Medicines and Medical Devices in the EU Single Market – Dreams and Reality

First AIJA Healthcare Seminar Held in Zurich from 27–29 June 2019

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I. Introduction

From 27 to 29 June 2019, 50 participants from 18 countries attended the first AIJA Healthcare Seminar on *"Medicines and medical devices in the EU Single Market – dreams and reality"* in Zurich.[1] The seminar was organized by members of the Association Internationale des Jeunes Avocats ("AIJA"), who had formed a Healthcare Special Interest Group with the goal of being instituted as new Commission of AIJA in the near future.

The topics discussed included parallel trade, the new Clinical Trials Regulation ("CTR")[2], the impact of the new medical devices regulations ("MDRs")[3] on study agreements and distribution contracts, challenges for the healthcare industry in view of Brexit, and the Falsified Medicines Directive ("FMD")[4]. In addition, two interesting keynote speeches on portfolio transformation and the Swiss regulatory system formed part of the program.

II. Summary of Keynote Speeches and Panel Discussions

A. Keynote Speech on Portfolio Transformation in Export Markets

The seminar was kicked-off with a keynote speech given by Dr. Stefan Ibing from Novartis Pharma Services AG (Switzerland). The speaker provided practical insights into portfolio transformation of a pharmaceutical company in export markets. Stefan Ibing explained to the participants that portfolio transformations are often structured as asset deals and that therefore, business units needed to be switched country by country, asset by asset and employee by employee. In a very interesting discussion with many questions raised by the audience, he talked in detail about possible issues with regard to the transfer of personnel, the transfer of product assets as well as the reorganization of the supply chain. The speaker

* The author co-organized the first AIJA Healthcare Seminar and moderated the panel on the new MDRs and their impact on study agreements and distribution contracts.

1 A full program of the seminar is available at https://www.aija.org/en/event-detail/442 (website last visited on 27 August 2019).

2 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ("CTR").

3 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ("MDR") and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ("IVDR") (together the "MDRs").

4 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products ("FMD").

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inter alia reminded the participants to always verify the tender situation, i.e. to clarify whether there are any open tenders that are still unfulfilled, whether tender applications have been filed and if so, what their status is. Clarifying the tender situation is particularly important in case of a change in distributor in a respective country.

B. Panel and Workshop on Parallel Trade

The panel moderated by Martin Abraham (Czech Republic)[5] and consisting of Marek Holka (Slovakia), Indrikis Liepa (Latvia), Dr. Philippe Seiler (Switzerland) and Koen T'Syen (Belgium) addressed experiences with parallel imports and exports of pharmaceuticals. In the session's first part, the panel discussed the legal situation in the EU and the individual Member States as represented in the panel. The speakers inter alia critically assessed the legality of strategies pharmaceutical companies could resort to in order to try limiting parallel trade, such as supply quota systems, dual pricing, "direct to pharmacy"-systems and product life cycle management strategies. The evaluation of these practices is to be made under the (EU and national) competition law rules and the EU pharmaceutical regulatory framework, including the obligation of continuous supply applying to marketing authorization holders and distributors. The panel further discussed whether and to what extent EU Member States are allowed to adopt legislation that restricts parallel trade to tackle the problem of medicine shortages. The speakers explained that the validity of such national legislation is to be assessed under the EU rules on the free movement of goods. With regard to Switzerland and based inter alia on the Swiss Federal Supreme Court's decision in the Elmex-case,[6] it was concluded that restrictions of passive sales were generally considered forbidden restrictions of competition unless justified for reasons of economic efficiency (e.g. reduction of distribution costs also in favor of end customers), whereby restrictions of active sales outside of a certain territory and selective distribution systems were generally considered allowed.

In the session's second part, the active participation of the audience was required, as a complex case scenario involving parallel trade of pharmaceuticals was presented that needed to be analyzed in small groups. After short preparation time, each group had to present and plead its case before the mock tribunal presided by Dr. Stefan Ibing and consisting of the panelists. The key learning from the mock trial was that even if the legal principles such as the principle of proportionality were clear, it was far from easy to apply them in practice. A careful analysis is required in light of the factual circumstances of each individual case.

C. Panel on the New Clinical Trials Regulation

Tímur Akhundov (Russia), Dr. Jan Henning Martens (Germany), Jackie Mulryne (United Kingdom) and Nina Studer (Switzerland) got to the bottom of the new Clinical Trials Regulation[7] that has entered into force on 16 June 2014, but will only enter into application after an independent audit and a period of six months starting from a confirmation notice published by the European Commission. It is currently estimated that the CTR will come into application during 2020.[8] The CTR harmonizes the assessment and supervision process for clinical trials throughout the EU and aims at setting the highest standards of safety for study participants as well as increasing transparency of trial information.[9] Against this background, the panel pointed out that the new CTR as "single entry point" particularly facilitates multicenter studies. Local ethics approval must, however, still be obtained.

