COVID-19 - Legal Implications for Pharmaceutical and Medical Device Companies in Germany

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The impact of Coronavirus (COVID-19) on pharmaceutical and medical device companies has been unique as, not only have these businesses had to set up emergency management systems practically overnight in order to maintain normal their business operations, the population also expects the sector to make significant contributions to the fight against COVID-19.

The current crisis mode raises a variety of legal and commercial questions. This article addresses a number of key issues that specifically affect the pharmaceutical and medical device industry in Germany.

IN DEPTH

Clinical Trials

COVID-19 is already causing considerable delays to numerous clinical studies, which may in individual cases lead to deviations from the study plan. The German Federal Institute for Drugs and Medical Devices (BfArM) will shortly publish EU-wide
harmonised recommendations for clinical trials, which at this point are still coordinated among the Member States.

BfArM is currently prioritising the processing of amendment notifications required owing to COVID-19. The authority has asked for a reference to COVID-19 in the subject line of the notification letter to facilitate this. As far as possible, BfArM also encourages pharmaceutical companies to submit their amendment notifications electronically via the Common European Submission Portal. For inquiries about clinical trials in connection with COVID-19, BfArM has set up a dedicated e-mail address: CT-COVID@bfarm.de.

The European Medicines Agency (EMA), together with the European Commission and the Heads of Medicines Agencies (HMA), on 20 March 2020 published an initial Guidance on the Management of Clinical Trials during the COVID-19 pandemic. EMA points out that sponsors should carefully and critically question whether or not they need to start a new clinical study or include new study participants in an ongoing study. With regard to ongoing studies, sponsors should in particular consider whether and to what extent they may temporarily suspend the study in certain facilities and/or extend the intended overall duration of the study. In individual cases—in the interest of the health of the study participants—it may also make sense to modify the conduct of a study, e.g., transfer study participants to another institution or replace visits with video or telephone conferences.

Pharmaceutical companies should review the effects of COVID-19 on their upcoming and ongoing clinical trials, revise their existing study concepts and, if necessary, contact BfArM or EMA at an early stage in order to submit any amendment notifications or clarify uncertainties.

Impending Supply Bottlenecks

The increasing spread of COVID-19 poses a medium and long-term risk to the supply of drugs. In India, many contract manufacturers have restricted or completely stopped production, which is why the Indian government has recently limited the export of 26 pharmaceutical ingredients to Germany. For several weeks now, attention has also been turning anxiously to China, where the majority of all generic drugs are produced for the German market.

Pharmaceutical companies should keep an eye on the production networks and supply chains relevant to them and, where possible, ensure that they do not depend exclusively on individual suppliers. If there is a risk of a supply bottleneck in a specific case, e.g., owing to a contract manufacturer having to reduce or discontinue its activities, pharmaceutical companies should review their rights under the respective contracts in order to at least limit adverse commercial effects.

BfArM Allocation Order

On 20 March 2020, BfArM published an allocation order on the storage and demand-driven supply of human drugs. The allocation order requests that pharmaceutical companies and wholesalers not to supply drugs beyond the usual demand.
The purpose of the order is to counteract the typical trend during crises of stockpiling by individual market participants, which leads to an unequal distribution of drugs in the market. BfArM is making use of its (only recently extended) powers to take vigorous action against drug supply bottlenecks.

The order applies to “supply-relevant drugs”, which includes prescription drugs with an active ingredient that is particularly relevant to public health. Pharmaceutical companies should examine to what extent their drugs are affected by the allocation order. The current list of supply-relevant active substances is available on the BfArM website.

**Expedited Digital Transformation**

Pharmaceutical and medical device companies are being required to carry out a digital transformation in the shortest possible time, at least in certain areas.

For example, the sales force is no longer able to carry out consulting and advertising activities at doctors’ premises, but it’s not clear whether and how the sales force can “work from home” instead. Internal and external trainings must be cancelled and, as far as possible, converted to digital platforms such as video conferences, webinars, etc. In the context of cooperation with other players in the health system, including healthcare professionals, communication channels may also have to be changed.

The new, primarily digital, approach to work raises particular data protection issues in individual cases. If, and to the extent that, these new digital approaches relate to cooperation with healthcare professionals, they must also be checked for compliance with existing applicable drug advertising, and social, criminal, and professional laws and regulations.

**Accelerated Market Access For Drugs to Treat COVID-19**

Legislation relating to the pharmaceutical sector provides for a number of procedures to ensure rapid market access for drugs in particularly sensitive cases.

