PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

First Delegated Legislation Committee

DRAFT MEDICINES FOR HUMAN USE (CLINICAL TRIALS) (AMENDMENT) REGULATIONS 2024

Monday 3 February 2025

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The Committee consisted of the following Members:

Chair: † Sir Desmond Swayne

† Bailey, Mr Calvin *(Leyton and Wanstead)* (Lab)
† Brandreth, Aphra *(Chester South and Eddisbury)* (Con)
† Brown-Fuller, Jess *(Chichester)* (LD)
† Dalton, Ashley *(West Lancashire)* (Lab)
† Ellis, Maya *(Ribble Valley)* (Lab)
† Gwynne, Andrew *(Parliamentary Under-Secretary of State for Health and Social Care)*
† Johnson, Dr Caroline *(Sleaford and North Hykeham)* (Con)
† Morgan, Helen *(North Shropshire)* (LD)
† Naismith, Connor *(Crewe and Nantwich)* (Lab)
† Opher, Dr Simon *(Stroud)* (Lab)
† Owatemi, Taiwo *(Lord Commissioner of His Majesty's Treasury)*
† Pitcher, Lee *(Doncaster East and the Isle of Axholme)* (Lab)
Rimmer, Ms Marie *(St Helens South and Whiston)* (Lab)
† Shah, Naz *(Bradford West)* (Lab)
† Shastri-Hurst, Dr Neil *(Solihull West and Shirley)* (Con)
† Stafford, Gregory *(Farnham and Bordon)* (Con)
† Welsh, Michelle *(Sherwood Forest)* (Lab)

Noorjehan Piperdy, *Committee Clerk*

† **attended the Committee**

First Delegated Legislation Committee

Monday 3 February 2025

[Sir Desmond Swayne *in the Chair*]

Draft Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024

6 pm

The Parliamentary Under-Secretary of State for Health and Social Care (Andrew Gwynne): I beg to move,

That the Committee has considered the draft Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024.

It is a pleasure to serve under your chairmanship, Sir Desmond.

I am grateful for the opportunity to debate these important amendments, which represent the most significant reform of UK clinical trials regulation in more than 20 years. Clinical research is the single most important way in which we improve our healthcare, by identifying the best way to prevent, diagnose and treat conditions.

Clinical trials are vital for patients with limited available treatment options, such as the estimated 3.5 million people living with rare diseases in the UK, together with the 17.5 million living with long-term conditions. This draft legislation will play a vital role in supporting the development of new treatments for those who so desperately need them by transforming the environment for clinical trials in the UK.

The changes respond to the sector's need for a more efficient and adaptable regulatory framework, while safeguarding the wellbeing of trial participants. The reforms will establish a proportionate, flexible and effective clinical research environment, placing patients at the heart of the process. The changes have been carefully designed in response to calls for reform, aligning with the direction set in our manifesto promise to build an NHS fit for the future and maximising the UK's potential to lead the world in clinical trials.

The reforms are further underpinned by the findings of Lord Darzi's independent investigation of the NHS in England and the recommendations of Lord O'Shaughnessy's review into commercial UK clinical trials. These changes to modernise the regulatory framework will cement the UK as a destination for clinical trials that is innovative, inclusive and international and will, most importantly, help to get life-changing medicines to the people who need them sooner.

Let me explain to the Committee why Government believe change is needed. It is necessary and timely. The existing legislation is based on the now repealed and replaced European Union clinical trials directive. It no longer reflects the rapid advancements in medicine and technology. We have the opportunity to reform our national regulations to deliver a world-class regulatory environment for clinical trials, supporting the safe development of innovative treatments benefiting patients and public health alike.

I will now briefly summarise the key aspects of the reforms. Of the key changes, the first is risk-proportionate regulation. Regulatory requirements will align with the risk level of a clinical trial, empowering researchers to adopt appropriate approaches. Low-risk clinical trials will benefit from faster approval processes through automatic authorisation, without compromising patient safety.

Secondly, there is future-proofing: the draft legislation is a purposeful move away from a one-size-fits-all approach, which does not reflect modern, innovative clinical trial methods. We have removed granular and duplicative legal requirements in favour of specific, tailored guidance, which will provide flexibility and adaptability for future advancements.

