ROUNDTABLE

The International Who's Who of Life Sciences Lawyers has brought together five of the leading practitioners in the world to discuss key issues facing lawyers today.

Who's Who Legal: ***Have there been any significant regulatory changes in your jurisdiction in the past year to 18 months or are you expecting any in the near future? What impact have they had, or will they have, on your practice and clients?***

Héctor Jausàs: Since March 2010 four Royal Decrees have been passed by the government. All of them provide for significant changes in the regulatory environment for pharmaceuticals, mainly aimed at reducing the financial impact of the Spanish health-care system. The last of them, Royal Decree-law 16/2012, dated April 2012, is having a deep impact on the budgets of laboratories. The new regulatory framework, whereby many products are being excluded from the reimbursement system, is resulting in a switch of policies to over-the-counter (OTC) products. It also provides the system of so-called "homogenous groups" which include the presentations of financed medicinal products with the same active ingredient, dose, content, pharmaceutical form and route of administration and which may be exchanged when it is dispatched; this system determines potential monthly updates of the price financed in a permanent way, thus creating a problem of stocks in pharmacies and laboratories. Amongst other changes, Royal Decree-law 16/2012 consolidates the system of selective pricing (based on the consumption and costs of certain medicinal products) and favours the prescription of active ingredients. Further legislations shall need to be enacted in order to detail the new procedure to fix certain prices and to request for reimbursement.

The new regulatory and financial framework described has increased our practice in regulatory matters, mainly regarding pricing and reimbursement strategies and litigation.

Koosje van Lessen Kloeke: As of 1 January 2012, the Dutch system for the funding and reimbursement of hospital care and medical care provided by medical specialists has undergone significant changes. These changes also affect medicinal products which are administered or used under the supervision of a medical specialist ("medicinal products for hospital use" or "medical specialist medicines").

As part of the so-called "overheveling" (transfer), step by step several medicinal products (eg, TNF-blocker medicines, oral oncology products, growth hormones) are no longer reimbursed under the Medicinal Products Reimbursement System (GVS) but only as hospital care. More products are expected to follow in 2014. Due to their transfer to the hospital care system, their funding has also changed.

Before 2012, the costs of all medicinal products for hospital use were allowed for in the standard set hospital budget. However, a specific financial accommodation was made for medicinal products, which placed a heavy burden on the hospital budget if they complied with certain rules and criteria set by the Dutch Health Care Authority (NZa). The majority of the products concerned are valuable biotech products for the treatment of chronic and rare diseases, for example certain cancers, eye conditions such as "wet" age-related macular degeneration (AMD), growth deficiency, haemophilia, and multiple sclerosis.

Since 1 January 2012 hospitals no longer receive a standard set budget. Under very strict conditions medicinal products are now eligible for an "add-on", meaning that hospitals are allowed to charge a higher maximum tariff for a specific medicinal product. It is important to note that, in principle, only (therapeutic indications of) medicinal products which have been authorised after 1 January 2012 are eligible for an add-on.

Although the NZa has provided for transitional measures, there are already examples of products which have fallen between the two stools. Although these products are generally considered as valuable and state of the art in medical science, they are not prescribed by medical specialists simply because there is no adequate funding, for example because the NZa refuses to set add-ons for these products or exceeds the time limits for its decisions on medicinal products. This leads to significant delays in the marketing of these products, which in turn slows down or limits the availability of these treatments for patients. Interestingly, although add-on decisions are likely to affect the free movement of the medicinal products concerned, the NZa does not consider pharmaceutical companies as interested parties and does not allow them to file an application for their medicinal products. In my view the NZa's position is contrary to EU law, in particular the Transparency Directive (Directive 89/105/EEC). I expect that these developments will continue to have a significant impact on our practice and clients.

Alexander Ehlers: On 1 January 2011, the German Act for restructuring of the drug market in the statutory health insurance (AMNOG) came into effect. Since then, new legal requirements have applied regarding the market access of medical products.