Specifically addressed was the rather tricky interplay between the CTR and the GDPR.[10] On the one hand, the GDPR provides that a data subject must at all times be able to withdraw consent and request the deletion of its data.[11] On the other hand, according to the CTR,[12] a withdrawal of the informed consent given to take part in a clinical trial shall only be possible for the future in the sense that activities already carried out and the use of data obtained based on informed consent before its withdrawal, are not affected. The speakers called the audience's attention to this issue and informed that the European Commission had addressed the interplay between the CTR and the GDPR in a Q&A document published on 10 April 2019.[13] In this document, the European Commission points out that the informed consent in the context of the CTR is a safeguard and not a legal basis for data processing, which is why it is important to distinguish between the requirement for consent from a person to participate in a clinical trial on the

5 Unless indicated otherwise, all speakers mentioned practice law at law firms based in the mentioned countries.

6 Decision Swiss Federal Supreme Court of 28 June 2016, 143 III 297.

7 See fn. 2 above.

8 See, e.g., https://ec.europa.eu/health/human-use/clinical-trials/regulation_de (website last visited on 27 August 2019).

9 See, e.g., the website of the European Medicines Agency at https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation (website last visited on 27 August 2019).

10 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) ("GDPR").

11 See in particular Articles 7(3) and 17 GDPR.

12 See in particular Article 28(3) CTR.

13 Full text available at https://ec.europa.eu/health/sites/health/files/files/documents/qa_clinicaltrials_gdpr_en.pdf (website last visited on 27 August 2019).

one hand, and the requirements for a lawful processing of personal data under the GDPR. According to the Commission's view, the withdrawal of consent to participate in a clinical trial under the CTR may, thus, not necessarily affect the processing of personal data gathered in the context of that trial. The personal data may continue to be processed where there is an appropriate legal basis for such processing under the GDPR. In such cases, the personal data of that person gathered before the withdrawal shall be kept for the purposes and under the conditions defined in the study protocol and the legislation. Based on these guidelines, the speakers discussed whether one should, in a clinical trial context, rather rely on other grounds for the processing of personal data than on consent, because (i) if consent is used as the lawful basis for processing, there must be a possibility for individuals to withdraw that consent at any time and there is no exception to this requirement provided for under the GDPR with regard to scientific research, and because (ii) withdrawal of consent under the CTR does not affect the processing operations that are based on other lawful grounds, such as legal obligations of the sponsor and the investigator (e.g. with regard to adverse event reporting).

The panelists also drew the audience's attention to the small differences between the CTR and current Swiss law and explained possible Brexit-scenarios with regard to the implementation of the new CTR and its impact on ongoing clinical trials. Finally, the panelists provided an introduction to the Eurasian Economic Union ("EAEU") unified market of medicines of which inter alia Russia forms part.

D. Keynote Speech on the Challenges and Opportunities of the New MDRs from a Swiss Perspective

Keynote speaker Dr. Carlo Conti (Switzerland) spoke on the challenges and opportunities faced by Switzerland in view of the transposition of the MDRs[14] into Swiss law. He particularly stressed the importance of negotiating – in parallel to such transposition by way of making the necessary adaptions to the respective Swiss laws (such as the TPA,[15] the MedDO,[16] etc.) – an update of the mutual recognition agreement in relation to conformity assessments ("MRA").[17] Only such update would allow Switzerland to continue participating in and preserving market access to the EU market as equal as today.

The speaker further emphasized that it was crucial for the Swiss regulator (Swissmedic) to be able to continue cooperating intensively with the market surveillance authorities of the EU Member States.

E. Panel on the New MDRs and Their Impact on Study Agreements and Distribution Contracts

Marco Blei (Italy), Arne Feber (Czech Republic), Dan Mihai (Romania) and the Author (Switzerland) of this seminar report (Switzerland) talked about practical impacts the new MDRs will have on study agreements and distribution contracts. Based on the increased transparency demands posed by the MDRs, the panel inter alia addressed the new Unique Device Identification ("UDI") requirements as well as the fact that rather extensive information on clinical studies with medical devices will become publicly accessible based on their inclusion into the European database on medical devices ("Eudamed"). The speakers further pointed out that the MDRs provide for disclosure of quite far reaching design and manufacturing information[18] and that stakeholders should, thus, be even more aware to accurately protect their trade secrets, know-how and intellectual property rights in time, e.g. by implementing sufficient confidentiality clauses into both, agreements relating to studies with and the distribution of medical devices.

The panelists also discussed the interesting question of whether a manufacturer of hi-tech medical devices may implement a selective distribution system in a manner that is compliant from a competition point of view.

Further views were exchanged on the impacts of the MDRs on liability clauses in distribution contracts. Despite the MDRs quite clear assignment of obligations and liabilities to the manufacturer, the authorized representative (if any), the importer and the distributor, it was deemed very important to clearly allocate liabilities in a distribution contract between the various subjects in the distribution chain and to answer at least the following questions: Who is responsible? For what? And to what extent?

