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Vital Signs

Our quarterly round-up of topics that matter to you in the life sciences sector

Winter 2024

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Introduction

Happy 2025 from the CMS Life Sciences & Healthcare Sector Team.

In a recent poll, 26% of US consumers apparently plan to take a weight loss drug to achieve their 2025 New Year's resolution goals. We are therefore on trend by once again offering a "slimmed down" version of the latest Life Science sector news to start your New Year. Its easily digestible and free too.

In this edition we review how the new Labour Government in the UK aims to bring about significant changes to the life sciences & healthcare sector. We consider some key aspects of the party's pre-election life sciences strategy and some sector-targeted actions taken by Labour since winning power. The Labour Government has also delivered on its promise to introduce an Employment Rights Bill within its first 100 days of office which it has described as the "biggest upgrade to rights at work for a generation". That, along with a new duty to prevent sexual harassment, are considered in the context of UK employment law. The new Government has also delayed the introduction of the new UK Procurement Act 2023 to February 2025, and we provide commentary on this and the new Procurement Pathway. Finally, shifting to EU matters, we summarise a recent event held by the SPCblog at CMS's London offices which looked at the recent developments in supplementary protection certificate law and practice, which affects the exclusivity period of marketed drugs.

If you would like to discuss these or any other developments, please get in touch. We would be delighted to talk about your interests and concerns.

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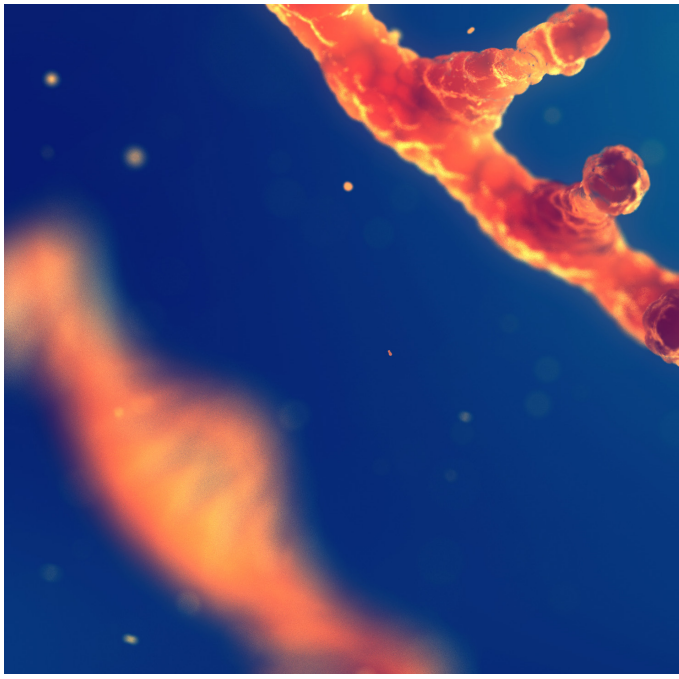
People & HR related issues