The AMNOG rules that the additional benefit of a new product has to be proven. This means additional formal requirements for our clients during the launch of pharmaceutic innovations. Legal advice is required concerning the study dossier design because the study dossier has an immense importance concerning the additional benefit of medicinal products: those study dossiers will be examined by the Federal Joint Committee (GBA) in order to determine the additional benefit of a new pharmaceutical product.

In the first quarter of 2013, the Patient rights Act (PatRG) comes into force. It stipulates the regulation of the contract governing medical treatment and patient rights in case of an error in treatment as well as new regulations concerning consent and acceptance and the burden of proof.

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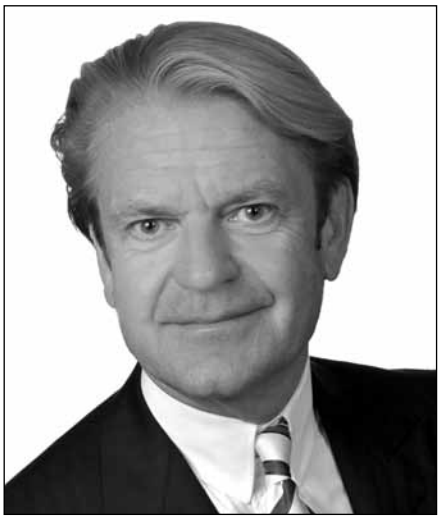

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Lincoln Tsang: It is important to recognise that the regulatory ecosystem is constantly evolving in response to many external challenges in relation to advancement in science and technology, healthcare delivery and the dynamics of industrial practices. Globalisation requires the life sciences sector to think beyond their geographical boundaries and regional specific requirements. The EU regulatory landscape and similarly in many other jurisdictions with an established regulatory system have to respond to those challenges to avoid the regulatory framework becoming obsolete.

There are a number of current issues. Firstly, society at large demands greater transparency in regulatory decision-making. This requires the regulatory authorities to consider ways to explain, justify and account for their decisions, and communicate benefit/risk effectively with the general public. The calculus of benefit/risk will need to be looked at afresh. In order to inform such an assessment, engagement with the relevant stakeholders will become important.

Secondly, greater focus is placed on devising appropriate regulatory pathways to permit products, which will provide significant contributions to patient care, to be authorised through a patient access scheme or an adaptive licensing procedure coupled with specific obligations imposed on the sponsors to generate data to address specific uncertainties arising from the initial benefit/risk assessment to stage market access of a product. What this means is that the regulatory process is changed from the traditional binary paradigm into a continuum process. This also underpins the increasing demand and emphasis to monitor the benefit/risk profile for authorised products continuously throughout the entire product life cycle through a prospectively designed risk management plan and risk mitigation strategy. This proactive approach essentially underpins the new EU pharmacovigilance legislation that has come into force since July 2012. Given the requirements will affect the product life cycle management, many companies have been particularly diligent in re-engineering their internal procedures as well as inter-company compliance procedures.

Thirdly, research and development of new products is increasingly complex. The industry has transformed from the a fully integrated company into a fully integrated network of expert collaborators encompassing experts from academia, small and medium-sized companies and patient organisations to inform the decision-making. As a result of these changes in the industry practices, compliance in terms managing the relationship and payments for the services rendered between companies, their external partners such as healthcare professionals and patients becomes more challenging given the complexity of the underlying process.

Fourthly, globalisation and increasing trends to engage third parties to supply raw materials and manufacture and distribute products will require greater vigilance and

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oversight in managing security and integrity of the entire supply chain.

