed by entering relevant data into the state register of pharmaceuticals).
• Based on Law No. 3539-IX dated 30 March 2020, the government must ensure expedited legal timelines for approving MA (variation) and clinical trial (significant amendment) applications of pharmaceuticals for treating COVID-19. The government must ensure that MA (variation) applications are approved within seven calendar days, while clinical trial (significant amendment) applications are approved within 10 calendar days. To become effective, the same timelines must be introduced by the MOH to its orders establishing the procedures for granting MA and clinical trial approvals. As of 27 April 2020, the MOH has not yet introduced the required changes to its orders.
Has the government relaxed regulatory rules for medical devices and personal protective equipment?

Yes. Based on Resolution of the Government No. 226 dated 20 March 2020, personal protective equipment, medical devices, in vitro diagnostics and active implantable devices for combating COVID-19 may be placed on the market without conducting the conformity assessment set forth in the applicable technical regulations. To place products on the market in derogation of technical regulations, the applicant must submit to the State Labor Service of Ukraine (for personal protective equipment) or to the MOH (for medical devices, in vitro diagnostics and active implantable medical devices) the application containing information on, e.g., the purpose of importation, the product and its manufacturer. The State Labor Service of Ukraine or the MOH should issue a notification on introducing personal protective equipment and medical devices into circulation in derogation of the relevant technical regulations.

Has the government relaxed regulatory rules for pharmaceuticals?

Based on Law No. 3539-IX dated 30 March 2020, the Parliament of Ukraine permitted the off-label use of certain pharmaceuticals. The off-label use is permitted if a pharmaceutical has proven efficiency in treating COVID-19 and/or if a pharmaceutical is recommended by the authorities of the USA, EU member countries, the UK, Switzerland, Japan, Australia, Canada, China or Israel for the treatment of COVID-19. The Parliament of Ukraine also permitted the use of unapproved pharmaceuticals if they are recommended by authorities of the states set forth above for the treatment of COVID-19. At the same time, Law No. 3539-IX does not provide guidance as to the form in which the authorities should recommend pharmaceuticals for treating COVID-19 or guidance on how the proven efficiency of a product in treating COVID-19 should be confirmed. Apparently, these criteria are yet to be clarified by the MOH. The use of unapproved pharmaceuticals and the off-label use of approved pharmaceuticals are only permitted subject to obtaining the patient’s consent. Such pharmaceuticals must be used in compliance with the clinical protocol approved by the MOH on 2 April 2020.
Have special measures concerning clinical trials been adopted?

- Yes, the regulator for clinical trials (the State Expert Center of the Ministry of Health of Ukraine (State Expert Center)) has issued recommendations regarding conducting clinical trials in view of the spread of COVID-19. Among other things, the safety measures that may need to be taken include the following:
  - replacement of personal meetings by phone calls, video calls, the use of electronic communication devices, etc.
  - remote monitoring, provided it does not create an extra burden on trial sites, and the subjects’ consent to the sharing of their personal information outside the trial site
  - withdrawal of subject from trials
  - temporary halt of a trial/recruitment of new subjects
  - transfer of participants to other sites
  - direct-to-patient shipment of trial products
  - laboratory testing outside of the trial site or at the patient’s home
  - visits to patients at their residential address by investigators for clinical and diagnostic tests
  - use of telemedicine technologies
  - when there is a need to re-consent, investigators may obtain oral informed consent supplemented with email confirmation

- An increase in study protocol deviations in relation to COVID-19 will not be considered as a serious violation, so there is no need to notify this to the State Expert Centre immediately (unless patients are being put at risk).

- Inspections of clinical trial sites by the State Expert Center scheduled for Q1 2020 were rescheduled for Q2 2020.
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