Key healthcare and life sciences developments: Ukraine

The Ukrainian regulatory framework in the Life Sciences and Healthcare Sector (medicinal products, medical devices, and veterinary medicinal products) has been undergoing significant changes recently, with some major reforms in progress. In this article, we discuss the key recent developments in 2021 and look forward to developments in 2022.

I. HEALTHCARE

In 2021, the Ukrainian authorities continued the implementation of healthcare reform initiated in 2017. The main developments included:

— Continued increase in public funding for healthcare. For 2022, the total financing for healthcare has been increased to more than UAH 194 billion, of which more than UAH 157 billion is allocated to finance the Guaranteed Package of Health Benefits covering primary, secondary, and specialised care, as well as outpatient reimbursement. The financing for the Guaranteed Package for 2022 increased drastically compared to 2020, when this financing was only UAH 70.4 billion.

— Further development of public funding infrastructure. This includes further institutional capacity building and strengthening of the National Health Service of Ukraine (the "**NHS**") and developing of the eHealth system.

— Adoption of the eHealth system development plan. At the beginning of 2021, the Ukrainian government adopted a development plan for the eHealth system to be effected by 2025, which will be implemented in the following two stages:

  First stage (2020–2022): improving the system and mechanisms for managing the e-Health system, creating a single medical information space, and the informatisation of healthcare facilities.

  Second stage (2023–2025): support for standardisation, technical regulation of electronic medical information systems, introduction of more detailed terminological dictionaries and classifiers, development of systems to support clinical solutions, personalised medicine, systems for processing large amounts of data, machine learning and artificial intelligence.

— Discussion around incentives to increase voluntary health insurance as a source of additional funding for local healthcare systems, initiated by public stakeholders.

II. PHARMACEUTICAL SECTOR

Comprehensive revision of pharmaceutical legislation

One of the highlights of 2021 is the development and consideration by parliament of a new draft law on medicinal products (the "**Draft**"). The Draft aims to revise comprehensively the regulatory framework of the Ukrainian pharmaceutical market (currently regulated by a law adopted in 1996), as well as align it with the respective EU framework.

Based on the available version of the Draft, several positive developments are expected, including:

— alignment with Directive 2001/83/EC on many topics, such as:

- clinical trials,
- marketing authorisation (with some exceptions),
- quality control,
- pharmacovigilance;

— improvement to the framework on combatting the falsification of medicines;

— introduction of expanded access to medicines, including compassionate use and post-trial access;

— regulation of the promotion of medicines to healthcare professionals.

However, some proposed changes raise concerns, such as:

— vesting all powers regarding medicine and medical device policymaking in one, supposedly new state body without adequate transitional provisions. While a single-body approach is practiced in some countries, this represents a complete overhaul of the existing system (consisting of a regulatory body and a separate quality inspectorate), which poses a high risk to the smooth functioning of the system;

— failing to align regulatory data protection and exclusivity provisions with Directive 2001/83/EC, which is contrary to obligations Ukraine has undertaken under the EU-Ukraine Association Agreement;

— legalising the parallel import of medicines without clear safeguards for their quality and safety.

The Draft is currently high on the political agenda. Its adoption is expected at the beginning of 2022. A minimum 30-month transition period is expected for most provisions to allow businesses to adapt to the new rules.

Health technology assessment (HTA)

The public HTA procedure concerning medicines was formally introduced into Ukrainian legislation at the end of 2020, and the government established the public HTA infrastructure in early 2021. The HTA is conducted for the purpose of including medicines on the National Essential Medicines List, other positive lists for procurement with state budget funds, the conclusion, extension and termination of managed entry agreements, as well as simplified regional procurement. Currently, the HTA is conducted by the HTA department at the State Expert Centre of the Ministry of Healthcare (the regulatory body under the MoH), but is expected to be taken over by a separate independent state enterprise before 1 January 2023. A key feature of the system is its transparency: both HTA applications and reports are public, except for information marked as confidential by the applicants. Despite its recent introduction, the HTA system is fully functional now, with at least a dozen HTA reports out by December 2021 that recommend various public financing options for innovative therapies.