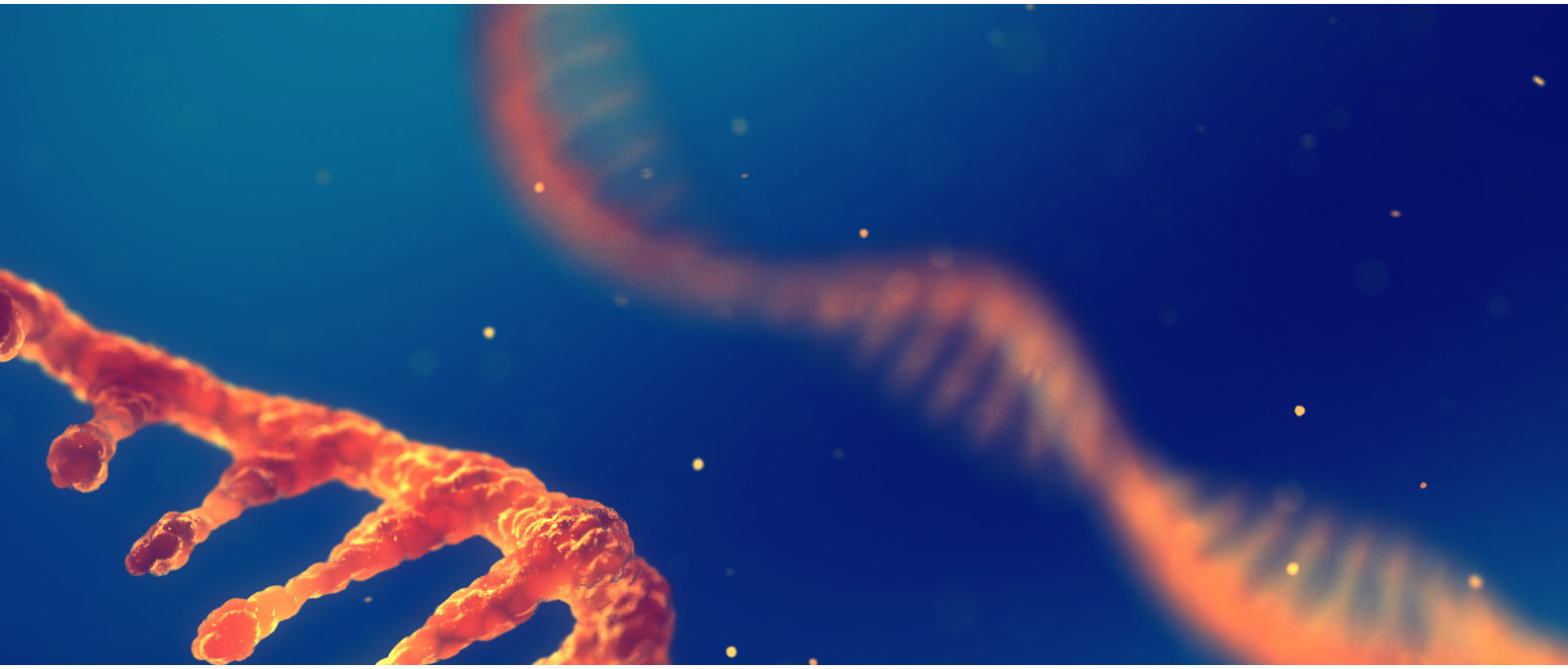
New duty to prevent sexual harassment

From 26 October 2024, all UK employers will have a new duty to take reasonable steps to prevent sexual harassment in the workplace including by third parties such as customers, contractors or research participants. The new duty introduces a positive and proactive obligation on employers to prevent sexual harassment at work. This means employers should not wait until a complaint of sexual harassment is made before taking any action. Instead, employers are required to anticipate situations in which employees may be at risk of sexual harassment and take action to prevent it from ever taking place.

The Equality and Human Rights Commisson (EHRC), the UK's equality and human rights watchdog, has updated its technical guidance on sexual harassment at work to reflect the new duty and what amounts to "reasonable steps". The guidance makes clear that what is reasonable will vary from employer to employer depending on factors such as their size and resources. For employers operating in the life sciences sector, other factors such as the particular risks present in their workplace (e.g. interactions with patients and third party healthcare professionals and suppliers) and high regulatory standards are also likely to be relevant. The guidance sets a high bar for reasonable steps, which will include:

1. **Developing an effective anti-harassment policy.** The technical guidance is prescriptive about what a good anti-harassment policy should cover which includes (i) a statement that sexual harassment will not be tolerated and is unlawful, (ii) a statement that the law requires employers to take reasonable steps to prevent employees from being sexually harassed at work, and (iii) an effective procedure for handling complaints of sexual harassment.
2. **Engaging your staff.** This includes conducting regular 121s, running staff surveys and using exit interviews to understand any particular risk areas within your business. It also includes raising awareness of internal reporting channels.
3. **Assessing and taking steps to reduce risk in your workplace.** The guidance makes clear that employers are unlikely to comply with the preventative duty if they do not carry out a risk assessment. Risk assessments should (i) identify the risks relating to sexual harassment in the workplace, and (ii) control measures to minimise those risks. Potential risk hotspots for life sciences employers might include lone working or field working, attending conferences and collaborative working with third party institutions which may have less developed or effective anti-harassment policies and procedures. Work social events where alcohol is served will be one of the key risks for most employers.
4. **Reporting.** Employers should use a reporting system that allows workers to raise any concern including on an anonymous basis. Most employers within the life sciences sector will already have well-established internal reporting channels but it will be important keep the effectiveness of those channels under review to ensure that potential issues do not go under the radar.
5. **Training.** Providing training is another important aspect of compliance with the new duty. Training should help employees to recognise sexual harassment, understand what to do if they are subjected to or witness sexual harassment and managers should know how to handle complaints of harassment.

