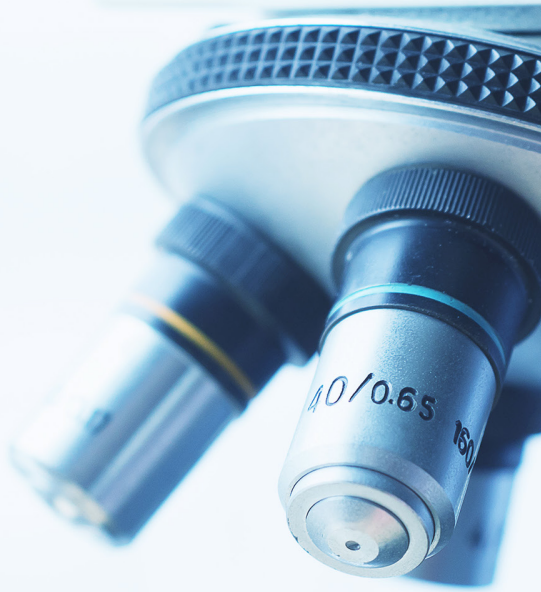
Chambers AND PARTNERS

CHAMBERS GLOBAL PRACTICE GUIDES

Life Sciences 2024

Definitive global law guides offering comparative analysis from top-ranked lawyers



Poland: Trends & Developments

Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał
Monika Duszyńska Kancelaria Adwokacka

Trends and Developments

Contributed by:
Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał
Monika Duszyńska Kancelaria Adwokacka

Monika Duszyńska Kancelaria Adwokacka is a boutique law firm focusing on the life sciences sector. It assists pharmaceutical and medical devices manufacturers. The firm has three senior lawyers who provide daily support in commercial and regulatory areas. It advises on IP (licences, R&D agreements, and purchases of registration dossiers), contracts with healthcare professionals, patients' organisations, contract manufacturers, suppliers, grants and donations. The firm assesses permitted relationships with healthcare providers, advises on or audits marketing studies and activities. It counsels in regulatory matters, pharmaceutical advertising, clinical trials and reimbursement. The firm also advises on distribution and manufacturing of medicines and medical devices, including drafting relevant contracts.

Authors

Monika Duszyńska has 24 years of professional experience, starting at Eversheds before moving on to CMS Cameron McKenna, where for three years she co-headed the life sciences practice in Central and Eastern Europe. For the past ten years Monika has managed a law boutique, Monika Duszyńska Kancelaria Adwokacka, focusing on providing legal assistance to international and local pharmaceutical companie. She advises on advertising, distribution, compliance, reimbursement and IP, as well as regulatory issues such as manufacturing, importation, Good Manufacturing Practices and GDP, under Polish and EU regulations. Her expertise covers pharmaceuticals, medical devices and food supplements. Monika has co-authored a number of books and other publications for the pharmaceuticals industry.

Tomasz Jędrejko has 18 years of professional experience - most of which have involved providing legal services for the life science industry. Tomasz has experience in M&A transactions, licensing and manufacturing agreements concerning medicinal products, as well as compliance processes for industry entities. In M&A transactions, he has been responsible for conducting due diligence investigations and verifying regulatory compliance. For the past three years, Tomasz has worked for Monika Duszyńska Kancelaria Adwokacka, advising on and negotiating various contracts, including license-out and license-in agreements, contract manufacturing and supply agreements, and product development agreements. He also handles multiple proceedings before the Chief Pharmaceutical Inspector regarding costs of quality tests on medicinal products.

Contributed by: Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał,
Monika Duszyńska Kancelaria Adwokacka

Paulina Konefał is a lawyer at Monika Duszyńska Kancelaria Adwokacka, with four years of professional experience and a postgraduate degree in Management Pharmaceutical and Compliance Officer Studies. Paulina provides legal advice on the distribution, importation and promotion of medicinal products, medical devices, dietary supplements, cosmetic and biocidal products, as well as on compliance matters. She counsels on advertising materials and campaigns, research and educational projects, and procedures for marketing activities for clients from the pharmaceuticals and medical devices sector. Paulina also conducts training on marketing and promotional activities for regulated products, pharmacovigilance, as well as clinical trials and patients' rights.