Fifthly, in the past, companies were required to develop their products from the bench to the market place through a demonstration of safety, quality and efficacy. This is no longer enough. Containment of health-care costs remains a challenging issue for the industry. The situation has not improved since 2008 when the global financial crisis started. Greater use of health technology assessment tools to justify adoption of new technologies and medicines in the national health services in order to establish the therapeutic position of the new product or technology and to justify pricing and reimbursement policies. Companies will not only have to show their products would be capable of treating a condition, but comparative effectiveness and pharmaco-economic efficiency will emerge as de facto regulatory standards. In order to respond to these challenges, a clinical development plan will need to include both elements relevant to benefit/risk as well as cost-effectiveness assessment to ensure timeliness of market and patient access. In the EU, there is exploratory discussion about convergence of these assessments to optimise access to new technologies and products.

Many practitioners, like myself, are asked to look at novel and challenging situations for clients and their practice base has broadened considerably as a result. This will mean that practitioners will have to think creatively and strategically through marshalling the underlying facts, laws and policy.

Melanie Ho: There were significant changes to the Medical Registration Act (MRA) and Regulations (MRR) in December 2010 which saw a streamlining of the complaints and disciplinary processes for doctors. Following these changes, the immediate flow on into the practice of lawyers involved in Singapore Medical Council (SMC) work would be providing advice to clients on the impact these changes have on the doctors and the SMC. Of course, adaptations to the processes is a natural consequence.

Insofar as court cases that test the regulatory framework of the MRA, 2012 saw a doctor applying to the High Court, to reverse and quash certain decisions that had been taken by the Complaints and the Disciplinary Committees that reviewed and investigated into her matter. The High Court dismissed her application and on her appeal to the Court of Appeal, the highest Court in Singapore, her appeal was also dismissed with costs.

Moving into 2013, we expect more refinement in the SMC processes. In October 2012, the SMC announced that they will set up a review committee to improve the disciplinary processes to "mitigate the increase in time and expense".

Who's Who Legal: ***Many lawyers have reported an increasing level of regulations and "heavyweight" regulatory scrutiny and thus an increased demand for regulatory counsel. Is this the case in your jurisdiction and how is your firm adapting to this?***

Héctor Jausàs: Yes – as explained above, the regulatory workload has significantly increased. We have reinforced our regulatory department and are working on a cross-disciplinary basis with other departments, mainly with expert lawyers in litigation and administrative law.

Koosje van Lessen Kloeke: This is also the case in the Netherlands. The increasing level of regulations and regulatory scrutiny has raised the demand for lawyers with expertise in many diverse and complex domains, and with a thorough understanding of the particulars of the life sciences sector. The multidisciplinary health care and life sciences practice group of Leijnse Artz consists of specialists in civil law, administrative law and criminal law that provide advice and litigate about medicinal products (human and veterinary), medical devices, health products, cosmetics, biocides, food for particular nutritional uses, food products and pharmaceutical health care services. We focus on preventing and resolving disputes, which goes far beyond simply drawing up contracts. We are often involved in an advisory capacity, and give advice regarding legal and compliance issues, so that enforcement risks can be foreseen and may be prevented as much as possible.

Lincoln Tsang: Compliance has always been a key element in regulatory oversight because the life sciences sector is highly regulated to ensure products in clinical development and in the market place would not compromise patient safety and public health. Regulators have considered the need to ensure that consumers' interests are properly protected.

Greater power is now given to regulators to investigate and take enforcement action against companies in case of breach of regulatory requirements. I have seen such regulatory measure being taken in areas concerning clinical research, advertising and promotion, product manufacture and pharmacovigilance. We advise companies on such related issues on a cross-border basis to identify potential sources of breach, and prevent potential enforcement action. Having a proper compliance procedure in place and regular reviews have become very important from a governance perspective.

Melanie Ho: In the area of regulatory work, since 2008, WongPartnership had in place a team dedicated to various regulatory aspects. For life sciences, we take a multidisciplinary approach as it involves elements of corporate law, intellectual property and disputes. As such, the partners from these three areas are in frequent dialogue on the development of life sciences. For the medical and dental profession, my team focuses on the advisory, disputes and investigations of breaches. It is from these areas that the boundaries of these regulations are circumscribed. These will then have an impact on setting professional standards and promoting higher levels of ethics and practices within Singapore.