Thirdly, there is international alignment: the United Kingdom will remain aligned with international standards to ensure that data from UK trials is accepted globally. That will help to secure the UK's place as a preferred site for multinational clinical trials, including those conducted across the European Union.

Fourthly, this new framework will cement the UK as a destination for international clinical trials. Streamlined and efficient processes will be introduced to simplify clinical trial applications. The legislation will include a combined regulatory and research ethics review, ensuring that approval timelines are internationally competitive.

Finally, there is increased transparency. We want to ensure that trusted information about clinical trials is publicly available for the benefit of all. The changes will, for the first time, introduce a legal requirement to register a clinical trial and to publish a summary of the results. Participants will be offered an easy-to-understand summary of what the research has found out. These new transparency requirements will build public trust in research, and ensure that participants, and the wider public, have access to information about ongoing research and can use research findings to help to make informed decisions.

I will now turn to the benefits of this new framework in more detail. Patients will have greater access to life-changing treatments, which will improve outcomes and save lives. These reforms ensure that UK patients will be among the first to benefit from cutting-edge therapies. The transparency requirements will ensure that trusted information about clinical trials is publicly available for the benefit of all, improving public trust and confidence in the innovative clinical trials taking place in our country.

Evidence also shows that hospitals that undertake research have better patient care outcomes and improved staff retention, and that it benefits the whole health and care system. Clinical trials are part of the solution for reducing the strain on our National Health Service. Improved efficiency in conducting clinical trials will enhance research efforts and foster innovation in prevention, diagnosis and treatment across various conditions.

Additionally, we are broadening the categories of healthcare professionals who can be accepted as investigators, encouraging more researchers to carry out clinical trials in their specialist areas. Innovators and industry will run clinical trials within a streamlined, risk-proportionate regulatory framework, with reduced delays and administrative burdens, which will support

industry growth and bolster the UK's life sciences sector—something that I am sure Members on both sides of the House support.

The impact on businesses has been evaluated; as the projected costs and benefits to businesses was below £5 million in any single financial year, a full impact assessment was not required, as originally stated in the accompanying explanatory notes. Instead, a de minimis assessment was produced and is published alongside this instrument.

To summarise, this new framework uses effective regulation to accelerate the development of medicines, turning tomorrow's emerging medicines into today's reality for patients. By modernising our approach, we can solidify the United Kingdom's position as a global leader in clinical research, fostering innovation while upholding the highest safety standards.

I want to end on a critical point: participant safety remains paramount. This new legislation, while streamlining processes and removing unnecessary barriers to innovation, prioritises robust oversight of clinical trials, ensuring that the safety of those participating in a trial is never compromised. I therefore commend these draft regulations to the Committee, and I hope that hon. Members will join me in supporting these transformative changes.

6.9 pm

Dr Caroline Johnson (Sleaford and North Hykeham) (Con): It is a pleasure to serve under your chairmanship, Sir Desmond. The Minister said that 17.5 million people in the United Kingdom are living with a long-term health condition. Every time the news comes on of an evening, they will hope that it brings some hope of a new treatment that promises the cure or effective treatment of their condition, or the condition of one whom they love. Unfortunately, the news today tells them that AstraZeneca has cancelled its investment in the UK, which is a big loss for life sciences and cures for people in this country.

Never the less, these regulations are a positive change. This instrument will reform the UK's clinical trial regulatory regime with the aim of delivering a more

"proportionate, streamlined and effective clinical research environment"

by amending the Medicines for Human Use (Clinical Trials) Regulations 2004. These draft regulations are a response to a public consultation launched under the Conservatives in 2022, which asked for feedback on how the regulation of clinical trials could be improved and strengthened in the UK.

I agree with the Minister that we have an opportunity, now we have left the European Union, to design a world-class, sovereign regulatory environment for clinical trials that supports the development of innovative medicines and ensures that the UK retains and grows its reputation as a world-leading base for life sciences, generating opportunities for skilled jobs in the UK. As Conservatives, we welcome innovation and want to support UK patients getting early access to new and innovative treatments. For those reasons, we welcome the changes.