Monika Duszyńska Kancelaria Adwokacka

ul Rydygiera 13 lok. 271
01-515 Warsaw
Poland

Tel: 0048 22 100 43 24
Fax: 0048 22 100 44 12
Email: monika.duszynska@md-law.pl
Web: www.md-law.pl; www.lawforlifesciences.pl

Law for Lifesciences

Contributed by: Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał,
Monika Duszyńska Kancelaria Adwokacka

Highlights

There have been many interesting events and topics relevant to the life sciences sector in the past year in Poland. This article covers the following:

- a major amendment of the Reimbursement Law;
- drug safety and support for the domestic manufacturing of medicines;
- the new Act on Clinical Trials on Medicinal Products for Human Use;
- first court judgments concerning costs for the quality tests on medicinal products imposed on marketing authorisation holders by the Polish supervisory authority; and
- new requirements applicable to the promotion of medical devices.

Major Amendment of the Polish Reimbursement Law

On 1 November 2023, a very broad amendment of the Reimbursement Law (in force since 1 January 2012) became binding. The draft amendment has been in public consultation for more than two years and raised huge criticism, especially from the pharmaceutical industry. Industry associations were even requesting to withdraw the entire draft. After arduous debates, some of the most controversial provisions were either deleted or softened, but the amendment itself was adopted in August 2023.

The most significant changes brought in by the amendment are as follows.

- Certain benefits are to be granted to holders of decisions approving applications for reimbursement for the manufacturing of medicines on Polish territory and for the manufacturing of the active pharmaceutical ingredients (API) in Poland; these may be either economic or administrative benefits. The aim of these measures was to boost manufacturing of medicines in Poland - something that was considered pivotal, given the existing excessive dependence on foreign suppliers (especially from India and China). The temporary shortages of certain critical medicines experienced during the COVID-19 pandemics, and the risk that such shortages may occur in future, were main reasons for adopting such measures. The most attractive benefit seems to be releasing the applicant from the price negotiations (in respect of pharmacy medicines only). As a consequence, the price offered by the applicant should be theoretically approved (subject, however, to the final decision of the Minister of Health).
- Holders of reimbursement decisions are to be granted, upon their request, the right to lower the patient's co-payment by:
  (a) 10% if the reimbursed medicine is manufactured in Poland or the API is manufactured in Poland; or
  (b) 15% if both the medicine and API are manufactured in Poland.

This measure, like the previous one, is also designed to boost the manufacturing of medicines in Poland. If the applicant obtains this privilege, the public payer will cover correspondingly 10% or 15% of the co-payment to be made by the patient, which is expected to increase sales of such medicines. It should be noted that this privilege, as well as the one referred to in the preceding point, is not reserved for Polish companies – it is available to any manufacturer that would move or place its manufacturing operations to Poland or would use API manufactured in Poland.

- Changes have been introduced that will affect the prices of reimbursed products. One such

Contributed by: Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał,
Monika Duszyńska Kancelaria Adwokacka

example is the application of a 25% compulsory decrease in the price after expiry of exclusivity - not only to the disclosed official price (as was the case before the amendment), but also to the "effective price" (ie, the price including undisclosed rebates/discounts).

- The powers of the Minister of Health (the Polish authority issuing decisions on price and reimbursement terms for medicines) during the reimbursement proceedings have been enhanced, including:
  - (a) removing the applicant's right to request suspension of the proceedings (often used in cases where the negotiations on the price and terms of reimbursement did not lead to reaching an agreement with the Minister of Health and the applicant wanted extra time to collect new evidence or arguments and reschedule negotiations);
  - (b) enhancing the powers of Economic Committee (the body negotiating financial terms with the pharmaceuticals company applying for reimbursement);
  - (c) limiting the number of negotiations' rounds to three; and
  - (d) removing the applicant's right to modify the offered terms of reimbursement after the negotiations with the Economic Committee are concluded, as previously some applicants whose proposed terms were not approved by the Economic Committee only offered terms that were more favourable to (or more likely to be accepted by) the payer once the negotiations were over – this option is now strongly limited (although the Minister of Health may still hold additional negotiations in exceptional circumstances).
- The Minister of Health has been granted the power to change the limit groups in which medicines with similar indications are included. This has a significant impact on the level of patient co-payment for pharmacy medicines. The larger the group, the higher co-payment level is - given that, in larger groups, the so-called financing limit (up to which the public payer contributes to the cost of the medicine) is usually lower.
- A new channel for reimbursing medical devices has been opened.
- The wholesale margin has been increased from 5% to 6%. On the other hand, the level of such margin for certain hospital medicines will be limited to PLN2,000 (approximately EUR500). Setting the maximum level of the wholesale margin for expensive hospital medicines is intended to reduce expenditure of the public payer on the most expensive reimbursed hospital medicines (used in chemotherapy and drug programmes).
- The obligation to ensure continuous and determined supplies of the reimbursed medicines has been broadened; failure to fulfil this obligation is subject to severe penalties. (This is one of the most controversial provisions, which has generated major criticism.)