Alexander Ehler: The German health-care system has become more and more regulated within the past decade. This concerns the regulation of the pharmaceutical market as well as the medical treatment itself. The regulatory framework for obtaining a marketing authorisation of a medical product is changing rapidly.

Our firm tries to sensitise our clients to the problems that regulatory procedures entail. Therefore we work closely together with renowned experts of the health-care sector who for example examine study design dossiers. As we are highly specialised in life sciences law, we have a broad overview of all legal changes and are very well connected within the health-care sector.

In order to keep clients updated, we inform them about every recent changes of the legal framework concerning the health-care system so that they have an adequate notice of what is new.

"Personalised medicine brings about a change in the way we manage health care. There is a need to balance the paradigm of treating the underlying conditions and embracing wellness"

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Who's Who Legal: ***Cloud computing and personalised medicines seem to have been hot topics over the past year. Are you seeing much advisory, compliance or risk management work in relation to these trends? Are there any other key trends you have seen in the past year?***

Héctor Jausàs: In Spain cloud computing is still more a political concern rather than a real one in our day-to-day work. Personalised medicines have definitely become a significant part of our work in 2012. As for other key trends, I would insist in the financial impact of regulatory measures undertaken by the government.

Koosje van Lessen Kloeke: Cloud computing is a hot topic in the Netherlands; there are heated discussions about the architecture and security issues in the Dutch Electronic Patient Record System (EPD). Another hot topic is "medical apps" intended to be used for diagnostic or therapeutic purposes: could such apps under certain circumstances qualify as medical devices? And if so, do certification and inspection procedures provide for sufficient safeguards as regards the safety, effectiveness and privacy aspects?

I also expect to see more advisory work in relation to personalised health care, not only as regards (diagnostic and biomarker) research, such as storage and (other) privacy issues related to biobanks for the storage of biological samples for use in clinical trials and other research, but in particular with regard to the reimbursement and funding of personalised medicines. Another key trend in the Netherlands seems to be the use of P4P (pay-for-performance) mechanisms for medicinal products, such as pay for efficiency or pay for value agreements between the Dutch government and pharmaceutical companies. Since P4P encompasses a broad range of design options, and many of these options have not yet been explored, this provides new possibilities for Life Sciences companies in the Netherlands.

Furthermore, in light of increasing regulatory scrutiny and enforcement action by the Dutch competent authorities, we see an increase in advisory and litigation work regarding cross-border care and the use of claims, and borderline discussions regarding medicinal products, medical devices, cosmetics, biocides, and food products.

Alexander Ehlers: Hosting and accessing clinical data in the cloud computing environment requires data protection and secure access. Likewise, legal issues about personalised medicines and individual pharmacotherapy are the confidentiality of patient information and personal databank as the knowledge of many individual attributes is necessary in order to create customised therapies.

The pharmaceutical industry as well as the statutory health system require advice concerning the legal framework of these confidentiality issues.

Another key trend in recent times is the enormous economic pressure of the statutory health insurance system (GKV) although they have never earned as much money as in recent years.

Lincoln Tsang: There is tremendous advancement in basic and applied science in understanding how the body responds to drug treatment at a cellular and genetic level, and increasingly sophisticated bioinformatics and enhanced data warehousing capabilities. These scientific endeavours collectively serve to provide a useful platform for exponential growth in development of personalised diagnostics and therapeutics.

Personalised medicine brings about a change in the way we manage health care. There is a need to balance the paradigm of treating the underlying conditions and embracing wellness. As many commentators have put it, there is a need to refocus a reactive, sporadic, disease oriented health-care system to one that is personalised, predictive, preventative and strategic. In delivering such efforts, there is a greater drive to encourage development of e-health and m-mobile through use of informational technologies.