It is expected that public HTA will be obligatory for medical devices from 2023.

Managed entry agreements (MEA)

The concept of MEAs was introduced into Ukrainian legislation in late 2020/early 2021. Ukrainian MEAs are confidential agreements between the government and innovative pharmaceutical companies for the reimbursement of novel therapies (without registered generics/biosimilars in Ukraine). MEAs can be concluded between the MoH (or the central medicines procurement agency if authorised by the MoH) and the applicant (the marketing authorisation holder for an innovative medicine in Ukraine or one of specific stringent regulatory jurisdictions).

MEAs can be applied for both in- and outpatient reimbursement. However, the regulatory framework is currently in place only for in-patient reimbursement, with the one for outpatient reimbursement expected in the future. The instrument of MEAs is currently in a test run until the end of 2023, with a more permanent legislative status expected on positive test run results.

Ukrainian legislation sets specific requirements for the negotiation, conclusion, amendment and termination of MEAs. The MEA process starts with positive HTA and recommendation from the HTA authority to start MEA negotiations regarding a particular medicine. Based on this, MoH initiates negotiations with the respective applicant. Successful negotiations end in a MEA and are followed by inclusion of the medicine on the necessary positive lists. Due to budget legislation constraints, MEAs may currently only be concluded for

a budget year, with the possibility of annual extension to up to three years. Interestingly, only the MoH can formally initiate the extension of a MEA based on a fast-track HTA. Both finance- and outcome-based, as well as mixed MEAs are possible. A MEA must be terminated by the end of the budget year once the first generic (or biosimilar) medicine is registered in Ukraine.

As of December 2021, negotiations for the first MEAs were already underway, and the first MEAs are expected very soon.

Outpatient reimbursement

Before October 2021, the government ran two different reimbursement programmes: one for insulin and the other for "Affordable Medicines" (medicines for diabetes type II, cardiovascular diseases, asthma). The programmes ran under different rules and were administered by different entities. On 1 October 2021, the insulins programme was merged with "Affordable Medicines", making the NHS, which administered the latter before October 2021, the sole administrator of the new version of the programme.

The list of reimbursable diseases has additionally been expanded, and now includes mental, behavioural disorders and epilepsy, in addition to those already mentioned. The NHS plans to expand the programme depending on availability of budget funds, including with modern classes of cardio-vascular products, neurology products and medical devices.

Inpatient reimbursement (public procurement)

The state enterprise "Medical Procurements of Ukraine", a central procurement agency (the "**CPA**") of the MoH, which was founded in 2018 to take over centralised procurement of medical products from the MoH, has since demonstrated positive results and gained a good reputation in the industry. It currently conducts centralised procurements alongside international procurement organisations (such as Crown Agents and the UNDP), that have temporarily fulfilled the centralised procurement function on behalf of the MoH since 2015. The procurement mandate of international organisations is effective until 31 March 2022 but is expected to be extended until 30 April 2023. Once the mandate is over, the CPA will handle the centralised procurement of medical products on its own.

Apart from centralised procurement, since October 2021 the CPA has been able to act as a procurer for regional healthcare authorities and medical institutions contracted to implement a guaranteed package of health benefits. Until 1 April 2022, this will be implemented as an experiment, with a possibility of it becoming a permanent functionality of the CPA on the positive results of the experiment.

III. MEDICAL DEVICES

Draft Law On Medical Devices

The Ukrainian regulatory framework on medical devices currently consists of:

— three technical regulations, in the form of subordinate legislation, adopted in 2013 based on the respective EU directives; and

— general laws (i.e. not specific to medical devices) on technical regulation, product safety and market surveillance.

For a while there has been talk of the need for a separate law focusing exclusively on medical devices, to regulate all aspects of this sector comprehensively, such as conformity assessment, clinical trials, imports, circulation, recognition of conformity assessment conducted abroad, etc.