Dealing with harassment by third parties and monitoring the effectiveness of the steps taken to prevent sexual harassment will also be important. This might include, for example, reminding patients or other service users via recorded messages or literature that they are expected to behave in an acceptable and respectful way towards staff members and that sexual harassment will not be tolerated. Where sexual harassment takes place, an employer should take action to stop it happening again.

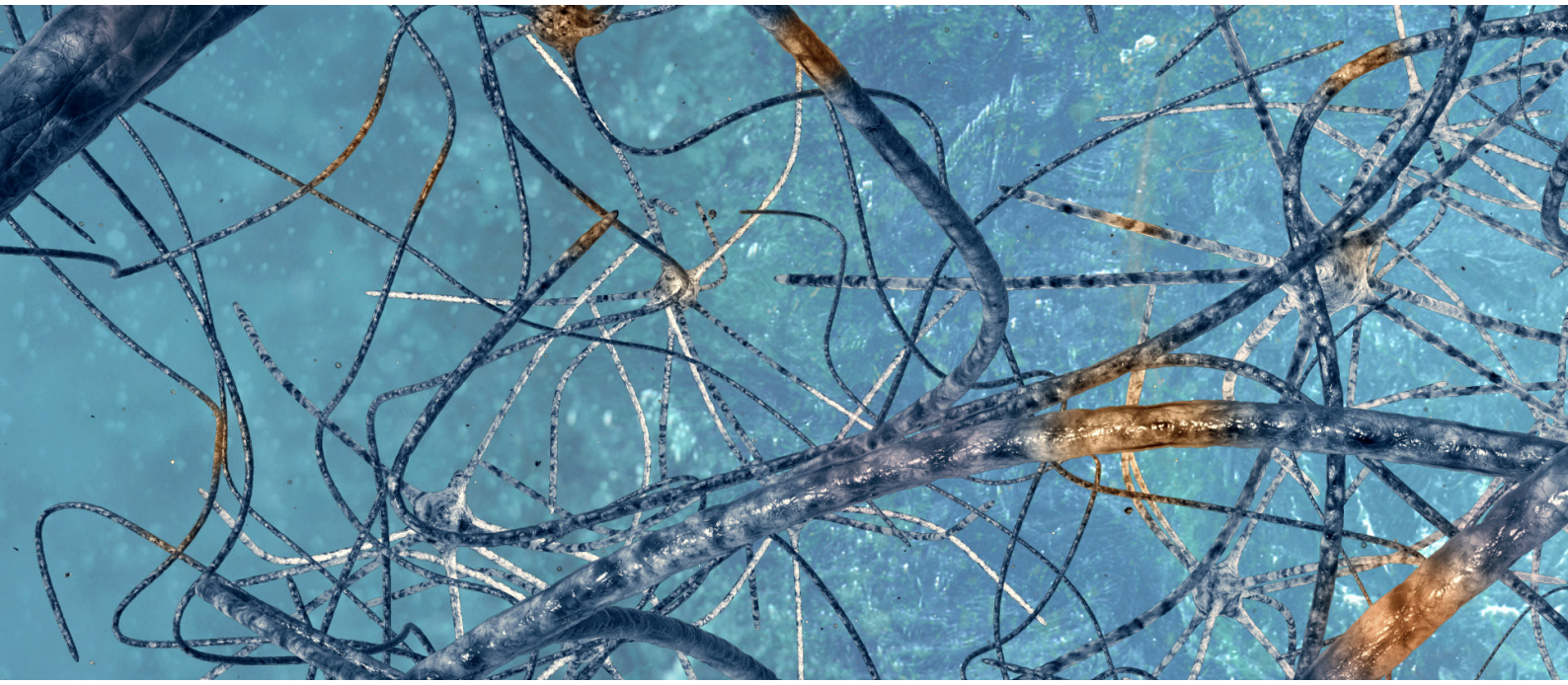


The Employment Rights Bill:
The Labour Government has delivered on its promise to introduce an Employment Rights Bill within its first 100 days of office which it has described as the ***"biggest upgrade to rights at work for a generation"***. Certainly many of the proposed changes will have significant, practical consequences for employers requiring careful preparation. There is currently limited information about the detail behind many of the proposals which will be subject to consultation by the Government and are not expected to come into force until 2026.