Cloud computing is an additional data management tool. The industry has begun to appreciate the impact of cloud

computing on areas relating to research, development, clinical trial management and healthcare information exchanges. The explosion of data from next generation sequencing, the growing importance of biologics in the research process is making cloud-based computing an increasingly important aspect of R&D and development of personalised medicines.

Complex genetic sequences and biomarker data could be hosted in the cloud by a few open source bodies. Data could be accessed in a secure fashion by individual companies for their research needs. However, there is still a need for more integrated data sharing across research, development, manufacturing, and sales functions to improve trials, increase time to market for drugs, and utilize feedback faster. There appears to be an increasing trend for industry exploring use of both public and private clouds for data storage, hosting and access needs.

The main impact to pharmaceutical companies of increased usage of cloud computing is a reduced dependence on their own IT infrastructures. Cloud computing provides the ability for companies to move away from capital expenditures. The business advantages of cloud computing include the standardisation and streamlining of operations, higher reusability, better integration and stronger collaboration with external entities and the health-care ecosystem.

The linkage between the use of cloud computing and personalised medicine is the use of the tool to facilitate data mining to permit identification of markers that may be helpful in patient stratification to personalise or individualise therapies.

As the uptake of cloud increases, one would expect a greater focus on security, privacy, data protection and IP management as reliance on the cloud grows. In the EU, the Commission's Article 29 Working Party released an opinion on Cloud Computing. This was closely followed by guidance issued by the UK Information Commissioner's Office.

"Clients must be aware of the fact that especially applied research with biotechnological products is highly restricted so that cost-covering research and development of new medical products depends on detailed legal assistance"

Alexander Ehlers, Ehlers, Ehlers & Partner

Who's Who Legal: ***Due to the challenges associated with assessing products of advanced technology, particularly related to biotechnology, is there concern by your clients that regulators are taking a more stringent and critical approach to these compared to more traditional pharmaceutical drugs? If this is the case, what impact is it having on biotech industry?***

Héctor Jausàs: We have not observed such change.

Koosje van Lessen Kloeke: One of the main concerns remains the approach of regulators regarding the pricing, funding and reimbursement of biotech products, in particular as regards biologicals and biosimilars. Our firm has been involved in discussions with the competent authorities and health-care insurers as well as litigation regarding the reimbursement of biologicals under a so-called "preference policy". Under a preference policy, health care insurers limit reimbursement to certain medicinal products from selected preferred suppliers. In return for a relatively low price, during a specific period of time the selected suppliers obtain exclusivity from the health-care insurer for the product concerned. Such preference policies historically favour generics and are based on the principle of automatic substitution in the pharmacy. There are ongoing discussions in the Netherlands if (a) biologicals with the same INN and/or the same ATC (5th level), and (b) biosimilars and the originator product may be considered interchangeable in medical practice, specifically with regard to the regulatory framework for biosimilars, the risk of immunogenicity and practical consequences for post-authorisation pharmacovigilance monitoring.

Alexander Ehlers: Mainly, the Regulation of Advanced Therapy Medicinal Products (ATMP) regulates the legal requirements for marketing authorisation by the European Medicines Agency (EMA). There are many formal requirements in order to obtain a European marketing authorisation. The legal framework for biotechnological research is restricted, too.

In addition to that, there are additional German legal requirements for those new technologies, for instance the Gene Diagnostic Law (GenDG) as well as several regulations within the Medicinal Product Act (AMG).

Clients must be aware of the fact that especially applied research with biotechnological products is highly restricted so that cost-covering research and development of new medical products depends on detailed legal assistance.

Lincoln Tsang: By definition, products developed by or produced from novel or advanced technologies intended for novel therapeutic targets will raise certain scientific uncertainties. Regulators in general are conservative in their approach because their role is to protect patient safety and public health. Any new therapeutic approach is likely to be subject to greater scrutiny because it is likely to be precedent-setting.