Pricing and reimbursement proceedings in Poland are held entirely electronically, through a specially designed electronic system (SOLR). All the applications and accompanying documentations are uploaded onto this system. All correspondence between the pharmaceuticals company (the applicant) and the authority (the Minister of Health) is exchanged through this system.

It should be noted that, following the change of government in Poland in December 2023, several other important changes are being discussed. Most of them are aimed at improving the provi-

Contributed by: Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał,
Monika Duszyńska Kancelaria Adwokacka

sion of healthcare services in Poland; however, to some extent, they also concern drug policy.

It is also worth noting that the National Rare Diseases Plan for 2021-2023 - adopted in 2021 and featuring 40 tasks that should have been performed between 2021 and 2023 - expired at the end of 2023. The current government did not extend its term, which means that right now Poland has no such plan. The new government has declared it is working on a new one.

Drug Safety, Support for the Domestic Manufacturing of Medicines, Tackling Shortages

Following the COVID-19 pandemic and temporary shortages of certain medicines, there has been a vivid discussion on how to ensure drug safety (meaning drug availability in actuality) for Polish citizens. Specifically, domestic manufacturers - acting both directly and through industry associations - and various stakeholders pointed out that there is a need to increase the profitability of local manufacturing in Poland. Availability of medicines is considered to be excessively dependent on supplies from Asiatic manufacturers (especially Chinese and Indian suppliers) - a challenge that is faced across Europe.

This dependence is also enhanced by the pressure from the Polish authority responsible for drug pricing and reimbursement (the Minister of Health) to decrease prices of reimbursed medicines in order to lower public expenditure and increase drug availability to patients. The terms of reimbursement are granted only for a limited time (two, three or five years) and often each time the price and other terms of reimbursement are renegotiated leads to further price decreases. The pharmaceuticals industry often claims that this may discourage the pharmaceuticals company from investing in new medicines or new manufacturing technologies, lines or facilities (or make investment seem less attractive).

As mentioned earlier, among the measures introduced to support domestic drug manufacturing were provisions allowing manufacturers performing their manufacturing operations in Poland to obtain certain privileges while applying for pricing and reimbursement of their medicines. Time will allow their efficacy to be assessed in terms of meeting declared goals. It should be noted that, as of 1 April 2024, approximately 400 medicinal products manufactured in Poland or with API manufactured in Poland (or both) are now provided to Polish patients against a co-payment discounted by 10% or 15% respectively. A special list of medicines enjoying this discount has been added to the reimbursement list, which is binding from 1 April 2024.

It is also worth emphasising how vital adequate monitoring of the availability of medicines is for collecting data on any shortages and preventing export of deficit products. The Integrated System for Monitoring Trade in Medicinal Products (ZSMOPL) has been operational since April 2019. It collects data on trade in medicinal products, reimbursed medical devices, and reimbursed food for special nutritional purposes. It is fed with data provided by marketing authorisation holders, wholesalers and pharmacies (both hospital and open ones). Even though ZSMOPL is said to be a useful tool to collect data on volumes of products traded on the Polish market, a tool for accurate monitoring of real shortages is missing. The measures introduced by the Polish government aimed at preventing export of medicines recorded on a special list of deficit medicines, published officially every two months, are not efficient enough.