With regard to data protection impacts, besides the generally strengthened conditions for consent and the enhanced information rights as well as typical data protection clauses in distribution and clinical study contracts, the panel elaborated on the required content of an informed patient consent to participate in a clinical study. Next to the essential information on the kind of personal data processed, the purpose as well as the legal basis for processing, the privacy information accompanying the consent form should also include information on how the data subject's rights are protected. Specific consent requirements may apply, for instance, to the collection of biological samples as well as to the further use of personal data for future scientific research.

14 See fn. 3 above.

15 Swiss Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act ["TPA"]) (SR 812.21).

16 Swiss Medical Devices Ordinance ("MedDO") (SR 812.213).

17 Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 21 June 1999 (SR 0.946.526.81) ("MRA").

18 See, e.g., Article 10 (4) in conjunction with Annex II (3) MDR.

F. Brexit-Panel on Challenges for the Healthcare Industry

A lot has already been written and said about Brexit – most of it sounds like a glimpse into the crystal ball. The panel consisting of Dr. Amalia Athanasiadou (Switzerland),[19] Michaela Herron (Ireland) and Ewan Townsend (United Kingdom), however, managed to present a very relevant and interesting analysis of the different Brexit-scenarios and the challenges for the healthcare industry (pharma and medical device companies).

The panel not only discussed what will happen to the marketing authorizations issued based on EU law, but also explained that Brexit gives raise to supply chain challenges, such as the need of finding a balance between the fear of "out of stock" versus the risk of overstocking. Also other challenges, such as the end of free movement of goods, questions of infrastructure locations and concerns with regard to quality risks due to delays at the border were addressed. Interestingly enough, pharma companies may have reservations about working with service providers having their servers in the UK, due to questions of data protection.

The speakers further pointed out that there were different possible scenarios to keep in mind with regard to the exhaustion of intellectual property rights and parallel trade as the UK will have to choose which exhaustion regime to apply: international exhaustion, exhaustion within the EEA (regional), or national exhaustion.

With regard to medical devices, a hard Brexit would mean inter alia that an authorized representative must be established within the EU27 and that UK notified bodies would no longer be listed on the EU Commission's information system.

G. Panel on the Falsified Medicines Directive

The panel consisting of Michal Chodorek (Poland), Per Hedman (Sweden), Clara Pirez (France) and Barbora Vrablova (Czech Republic), moderated by Ilja Czernik (Germany), introduced the Falsified Medicines Directive.[20] The audience was informed that the safety features provided for by the FMD applying since 9 February 2019, such as the inclusion of a Unique Identifier ("UI") on the outer packaging as well as a device allowing verification of whether the packaging has been tampered with (so called Anti-Tempering Device ["ATD"]), needed to be mandatorily followed for prescription drugs (unless for prescription drugs listed on the exemption list), but not for OTC-products (unless for OTC-products listed on the mandatory list). The panel, however, cautioned to bear in mind that each EU Member State had the opportunity to be stricter, so the locally applicable requirements should always be checked. The speakers further explained that the FMD was only applicable to drugs for human use placed on the European market, but not to veterinary use products.

According to the panelists, the biggest challenges in implementing the FMD lie with the middle of the supply chain, because both, the manufacturer's responsibilities (e.g. to seal the products, to affix the UI and upload it to the European hub [the EMVS[21]]) and the dispensing healthcare institution's duties (e.g. to verify and decommission each product against the EMVS and national verification systems) are quite clearly regulated. This is, however, not the case with regard to the responsibilities of wholesalers and distributors, despite the Commission Delegated Regulation (EU) 2016/161[22] detailing how medicine authenticity shall be verified and by whom. In general, Article 10 of the Commission Delegated Regulation states that also wholesalers must verify the authenticity of the UI and the integrity of the ATD. Chapter V then, however, only addresses the case of a middle supply chain consisting of one wholesaler only. I.e., it remains unclear if and to which extent the safety features must be verified as well by other stakeholders of the supply chain, such as distributors, sub-distributors or logistic providers. The speakers further pointed out that verification of compliance was additionally complicated as there are no aggregated product codes. It is, thus, not sufficient to check one code, but every single code and package must be checked, which is impracticable.

III. Closing Remarks

The first AIJA Healthcare Seminar has shown the need for a forum to exchange views and practical experiences in the highly regulated field of life sciences. Both, in-house and external counsels of pharmaceutical as well as medical device companies benefit from such exchange in their daily practice.

The seminar in Zurich was hopefully only a first step in this direction. In any case, the AIJA Healthcare Special Interest Group is already planning further seminars and expects to organize them, in the near future, as formal AIJA Commission.

19 In-house counsel/industry speaker.
20 See fn. 4 above.
21 EMVS stands for the European Medicines Verification System.
22 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.