I do not think characterising the regulators' as stringent or critical is a fair characterisation. Rather, industry should take a more a proactive approach in entering into dialogue with regulatory authorities to inform their decision and to share knowledge.

In the EU, regulatory oversight of advanced therapies based on tissues, cells and genes is based on risk mitigation and management through a proper characterisation of the underlying mechanism of action, mode of use and the target population in order to define the optimal conditions of use of such novel therapeutic approaches. Fundamentally, the approach is not significantly different from the way conventional small molecules are regulated. However, in the area of advanced therapies, there is a greater demand for elucidating the product characteristics for the purpose of identifying, characterising, assessing and managing the potential harms.

Melanie Ho: Since 2009, Singapore has put in numerous measures to grow the pharmaceutical and biotechnology industry to drive innovation and lure international and leading companies to set up their base in Singapore. This has seen an influx in the world's brand names set up in Singapore. The Singapore Health Sciences Authority has refined its regulatory framework for research.

One area of special interest is IVF, which is one of the upcoming areas of life sciences in Singapore. The Ministry of Health is in consultation with some of the institutions that perform IVF procedures and are now taking a consultative approach to develop further guidelines and regulations. This is usually done in consultation with the key stakeholders, professionals and institutions to ensure that the regulatory framework does not impede processes.

Who's Who Legal: ***Developing countries are presenting incredible growth opportunities but also risks for many clients. How has this impacted on you, your firm's practice and the advice you give your clients?***

Héctor Jausàs: In a context where the businesses in Spain tend to reduce its pharmaceutical expenditure, many companies are increasingly looking for opportunities in other EU and non-EU countries. In this regard we have provided advice for several investments in such countries as China (via Hong Kong) or Russia (Skolkovo).

Koosje van Lessen Kloeke: In international and cross-border life dciences cases, we work closely together with leading law firms in the applicable jurisdictions so that we can meet the specialised needs of our life sciences clients.

Alexander Ehlers: We regularly advise our clients to develop foreign markets as this means high economic potentials. However, we suggest investigating in advance what the legal framework of the health-care sector would imply and what potential conflicts would arise.

Certainly our law firm is prepared for these international legal challenges and can provide our clients with international legal expertise which is crucial in order to face global challenges.

As members of the Conférence Bleue (a lawyers' network on pharmaceutical, health-care and medical law), we are expanding our legal network all over the world.

Lincoln Tsang: This is an important challenge that is faced by many law firms. Disease sees no geographical boundaries and research and development efforts are increasingly globalised and regionally competitive. We have witnessed in the recent years many emerging "tiger" economies which are aggressively developing their infrastructure to attract inward investment through providing greater incentives for foreign companies to collaborate with local talents, research groups and companies. In this sector, as a service provider, we will have to respond to clients' needs. The bulk of my practice is not concentrated solely on the UK or EU and a lot of the work I do has a global dimension. Similarly, I have seen an increasing need for cross-border support for lawyers to deal with contentious matters such as those relating to highly complex litigation, investigations and enforcement actions as well as transactional matters. Many firms will either set up bases in emerging markets or establish "best friends" in those markets to provide a more integrated service to international life sciences clients. But what matters is the quality of the service being delivered to meet clients' specialised needs.

Melanie Ho: In the pharmaceuticals industry, production is carried out in these countries and there is a huge aspect in internal regulation. This is largely done by the in house counsel. Where we see as a growth area of practice in our expertise as regulatory lawyers is the focus on health-care tourism in other countries, eg, UAE, China and Korea. Many of them are modelled after or use Singapore, an established medical hub, as a reference point. We provide advice in these areas of regulation which is vital to establishing a medical hub with international standards.