At EU level, these procedures include, in particular, the Priority Medicine (PRIME) system, which enables accelerated assessment and granting of conditional approval for priority medicines. The EMA currently offers free scientific advice for the benefit of companies developing vaccines or therapeutics against COVID-19. These companies are invited to contact EMA at 2019-ncov@ema.europa.eu.

BfArM and the Paul-Ehrlich-Institute (PEI), which is responsible for the marketing authorisation of vaccines in Germany, currently give priority to projects that relate to the diagnosis and/or treatment of COVID-19. This concerns in particular applications for scientific advisory procedures and applications for authorisation of clinical trials, in relation to both drugs and medical devices. BfArM and PEI currently accept successive submission of marketing authorisation application documents in order to speed up the review of the application. The consultation fee in relation to COVID-19 treatment can be reduced to a quarter of the statutory fees.
Pharmaceutical companies that possess a potential active substance against COVID-19 should immediately contact the competent national drug authority (BfArM and/or PEI) and/or the EMA in order to speed up the market entry procedures for these substance as much as possible. Without an authorisation for the treatment of COVID-19, the pharmaceutical company must carefully examine whether and to what extent it may use the active substance outside clinical studies, for example in Compassionate Use Programs. Drugs that already have a marketing authorisation outside the European Union may in certain circumstances be imported to Germany on an individual basis.

**Restricted Applicability of Rebate Contracts**

Several statutory health insurance funds have already restricted the application of their rebate contracts. In these cases, instead of a discounted drug that is not in stock, pharmacists may supply a non-discounted drug to insured persons. This facilitates patient care in the case of supply failures caused by COVID-19.

It is likely that other health insurance funds will follow suit.

**Market Entry Facilitation For PPE And Selected Medical Devices**

The spread of COVID-19 has led to an extraordinarily high and further increasing demand for protective goggles and visors, mouth-nose protection equipment, and protective clothing and gloves. These products qualify as personal protective equipment (PPE) or medical devices whose market entry usually requires a—sometimes lengthy—conformity assessment procedure and Conformité Européene (CE) marking.

In order to adapt the supply of these products to the increasing demand as quickly as possible, the European Commission seeks to simplify, to a considerable extent, the market entry for PPE and medical devices with its Recommendation (EU) 2020/403 of 13 March 2020.

In the Recommendation, the Commission requests the competent market surveillance authorities and notified bodies to take all available measures to provide immediate access to PPE and medical devices for healthcare professionals for the duration of the current health threat. Accordingly, PPE and medical devices may be placed on the market temporarily and in certain circumstances even without CE marking.

Medical device companies should carefully consider, and coordinate with the competent supervisory authorities and notified bodies to determine, whether or not their products are eligible for market access facilitation in line with the Commission Recommendation.

**Export of PPE And Selected Medical Devices Subject to Authorisation**

PPE and certain medical devices in particular demand as a result of COVID-19 are currently manufactured in only a few Member States. Some countries have already prohibited the export of protective equipment to ensure they meet their own needs.
In order to continue to meet the high demand for PPE and selected medical devices in the European Union in the future, the Commission, in Regulation (EU) 2020/402 of 14 March 2020, temporarily made the export of certain products subject to authorisation. An export license will only be issued in special, individual cases.

These new export restrictions are problematic for companies whose products fall within the scope of the Regulation and which are contractually obliged to supply these products to third countries. In these cases, the companies will have to assess whether an export license can be considered and, if not, what legal and other options exist to deal with the export ban in the context of the business relationships concerned.

**Moratorium And Emergency Plan for The Medical Devices Regulation?**

In the light of COVID-19, leading associations in the medical device industry are calling for a moratorium on the conversion to the Medical Devices Directive (MDR), which could barely be achieved in time even before the crisis.

The temporary closure of competent authorities and notified bodies is making it even more difficult for medical device companies to obtain new CE certificates under the MDR requirements. Whether and to what extent COVID-19 will have an impact on the date of application of the MDR is, however, currently still open.

In addition to the moratorium at EU level, the German Medical Technology Association (BVMed) is calling for the preparation of a national MDR emergency plan for Germany. In particular, BVMed calls for the plan to provide for a special national approval for the entire product range certified to date in order to exclude supply bottlenecks for patients in the course of the MDR conversion. Moreover, BVMed proposes inventory protection for established old products for which an MDR certification procedure is already pending but which, owing to the ongoing crisis, will probably not be completed in time.

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