Contributed by: Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał,
Monika Duszyńska Kancelaria Adwokacka

There has been a long discussion around making certain biological medicines (such as monoclonal antibodies) available in pharmacies. Until recently, they have only been available in so-called drug programmes, which have strict inclusion criteria restricting their availability. This was initially supposed to cover biosimilar medicines and the reference medicines used in rheumatology and gastroenterology following expiry of exclusivity (when their prices drop by at least 25%). This has been a long-awaited change and hopefully other medicines so far only used in drug programmes will enjoy reimbursement status in the pharmacy channel.

New Act on Clinical Trials on Medicinal Products for Human Use

Since 14 April 2023, a new Act on Clinical Trials on Medicinal Products for Human Use has been in force. The purpose of this new regulation was to adapt the provisions of the Polish laws and regulations on clinical trials to the EU Regulation 536/2014 on clinical trials on medicinal products for human use. As declared by the Polish Ministry of Health, the adopted regulations aim to increase the attractiveness of clinical trials in Poland, as well as secure interests of study subjects.

The key changes with regard to the preceding regulation include:

- some new aspects of the ethical evaluation of the trial;
- the sponsor of the study will bear significantly higher costs related to the authorisation of a clinical trial;
- study subjects will be covered by a new system of compensation for damage suffered by a subject and resulting from participation in a clinical trial - a special compensational fund will be fed with fees contributed by the sponsors of clinical trials;
- a vital change with regard to non-commercial clinical trials financed in full from the public resources, making it possible to commercialise data obtained in such studies; and
- an option to restrict determined data privacy rights applicable to clinical trials of a scientific nature, especially if necessary to achieve the goals of the study.

The new Act on Clinical Trials on Medicinal Products for Human Use also regulates many other matters - in particular, the following:

- in a non-commercial clinical trial, it is permitted to use investigational medicinal products obtained from a manufacturer or a marketing authorisation holder free of charge or at a reduced cost or to obtain some scientific, technical or financial support from a marketing authorisation holder or manufacturer - provided, however, that such use or support will be disclosed in the application for the authorisation of a clinical trial;
- the president of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (the Polish regulatory agency) will be the local contact point referred to in Regulation 536/2014;
- details of the procedure before the Ethical Committee on the evaluation of a clinical trial;
- details of the civil liability of the investigator and sponsor, as well as the requirements regarding compulsory insurance against damage inflicted on the study subjects;
- amounts of compensation payable to the study subjects;
- regulatory fees for application for various types of authorisations of clinical trials;

Contributed by: Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał,
Monika Duszyńska Kancelaria Adwokacka

- entities authorised to conduct inspections of clinical trials and the course of the inspection; and
- criminal liability for determined violations of the requirements included in Regulation 536/2014 and the Polish Act on Clinical Trials on Medicinal Products for Human Use.

It should be noted that the special compensation due to the study subject under the system for such compensation managed by the Chief Patients' Ombudsman does not preclude the subject's right to seek ordinary damages in civil court proceedings. Therefore, this is an additional option to better protect the study subject in the event of suffering injury, health deterioration or death as a result of taking part in a clinical trial.

Costs of Quality Tests on Medicinal Products Imposed on Marketing Authorisation Holders

From 2022 onwards, marketing authorisation holders began receiving decisions of the Chief Pharmaceutical Inspectorate (*Główny Inspektorat Farmaceutyczny*, or GIF) imposing on them an obligation to reimburse the costs of quality tests on their medicinal products conducted as part of regular quality supervision of medicinal products that are already on the market (ie, other than quality tests carried out in relation to newly placed medicines). These tests were conducted between 2018 and 2020 and marketing authorisation holders were not notified of them at all. Marketing authorisation holders started to receive dozens or even several dozens of decisions requiring them to reimburse such costs and these decisions were issued in a very short space of time, resulting in significant accumulation of such costs to be reimbursed. The costs of the tests varied in each case, but they could jointly amount to hundreds of thousands of Polish złoty (EUR1 = approximately PLN4.3).