Who's Who Legal: ***In many jurisdictions there have been changes in reporting obligations for life sciences companies regarding their relations with health-care professionals and/or institutions/hospitals. Have there been any changes regarding this in your jurisdiction or are you expecting any? What is/will be the impact of these changes?***

Héctor Jausàs: This has been developed at the deontological level, and the regulations are therefore applicable only to the members of the relevant associations. Reporting obligations to the surveillance unit of Farmaindustria (the Spanish association of the pharmaceutical industry) have existed since 2008 with respect to certain events organised or sponsored by the members of Farmaindustria; also, since 2008 scientific studies must be shared with the surveillance unit. Since 2010, the provision of services by institutions or health professionals involving at least 20 professionals must be reported.

Perhaps more recent is the increase of transparency of companies associated to EUCOMED, which establish appropriate procedures to communicate to employers of the health care professionals their participation in forthcoming events or services.

All in all, the adoption, periodic review and training on compliance procedures – which include reporting obligations – for both pharmaceutical and medical devices companies is an area where our legal support is continuously and increasingly requested.

Koosje van Lessen Kloek: The Dutch Foundation for the Code for Pharmaceutical Advertising (CGR) has published self-regulatory rules regarding the self-disclosure/transparency of financial relations between (a) pharmaceutical companies and (b) Netherlands-based/practising HCPs, HCP partnerships and/or institutions in which HCPs participate or work. This Code of Practice requires pharmaceutical companies and HCPs/institutions to disclose the monetary value of payments and (indirect) financial support relating to certain service agreements and sponsoring agreements if the total amount paid per calendar year to the HCP/HCP partnership/institution exceeds €500. These financial relations have to be publically reported in a central database. Service agreements and sponsor agreements which are entered into by a third party, not in the name of a pharmaceutical company but on the company's instructions, also fall under the scope of the Code of practice. The requirement to disclose this information must be made by companies and HCPs/HCP partnerships/institutions for the first time by the end of the first quarter of 2013 (covering activities commenced as of, or ongoing on, 1 January 2012).

As of 1 January 2012 there is also new self-regulatory code for the medical devices industry, the GMH. Although the GMH requires that financial relations between suppliers and HCPs must be transparent, this Code does not yet include "sunshine rules". The Dutch Minister of Health, Welfare and Sports would like to see that the medical devices companies will also disclose their financial relations with HCPs and institutions.

Alexander Ehlers: The legal requirements for the collaboration of pharmaceutical companies with health-care professionals are partly laid down in the Advertising of Medicines Act (HWG) and the Act Against Unfair Competition (UWG). These statutes apply to health-care professionals from the outpatient sector as well as to health-care professionals who work in hospitals. Furthermore, the German Criminal Code (StGB) sets out in section 299 and 331 legal requirements regarding attempts to influence health-care professionals who work in public hospitals in their prescription of medicines.

Also, the Professional Code for Physicians stipulates principles for the interactions of physicians, either from the in-patient or the hospital sector, with the pharmaceutical industry, in its sections 31 to 33.

In addition, several industry guidelines govern the interaction of pharmaceutical manufacturers with health-care professionals. These are the FSA Code of Conduct of Health-care Professionals, the respective AKG Code of Conduct, and the Common Position Concerning the Consideration of Cooperation between Industry, Medical Institutions and Staff from the Aspect of Criminal Law. As mentioned, these industry guidelines are binding for members of these industry associations, and shall furthermore be observed since they serve as a means of interpretation for German courts when assessing if certain collaboration with health-care professionals infringes respective legal provision.

Lincoln Tsang: Interactions between industry and healthcare professionals and stakeholders very often are necessary to inform clinical research, to benefit patient care, and to enhance practice of medicine. There is however, an increasing demand for transparency for interactions between industry and health-care professionals to control potential inducement to prescribe, supply and use of healthcare products. The interplay of anti-corruption laws and sector-specific rules governing advertising including control of inducement is gaining prominence every year. Some commentators say that authorities are starting to apply US-style enforcement strategies to hold companies and their senior management accountable for failing to prevent corruption and bribery or inducement activities. The UK Bribery Act has added another layer of complexity to the implications of the application of the US Foreign Corrupt Practices Act and the implementation of the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. The US Sunshine Act, the French Sunshine Act as well as the industry's own self-regulatory code of practice, such as the UK Prescription Medicines Code of Practice Authority, have sought to tighten the transparency requirements. In this environment, there is a need for companies to maintain adequate compliance procedures that seek to prevent, identify and address wrong doing is not an option, rather, a necessity. Any potential breach may lead to potential prosecution or enforcement action that may result in irreparable reputational risks to the corporation.