The intention to have a separate law was formalised in the Order of the President of Ukraine #369/2021 on urgent measures in Ukrainian healthcare, under which the Ukrainian government was instructed to submit the draft to the parliament before 15 December 2021. The draft was developed by the MoH and published for public discussion but has not made it to the parliament yet. The consensus appears to be that it is very raw and does not offer anything substantially new to the current regulation, and therefore requires significant revision. Given this, we expect the draft will be further developed and submitted to the parliament in 2022.

IV. PERSONAL DATA PROTECTION

Comprehensive revision of data protection legislation

Ukraine is striving to revise comprehensively its data protection legislation (currently based on data protection Directive 95/46/EC) and align it with new EU standards as a commitment under the EU-Ukraine Association Agreement. To this end, two draft laws are registered in the parliament:

— on Personal Data Protection, aimed at revising **substantive** data protection provisions; if adopted, it will replace the existing Law on Personal Data Protection;

— on the National Commission for Personal Data Protection and Access to Public Information, aimed at providing an adequate **procedural** framework to implement new substantive data protection provisions.

If adopted, the new legislative framework will to a significant extent implement GDPR provisions.

In particular, the drafts:

— regulate in detail the rights, duties and responsibilities of the data controller and processor;

— establish detailed and transparent requirements for consent for data processing;

— significantly increase fines for breaches of data protection legislation;

— establish a procedure for notifying the competent authority of a data breach;

— introduce the concept of the Data Protection Impact Assessment;

— regulate in more detail cross-border transfers of personal data;

— significantly expand the rights of the data subject.

The drafts also envision the creation of a new independent executive body with a special status capable of implementing best international practices at the national level in the field of personal data protection.

The new Law on Personal Data Protection is supposed to have its first hearing in parliament in early 2022. If adopted in its current wording, it will come into force on 1 January 2023.

The second draft (on procedural matters) is still being considered by parliamentary committees. Voting on it is expected in 2022–2023.

V. CANNABIS

In recent years, Ukrainian officials, including the president, numerous MPs and MoH representatives, have been repeatedly raising the question of whether to legalise the medical use of cannabis.

In April 2021, the Ukrainian government introduced amendments to its bylaw, which lists the schedules of controlled psychoactive and narcotic substances under Ukrainian law. The amendments allow for the limited use of certain cannabinoid-based psychoactive substances (Nabilone and Nabiximols), and clarify the legal status of CBD isolate and CBD isolate-based products in Ukraine.

Additionally, in July 2021 a consolidated draft of new legislation on medical cannabis, sponsored by a large cross-party group of MPs including leaders of the majority party and heads of key parliamentary committees, was submitted to the parliament, but failed to receive the number of votes needed for adoption.

In November 2021, another attempt to amend current regulations on cannabis use was made. This time it originated from the MoH. On 17 November 2021, the MoH published a Draft Law “On Amendments to Certain Legislative Acts of Ukraine On the Regulation of the Circulation of Cannabis Plants for Medical, Industrial and Scientific Purposes” for public consultation.

If adopted, the Draft will introduce substantive changes to the current legislative landscape; specifically, it will:

— legalise the cultivation of medical cannabis and its use by patients on a prescription basis;

— allow the limited use of medical cannabis for scientific purposes;

— clearly define industrial hemp, products derived from it and products of its processing, containing less than 0.2% THC in dried straw, as non-controlled substances;

— establish more transparent rules for the cultivation of cannabis plants for medical purposes;

— establish more detailed and transparent rules on control over cannabis circulation.

We expect that it will be able to generate the required support and parliament will adopt it at the beginning of 2022 at the latest.

VI. ANIMAL HEALTH

New Law on Veterinary Medicine

On 21 March 2023, the new Law On Veterinary Medicine (the "**Law**") will come into force, subject to the transitional provisions detailed below. The Law is aimed at approximating Ukrainian veterinary legislation with EU directives and regulations as a part of the fulfilment of obligations under the EU-Ukraine Association Agreement.