A lot of attention has focused on removing the existing two-year qualifying period for unfair dismissal and making it a 'day one' right. The Bill makes clear that the right will be subject to a probationary period during which employers will have greater flexibility to dismiss an employee for specified reasons including their capability or conduct. The Government's preference is for a nine-month probationary period although that detail is awaited. Certain other statutory rights will become available from day one of employment including sick pay (removing the lower earnings limit eligibility requirement and the current three-day waiting period) and paternity leave and parental leave (where qualifying service of one year and 26 weeks respectively currently apply)

Related to the Labour party's manifesto pledge to end 'fire and rehire' practices, the Bill also introduces a new category of automatic unfair dismissal where the reason for the dismissal is that an employer sought to vary an employee's contract of employment and the employee did not agree to the variation. Employers will be able to avoid a finding of unfair dismissal in certain limited circumstances. While this reform does not go so far as making dismissal and reengagement processes unlawful, it does raise their risk profile.

The Bill also sets out various ways in which protections from sexual harassment in the workplace will be strengthened. This includes raising the threshold for compliance with the new duty to prevent sexual harassment at work from "reasonable steps" to "all reasonable steps" and introducing a new category of protected disclosure to the whistleblowing regime where sexual harassment is reported. The Bill will also impose employer liability for third party harassment which will be challenging for employers operating in the life sciences sector where interactions with third parties are frequent and often take place outside of the workplace where the same checks and balances may not be in place.



Revitalising innovation: The Labour Government's influence on the Life Sciences sector

The new Labour Government aims to bring about significant changes to the life sciences industry in the UK. In this article, we consider some key aspects of the party's pre-election life sciences strategy and some sector-targeted actions taken by Labour since winning power.

Pre-election Strategy

Labour's pre-election life sciences strategy, "A prescription for growth" (the "Strategy") was published in February 2024 and set out the Government's sector plan for life sciences:

Industrial strategy

— As set out in the Strategy, a central part of the Government's plan is to introduce an independent Industrial Strategy Council on a statutory footing to hold government to account and provide continuity across the political cycle. It will have representatives from businesses, trade unions and academic experts. The Industrial Strategy Council will monitor progress in priority sectors such as life sciences.

— Labour states in the Strategy that it will strengthen the Office for Life Sciences, which supports the delivery of the Government's life sciences policy by connecting decision making across Government.