The supervisory authority's practice and the procedure used raised huge opposition within the pharmaceuticals industry. The principle that marketing authorisation holders may be obliged to reimburse the costs of tests in the case of a positive result is explicitly articulated in the regulations, but the procedure itself is far from clear. The main allegation by the industry and lawyers was that before a decision requiring marketing authorisation holders to pay these costs, the GIF should have issued a decision ordering such tests in line with the provisions of the Polish Pharmaceutical Law. The GIF refuted this allegation, claiming that it was not necessary and that the GIF could impose such costs on marketing authorisation holders on the ground of a general provision stating overall powers of pharmaceutical inspection.

In other words, legal provisions referred to by the GIF as the grounds for its decisions imposing costs of the quality tests on marketing authorisation holders raised interpretational doubts and the GIF followed the least favourable interpretation, limiting the rights of marketing authorisation holders and the scope of control over decisions. It is worth noting that after having faced huge criticism over the legality of the decisions requiring marketing authorisation holders to cover the costs of the quality tests, the GIF changed its practice and started to issue decisions ordering such quality tests. Such a change clearly suggests that the GIF may have finally agreed with the above-mentioned argument.

The GIF's decisions were massively appealed against and final administrative decisions began to be issued in 2023, upholding first unfavourable decisions. Appeals against these final decisions were then brought to administrative courts. In recent months, the first court judgment appeared. Although it is still difficult to speak of a

Contributed by: Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał,
Monika Duszyńska Kancelaria Adwokacka

unified line of case law, there is at least one court verdict that confirmed that marketing authorisation holders were right in challenging the actions of the GIF. In the judgment regarding case V SA/Wa 1767/23, the Voivodship Administrative Court in Warsaw repelled two decisions of the GIF, confirming that:

- each decision requiring marketing authorisation holders to reimburse the costs of quality tests should be preceded by a decision ordering such tests; and
- if the GIF failed to issue such decision, it cannot require marketing authorisation holders to reimburse its costs.

Considering that administrative court procedure in Poland is two-instance, the end of the judicial battle in these cases awaits. However, judgments issued in the first instance give hope for a positive conclusion to the industry's dispute with the GIF.

Further Restrictions on the Pharmacy Market

In September 2023, certain regulations came into force providing for further restrictions on concentration in the pharmacy market. In addition to the existing limitations, there is now a ban on taking control of entities holding authorisations to operate pharmacies if the acquiring entity or their affiliates themselves operate at least four pharmacies. Violation of the ban results in the withdrawal of authorisation to operate pharmacies held by the acquired entity and the imposition of a fine ranging from PLN50,000 to PLN5 million. The President referred the new regulations to be assessed by the Constitutional Court, but the law came into force and is effective, which might pose a risk to M&A transactions.

The result of the new regulations may be a further reduction in the number of pharmacies in Poland (a trend that has been observed for several years). At the same time, establishing or joining existing franchise pharmacy chains may be more attractive for entities operating in the pharmacy market (although caution should be exercised in this case as well, as some franchise models involving subordination to the organising entity are considered control by administrative courts).

New Requirements Applicable to Promotion of Medical Devices

The year 2023 brought significant changes regarding permitted advertisement of medical devices. The new Act on Medical Devices, binding since 1 January 2023, repelled the existing Act on Medical Devices of 2010. It included an entire chapter dedicated to the advertising of medical devices, which imposed a number of entirely new requirements on entities promoting these. In addition, the new Act on Medical Devices includes numerous provisions completing and developing the provisions of the EU Medical Device Regulation (MDR) and the EU In Vitro Diagnostic Regulation (IVDR). It also introduces a significant number of financial penalties for determined violations of EU regulations and the provisions of the Act.

The new Act on Medical Devices introduced several determined requirements applicable to the advertisement to the general public. One of these is a prohibition on using the image of healthcare professionals, persons pretending to be such professionals, or persons presenting a medical device in a way suggesting that they may be healthcare professionals (eg, actors playing doctors). It meant that doctors, nurses and pharmacists could no longer appear in advertisements for medical devices.

Contributed by: Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał,
Monika Duszyńska Kancelaria Adwokacka

The said prohibition constituted a significant change with regard to the existing practice. As for medicinal products, prohibition of the use of healthcare professionals in advertisements was very well established, whereas medical devices could have been promoted without such limitation. As a result, numerous promotional materials for medical devices used images of healthcare professionals to attract recipients and build trust in the promoted products. Consequently, one of these key differences between advertisement of medicinal products and medical devices has been removed.