Among the many changes this instrument would make, it would legislate for a notification scheme to enable lower-risk clinical trials to be automatically approved by the licensing authority, where the risk is similar to that of standard medical care. A favourable opinion from an ethics committee would still be required to safeguard people taking part in the trial. The impact assessment estimates that around 20% of initial clinical trial applications would qualify for the notification scheme.

When asked about eligibility criteria for the scheme, the Medicines and Healthcare products Regulatory Agency explained that an application would be eligible if the medicine being investigated is used in line with its authorised use or established practice, supported by evidence; a previous similar clinical trial of a product has been approved in the last two years; or the same trial has been approved in the United States or a European economic area country.

While the clinical trial sponsor is responsible for determining whether the application meets the criteria for notification, the MHRA stated that a verification process would ensure their determination is correct. The notification scheme currently exists on an opt-in basis. The MHRA says that that has reduced the time required to initiate lower-risk clinical trials by more than 50% without compromising patient safety. That will clearly help people to get the new treatments quicker, and is to be welcomed.

We consider that the draft regulations will simultaneously remove obstacles to sponsors' carrying out clinical trials, while ensuring the focus remains on protection of those participating in the trials. It will remove the aspects of legislation that are more prescriptive, in favour of introducing greater flexibility and more risk proportionality, to reflect that trial design and operation is evolving with innovations in the products that trials investigate. Ultimately, these proposed new requirements will ensure that trial participants and their safety are at the heart of legislation.

One thing I would like the Minister to clarify is that on the one hand he was saying that this change in regulation will be revolutionary for people getting trials and drugs more quickly, whereas on the other hand he gave a de minimis amount in terms of the financial benefit. Could he explain that contradiction?

6.13 pm

Andrew Gwynne: I thank the shadow Minister for her support for this piece of secondary legislation, which marks the most substantial update to UK clinical trial regulations in more than two decades. This is an important step forward to deliver a more efficient and adaptable regulatory framework, all while ensuring the safety of the trial participants. The reforms will deliver a proportionate, flexible and efficient clinical research environment, with patients at the very heart of the process.

The shadow Minister raised the issue of AstraZeneca and the support for life sciences in the UK. Without straying too much from the measures before us, Sir Desmond, I want to reassure the Committee that this Government are fully committed to supporting the UK's life sciences sector. Today we have heard about how vital clinical trials are in driving the health and wealth of the UK. The sector has experienced strong growth in recent years; between 2022 and 2023, the number of UK industry-led clinical trials increased by 3.7%. The UK has also gone up in the global rankings for phase 2 trials, moving from sixth to fourth place.

That progress is a testament to our thriving research ecosystem, something that was developed under the previous Government and that we want to build on,

[Andrew Gwynne]

which is what this set of regulations is all about. They are about making sure that our country is at the cutting edge of the latest developments in medical science and that British patients are able to access those treatments as early as possible, through clinical trials and then through the early adoption of those medicines once they are brought to market.

The shadow Minister asked about the de minimis assessment. An assessment of the updated legislation has been produced, which estimates that there will be a total transition cost of approximately £720,000 to business for organisations to familiarise themselves with and operationalise the changes. It is expected that the annual total benefit to businesses will be £1 million, primarily due to the changes in the approval processes. I sought to correct the record in my opening remarks because it had originally been anticipated that we would need to have the full assessment, but on closer scrutiny that is not necessary because of the reasons that I have just set out.

Dr Johnson: When the Minister talks about £1 million, is that the benefit to businesses in the current level of trials? Or is that his estimate of the rise in the number of trials as a result of the changes?

Andrew Gwynne: That is my understanding—I look for inspiration if I am wrong—of the situation today. If that is not correct, I will ensure that the hon. Lady and members of the Committee are informed in writing. The impact on businesses is the impact on business as it stands now, but we want to grow the business and ensure that the ecosystem grows and that the life sciences sector is booming in this country, for all the reasons that I set out in my opening speech.

In conclusion, by modernising our regulatory framework we will ensure that lifesaving treatments are accelerated by streamlined, efficient processes without compromising safety standards. The reforms will strengthen the UK's position as a global leader in innovative clinical trials and help to get lifesaving, life-changing medicines to the people who most need them sooner. I am grateful to the shadow Minister for her support and to Members for considering the regulations today; I hope they will all join me in supporting them.

Question put and agreed to.

6.18 pm

Committee rose.