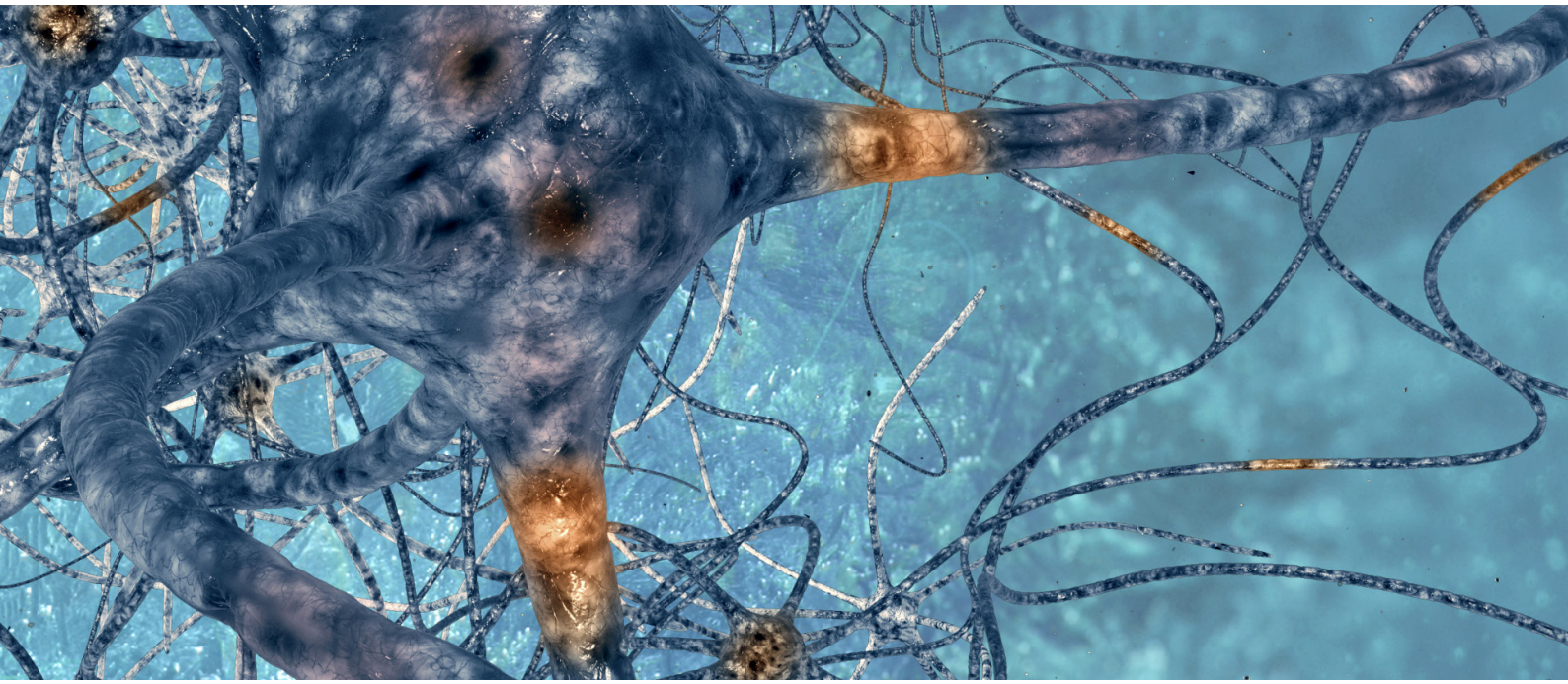
Access to finance

— The Strategy proposes to broaden the remit of the British Business Bank to include growth capital, regional development and streamlining support for SMEs.

— It also proposes to establish an opt-in scheme for defined contribution pension funds, allowing them to invest a proportion of their assets into UK growth assets, including venture capital and small cap growth equity, in a similar manner to the French "Tibi" scheme.

— Labour commits to maintain the current system of R&D tax credits over this parliament to reduced uncertainty as to the availability of this funding source. They have also committed to maintaining the patent box regime.

— The Strategy states that Labour aims to create a more certain funding environment and a more streamlined funding process to attract long-term investment. In particular, it will set 10-year budgets for funding bodies – UKRI and the National Institute for Health Research – and key research institutions such as the Francis Crick Institute, the LMB and the Cell and Gene Therapy Catapult.



Innovation

— Labour plans to ensure that the NHS bank of health data can be used for R&D, with appropriate safeguards in place, for the public good.

— Labour aims to increase the number of university spinouts and structure the innovation funding system to ensure more of them successfully scale-up. This is stated to include working with universities to encourage them to offer spin-outs a 'founder-track' option, one where the university takes a share of equity at or below 10 percent. This is designed to address concerns that higher equity stakes taken by some UK universities could be hampering UK spinout formation and growth relative to other countries.

— Labour identifies clinical trial backlogs at the MHRA as a factor inhibiting UK competitiveness. Separate to the Strategy, they announced an intention to create a Regulatory Innovation Office to hold the MHRA and other regulators accountable for delays that are holding back innovation.

— The Strategy provides that Labour will review the system for making planning decisions in respect of lab spaces falling within life sciences centres of excellence, noting that Cambridge in particular has suffered from a shortage of space.

Future implementation

A comprehensive sector plan is set to be published in Spring 2025, detailing specific strategies for implementation.

The Labour Budget

In October, Chancellor Rachel Reeves unveiled a new Labour budget that introduced the Life Sciences Innovative Manufacturing Fund (LSIMF). The LSIMF will allocate up to £520 million in capital grants to produce drugs and medical technologies. This initiative is designed to bolster the UK's preparedness for future health crises and leverage the broader life sciences sector. In addition to the LSIMF, the budget featured a real-term funding increase for the National Institute for Health and Care Research. Such funding is intended to support the NHS and the wider healthcare system in advancing research, medical technology, and data initiatives.

Conclusion

The Strategy outlines a bold vision for the UK life sciences sector, incorporating essential components to enhance the current ecosystem and tackle existing challenges. However, the effectiveness of this plan hinges on its implementation. Industry stakeholders will closely monitor how the new Government advances these initiatives.

Procurement Act go-live delayed to February 2025; but no hold-up in preparations for the new regime

The six-month implementation period for entry into force of the new UK Procurement Act 2023 has been delayed a further four-months, with the new go-live date now being pushed back to 24 February 2025. This delay has not held up the Cabinet Office's engagement with public sector and suppliers on the new features of the new Act, introducing the new Procurement Pathway for contracting authorities and engaging with suppliers on registering with the new Supplier Registration Service.