The Law provides for a comprehensive regulatory framework in the field of veterinary medicine, animal health and wellbeing, veterinary practices, and the use of veterinary medicines. It defines the system of governance and functions of regulatory bodies, principles of development, approval, review and application of veterinary measures, e.g. anti-epizootic measures, defining the criteria for inspections, testing, and certification.

The key novelties of the Law concerning **veterinary medicines** are:

— Only legal entities (dossier holders) incorporated in Ukraine can apply for and obtain registration certificates (marketing authorisation). If the dossier holder is a foreign legal entity, it must appoint an official representative in Ukraine: either a local subsidiary or a contracted third party.

— In addition to the manufacturing of veterinary medicines, the new law establishes licensing requirement for all activities related to the circulation of veterinary medicines: manufacturing, import, wholesale and retail.

— The Law permits licensed retailers to sell veterinary medicines remotely in accordance with e-commerce legislation. The remote sale of prescription veterinary medicines is prohibited. The Law also provides for special requirements for websites, where veterinary medicines are offered for sale online.

— The Law provides for the protection of regulatory data in the registration dossier for novel veterinary medicines. The marketing authorisation holders will be granted exclusivity for 10 to 18 years, depending on the type of veterinary medicine. This provision will be subject to a transition period: the exclusivity period for the veterinary medicines submitted for registration during the first five years after the Law's entry into force will be half as long.

— The Law amends the Law On Advertising by establishing specific requirements for advertising veterinary medicines and medicated feeds, partly aligned with the respective EU legislation.

— The Law also introduces a national system of veterinary pharmacovigilance.

From the international industry perspective, the adoption of the Law is a positive development in the field of veterinary medicines. The Law implements measures to ensure better quality, safety and efficacy of veterinary medicines, e.g. licensing, the requirement to appoint a qualified person, pharmacovigilance, and provides for better protection for innovative companies. Following the full enactment of the Law, the regulatory framework of Ukraine in veterinary medicines will become compatible with the EU's.

Currently, the Ukrainian government is developing secondary legislation so the Law should be adopted by 23 March 2022.

VII. HEALTH TECH

Ukraine is an attractive destination both for local and international big tech and outsourcing companies, as well as for local health tech product companies and start-ups that are developing products and technical solutions, mainly with a focus on the US, EU and significant Asian markets.

A recent legislative development that can potentially contribute to the development of the tech sector as a whole, and the health tech sector in particular, is the adoption of the Law On Stimulating the Development of the Digital Economy in Ukraine (the "**Diia.City Law**") by the Ukrainian parliament on 15 July 2021.

The Diia.City Law establishes a special preferential regime for IT companies that are residents of the Diia.City technology park. It sets general requirements for such residency and guarantees the protection of the residents.

Another long-awaited pillar of the Diia.City regime is the tax incentives, implemented through a separate law, adopted on 14 December 2021.

The key novelties of the Diia.City Law are:

— the introduction of a gig-contract as a new contractual model for Diia.City residents to engage IT personnel, which combines the features of typical employment and civil law service agreements;

— permission to conclude non-compete agreements with IT personnel and the requirements for these agreements (maximum duration, conditions of remuneration, etc.);

— enabling the appointment of legal entities as the management bodies of Diia.City residents;

— additional intellectual property rights' protection for IT companies engaging IT professionals under gig-contracts.

Diia.City benefits will be available only to entities registered in Diia.City. This residency is subject to compliance with a set of specific eligibility requirements, including registration in Ukraine, conducting an IT-related business, having at least nine employees or gig-contractors, and ensuring that the average monthly compensation of such employees or gig-contractors exceeds EUR 1,200 (in UAH equivalent).

The Diia.City regime is expected to function for at least 25 years from the date of registration of the first Diia.City resident.

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