Melanie Ho: In Singapore, there is an ethical obligation for doctors to disclose any financial benefit or advantage they may receive if there are affiliations to a life sciences company. I have encountered some cases where the line is blurred when drugs sponsored by a company is not yet generally accepted as the

first line treatment but is used for therapy and applied outside the context of a clinical trial. So there may be a "tie-up" or relationship but not necessarily with a financial payout. Presently, the obligation rests with the doctor to disclose his relationship and to raise any possible conflict of interests. Ultimately, the professional is ethically bound to act in the best interests of the patient and to render treatment that is indicated and evidence-based. With the advent of medicine and the lucrative aspects of a possible "breakthrough", there may be lines crossed and I expect more cases on this not just in Singapore but worldwide.

"2013 will be a year of major developments for the life sciences sector especially in the regulation of medical professionals. As mentioned earlier, changes to review and streamline the processes have been forecasted by the SMC"

Melanie Ho, WongPartnership LLP

Who's Who Legal: *What do you for the future regarding the life sciences regulatory legal marketplace in your jurisdiction and developments in the market?*

Héctor Jausàs: We expect more work within the regulatory aspects of pharmaceutical law, and namely pricing and reimbursement. Spain has adopted the basic framework to regulate pricing and reimbursement, oriented to reimburse the least at the cheapest possible price, but now all this needs to be developed by means of appropriate legal and administrative measures. The legal advice is likely to shift from purely technical support to understand the new rules of the game, towards a broader support encompassing tactical (how to react/oppose to the measures) and strategic one (how to position the products of the company having regard to the new regulations).

Koosje van Lessen Kloeke: In light of the aforementioned developments in the Dutch market and the significant regulatory changes foreseen in the near future, particularly with regard to pricing, funding and reimbursement, Life Sciences companies in the Netherlands will be faced with many (new) challenges, but also with interesting business opportunities, for example with regard to developing and implementing new P4P mechanisms which perhaps could also be used in other jurisdictions.

Alexander Ehlers: Additional statutes as well as modifications of applied law can be expected at any time in the future to ensure the topicality of this challenging and rapidly evolving field of law. Currently there is a lot of movement in the legal framework of the health-care sector.

The upcoming parliamentary elections in September 2013 may lead to a change of the coalition partners. If the current coalition will be deselected and a different government comes into force, priorities in the health-care system may be modified significantly. The current model of both statutory and private health insurances may be altered to a uniform insurance. For the pharmaceutical industry, such changes would have immense consequences.

Lincoln Tsang: I think there is likely to be greater demand for regulatory lawyers with the ability to marshal complex technical details and to think creatively to provide strategic directions and legal solutions to companies in all aspects of research and development and marketing activities. The opportunities apply to both in-house as well as private practitioners. The ability for practitioners to work collaboratively with business, research and development to provide practical solutions in a multidisciplinary fashion for both contentious and non-contentious matters will become a premium.

Melanie Ho: 2013 will be a year of major developments for the life sciences sector especially in the regulation of medical professionals. As mentioned earlier, changes to review and streamline the processes have been forecasted by the SMC.

At a macro level, we foresee that there will be an increase in younger lawyers entering this sub-specialty of medical law and regulation. The number of hospitals and medical centres has increased over time and these institutions will require expertise in this area. With more patients, local and foreign, seeking treatment in Singapore, the trend is a steady increase in the number of malpractice suits and disciplinary actions.