Cabinet statement – reasons for delay

The new National Procurement Policy Statement (NPPS) issued in May before the General Election was set to take effect on 28 October 2024, the original go-live date for the Procurement Act (the Act). The new Labour Government has postponed the implementation of the Act to allow time to produce a new NPPS. They explained that the NPPS, as it stands, does not fully align with their broader policy objectives for procurement. The Government has said that it intends to use the new legal framework to deliver greater value for money and improved social value, which is intended to *"help raise standards, drive economic growth, and open up public procurement to new entrants such as small businesses and social enterprises"*. To better reflect these priorities, the current administration is working on a new NPPS.

Legislating for the new date

Within days of the Government's announcement, they made the Procurement Act 2023 (Commencement No. 3 and Transitional Saving Provisions) (Amendment) Regulations 2024/959 to amend the coming into force date of the Act (set out in the Procurement Act 2023 (Commencement No. 3 and Transitional and Saving Provisions) Regulations 2024).

There have also been changes to dates associated with the transitional provisions. Under the transitional provisions, any dynamic purchasing system or qualification system established under the current rules must come to an end four years after the new regime comes into force. The sunset date has been changed from 27 October 2028, to 23 February 2029.

Impact on suppliers/contractors and contracting authorities

In light of the delay, authorities and suppliers/contractors will have more time to consider the upcoming regime and to take measures to prepare.

For authorities, this provides a window of opportunity for additional staff training, review of internal processes and ultimately more time to ensure the transition to the new regime is as seamless as possible.

Authorities will need to keep an eye out for the new NPPS and ensure that its content is factored into the procurement strategies for planned procurements due to launch from 24 February 2025.

For procurements that had been due to launch between 28 October 2024 and 23 February 2025, authorities will be deciding whether to proceed with the procurement ahead of the new 'go-live' date under the current rules, or whether to delay procurement in the hope of enjoying a more simplified and flexible procedure under the new Act. Authorities who had been ready to launch under the Act on 28 October, but unable or unwilling to delay to the end of February next year, will need to review/rework the procurement documents to align to the PCR/UCR/CCR rules. For most authorities, our sense is that the short delay to implementation is welcomed.

The delay offers several benefits for suppliers/ contractors, the key one being more preparation time. Suppliers to the public/utilities and defence sectors should use the additional time to educate their organisations on the changes that are coming.

What else is new?

The Procurement Pathway

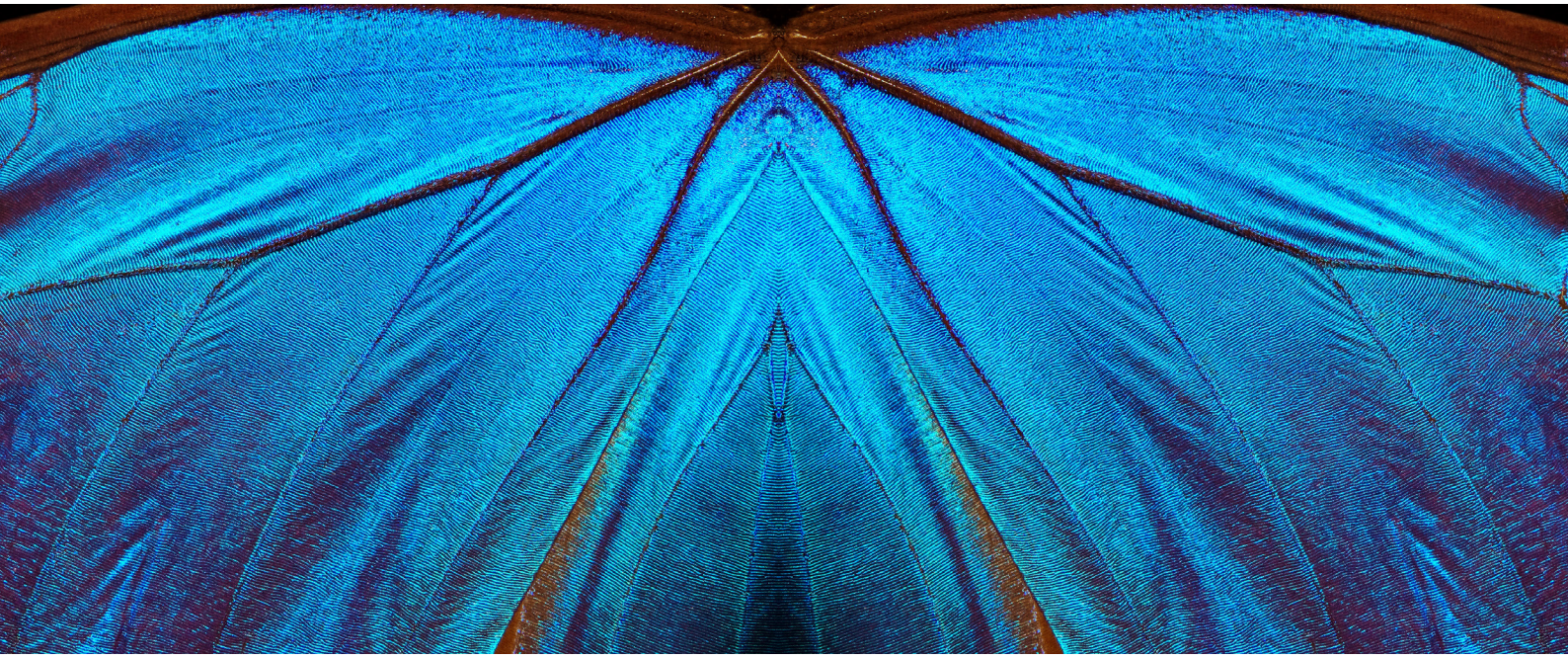
On 27 September 2024, the Procurement Pathway tool was launched. Procurement Pathway is intended to bring together various procurement documents published on http://GOV.UK, for example PPNs, playbooks and standard commercial templates.