Furthermore, the list of certain healthcare professionals has been drafted in another legal act (the Act on Certain Medical Professions), adopted in August 2023. Therefore, apart from the obvious physicians and nurses, medical professionals such as medical assistants, optometrists and hearing care professionals can no longer appear in medical devices' promotional materials - given that they are also considered healthcare professionals for the purpose of the Act on Medical Devices.

A prohibition that addressed advertising aimed at children was also included in the new law. However, a requirement that was among those most widely discussed was a new prohibition on promoting medical devices for professional use to the general public. This particularly affected products such as fillers and certain appliances or instruments used in aesthetic medicine (eg, lasers). Doctors offering aesthetic medicine services often promoted them by referring to determined brands of medical devices they used while providing specific treatments. As long as such devices are for professional use, they cannot be promoted any longer at present - neither alone nor in combination with medical services in which these may be applied. This new limitation changed the practice significantly and noticeably.

The new legislation also imposed a number of elements required in the content of each advertisement. As with advertising OTC medicines to the general public, medical device advertisements aimed at the general public must include a special warning saying that this is a medical device and it should be used in accordance with its instructions for use or its label. The Regulation of the Minister of Health provides for detailed requirements for this warning. The new law also introduced other elements required in advertisements for medical devices, such as the name, intended use, names of the manufacturer (as well as the authorised representative, if appointed) and the entity conducting advertisement. The intended use of the device raises doubts, in particular, as it is not necessarily equivalent to its indications and there have been doubts on how detailed this information should be.

A novum is the extension of the application of new requirements for medical device advertisements to influencers - ie, individuals (entities) addressing their opinions on given medical devices to the general public on social media. It should be noted that in 2022 the Polish Office of Competition and Consumer Protection issued specific guidelines for influencers concerning the transparency of promotional content in their posts and other types of communication to the general public.

In line with the new Act on Medical Devices, Polish entities engaged in advertising medical devices are also required to archive designs of any promotional materials, as well as keep records of where these were distributed.

Contributed by: Monika Duszyńska, Tomasz Jędrejko and Paulina Konefał,
Monika Duszyńska Kancelaria Adwokacka

Despite the very recent adoption of this piece of legislation, it is not clear how the new rules should apply to various promotional contents - especially those placed on social media, where meeting certain technical requirements is challenging. However, despite initial concerns, the market has somewhat adapted to them by now.

It should be noted that the Polish Act on Medical Devices provides for a number of severe penalties for failure to comply with both the EU and Polish requirements applicable to advertisements. By way of example, violating the legal provisions on advertising - be they EU or Polish - is sanctioned by a financial penalty of up to PLN2 million (a little less than EUR500,000), while failure to keep designs of the advertising results in fines of up to PLN50,000 (approximately EUR12,000).

The Act on Medical Devices was also accompanied by a Regulation on the Advertising of Medical Devices, adopted in April 2023, which includes detailed provisions on the required content of such advertisements and compulsory warnings on how advertisement should be conducted in certain places (such as pharmacies or healthcare centres).

Conclusions

The pharmaceuticals and medical devices market in Poland is very active and keeps expanding, along with the growing Polish economy. More new innovative therapies are being granted reimbursement terms and becoming available on the Polish market, while the generic market is also very powerful, despite various challenges.

Great attention is focused on ensuring the availability of medicines to Polish patients and avoiding drug shortages. For this purpose, various mechanisms have been put in place. It is worth noting that a huge number of companies operating in these sectors contributed and keep contributing to Ukraine throughout the Russia invasion, providing significant volumes of medicines and medical devices as humanitarian aid through various channels, thereby demonstrating noticeable Corporate Social Responsibility.

CHAMBERS GLOBAL PRACTICE GUIDES

Chambers Global Practice Guides bring you up-to-date, expert legal commentary on the main practice areas from around the globe. Focusing on the practical legal issues affecting businesses, the guides enable readers to compare legislation and procedure and read trend forecasts from legal experts from across key jurisdictions.

To find out more information about how we select contributors, email Katie.Burrington@chambers.com