Authorities should explore the tool and standard templates for use under the Act. Templates published so far include an Assessment Summary and Direct Award Justification Report.

The Procurement Pathway can be found here: Disclaimer | Procurement Pathway (civilservice.gov.uk)

Supplier Registration Service

Suppliers should register for the new Supplier Registration Service, if they have not done so already: Supplier Registration Service (cabinetoffice.gov.uk)



SPC update

After a five-year break, the SPC Blog live event was held at the offices of CMS in central London, and chaired by CMS partner Dr Robert Stephen, founder of "the SPC blog", and with an audience including a number of representatives from public administration in UK, Ireland, France, Netherlands, Sweden and European Commission.

The first update was on the **EU SPC reform progress.** Whilst things had initially been proceeding quickly within the EU, the recent stumbling block has been the involvement of the EUIPO in invalidity proceedings of uSPCs. The majority of EU member states have expressed a strong plea for deleting the invalidity procedure before the EUIPO from the EU SPC reforms, and to give that task to the UPC, in order to ensure coherence of jurisprudence regarding unitary and national SPCs and to avoid conflicting judgements concerning the scope of protection of the basic patent and the scope of protection of a unitary SPC.

Current proposals would see the actual grant of SPCs be moved from the EUIPO to the national offices, to procedurally allow the UPC to be involved in any review on validity. There is, apparently, even some discussion of the involvement of the EPO. Whilst this debate continues, the legislative process has stalled.

Second, following the Brexit decision, the UK Courts of Appeal and Supreme Court can now in theory **diverge from the CJEU decisions.** Merck Serono are trying to persuade the CoA to do just that, in respect of **second medical use SPCs.** In the EU that route is firmly closed, with the Santen decision of the CJEU reversing Neurim, but in the UK it still remains possible for a new medical use to be rewarded by SPC protection, albeit only if the UK departs from the EU law it retained. The Merck Serono hearing is in December 2024 and will be keenly watched.

Dr Dolores Cassidy from the Irish IPO took up the **Halozyme** case which relates to the nature of excipients as actives, as that case has been referred to the CJEU by the Czech IPO. Whilst the case law appears to suggest that excipients listed in a MA are not actives, a number of SPCs have been granted to Halozyme, requiring a further CJEU intervention.

Finally, at the CJEU level, the advocat general's (AG) opinion in joined cases **C-119/22 & C-149/22** was reviewed by Lawrence Cullen, the ex Deputy Director of the UKIPO. The AG opinion lays out the issues in understanding Article 3a and 3c of the SPC regulation, and explains where and why uncertainties have arisen and presents a possible solution.

That decision was published on the 19 December 2023, with a link here, and importantly explains that, for SPC purposes, a product (active ingredient or combination of actives) must fall "under the invention" covered by the patent used for the SPC application, which is a different test to the inventive step of the patent itself. Please go to theSPCblog here for more commentary!

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SPC update

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