

# PARLIAMENTARY DEBATES

HOUSE OF COMMONS  
OFFICIAL REPORT

Third Delegated Legislation Committee

## DRAFT HUMAN MEDICINES (AMENDMENTS RELATING TO CORONAVIRUS AND INFLUENZA) (ENGLAND AND WALES AND SCOTLAND) REGULATIONS 2024

*Tuesday 30 January 2024*

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**The Committee consisted of the following Members:**

*Chair:* DAME MARIA MILLER

- |   |   |
|---|---|
| † Baillie, Siobhan ( <i>Stroud</i> ) (Con)  | † McDonnell, John ( <i>Hayes and Harlington</i> ) (Lab)                 |
| † Baker, Duncan ( <i>North Norfolk</i> ) (Con)  | † Morris, David ( <i>Morecambe and Lunesdale</i> ) (Con)                |
| † Caulfield, Maria ( <i>Parliamentary Under-Secretary of State for Health and Social Care</i> ) | † Morrissey, Joy ( <i>Lord Commissioner of His Majesty's Treasury</i> ) |
| † Gideon, Jo ( <i>Stoke-on-Trent Central</i> ) (Con)  | Oppong-Asare, Abena ( <i>Erith and Thamesmead</i> ) (Lab)               |
| † Howell, Paul ( <i>Sedgefield</i> ) (Con)  | † Qureshi, Yasmin ( <i>Bolton South East</i> ) (Lab)                    |
| † Hussain, Imran ( <i>Bradford East</i> ) (Lab)   | † Tarry, Sam ( <i>Ilford South</i> ) (Lab)                              |
| † Jenrick, Robert ( <i>Newark</i> ) (Con)   | † Wakeford, Christian ( <i>Bury South</i> ) (Lab)                       |
| Johnson, Dame Diana ( <i>Kingston upon Hull North</i> ) (Lab)                                   | † Wheeler, Mrs Heather ( <i>South Derbyshire</i> ) (Con)                |
| Liddell-Grainger, Mr Ian ( <i>Bridgwater and West Somerset</i> ) (Con)                          | Luanne Middleton, <i>Committee Clerk</i>                                |
|   | † <b>attended the Committee</b>   |

## Third Delegated Legislation Committee

Tuesday 30 January 2024

[DAME MARIA MILLER *in the Chair*]

### Draft Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024

9.25 am

**Mrs Heather Wheeler** (South Derbyshire) (Con): On a point of order, would it be in order for us to say happy birthday to our wonderful Whip, my hon. Friend the Member for Beaconsfield?

**Christian Wakeford** (Bury South) (Lab): Object! [*Laughter.*]

**The Chair:** I am sure the Chairman of Ways and Means would always want to acknowledge that sort of event, so happy birthday to the Government Whip. I call the Minister to move the motion.

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

That the Committee has considered the draft Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024.

It is a pleasure to serve under your chairmanship, Dame Maria. I also want to pass on my best wishes to my hon. Friend the Member for Beaconsfield; it is always best to keep in with the Government Whip.

In autumn 2020, as part of the response to the covid pandemic, a number of temporary amendments were made to the Human Medicines Regulations 2012 to support the deployment of covid-19 and flu vaccinations following public consultation. This instrument looks to amend the temporary provisions in those regulations—regulations 3A, 19 and 247A—in order to maintain them and support the ongoing delivery of covid-19 and influenza vaccination.

Regulation 3A enables trained healthcare professionals or staff under the supervision of healthcare professionals to conduct the final stage of assembly, preparation and labelling of covid-19 vaccines without requiring additional marketing authorisations or manufacturer's licences, provided that vaccines are supplied under NHS arrangements or by suppliers of medical services to His Majesty's armed forces. Regulation 3A allows for the reformulation and reassembly of authorised covid-19 vaccines without the need for additional marketing authorisations.

Regulation 19 has enabled covid-19 and flu vaccines to be moved safely between premises at the end of the supply chain by providers operating under NHS arrangements or suppliers of medical services to His Majesty's armed forces without the need for a wholesale dealer's licence. Regulation 247A has provided a mechanism to expand the workforce that is legally and safely able to administer a covid-19 or flu vaccine without the input of a prescriber, using an approved protocol. Regulations

3A and 19 have sunset provisions and will cease to have effect on 1 April 2024 unless extended today. Regulation 247A is only permitted for use during a pandemic, so we want to amend it to be valid outside a pandemic for a temporary period.

The regulations continue to play a vital role in the covid-19 and flu vaccination programmes and have helped us to roll out both vaccines this autumn and winter. We are committed to protecting those who are most vulnerable, guided by the independent Joint Committee on Vaccination and Immunisation. Although for most people covid-19 is no longer a serious risk, for some it remains one and vaccines are still the first line of defence for those people. In our latest roll-out, more than 11.8 million covid vaccines have been administered by NHS England since national bookings opened on 11 September last year, and more than 17.9 million flu vaccinations were administered in England during the latest autumn campaign. That includes more than 4.5 million people who received their flu and covid-19 vaccines at the same appointment. The regulations we wish to extend today play a huge part in making that happen.

The Government have engaged a broad range of stakeholders to determine whether to retain the provisions in the 2012 regulations beyond their current period, which ends in April. That initial engagement led the Government to propose an extension, as key stakeholders, including NHS England, said that without these regulations the covid-19 and flu vaccination services would be negatively impacted. Following that engagement, the Government ran a public consultation from 7 August to 18 September 2023 on proposals to temporarily extend the regulations until 1 April 2026 while a permanent solution is developed.

In regulation 247A, condition A, which requires there to be a pandemic for it to be used, would be removed. We had 220 responses, and there was a high level of support for the change.

Eighty nine per cent of respondents agreed that regulation 3A should be extended. It is important to note that covid-19 vaccinations are not available as pre-filled syringes, so a lot of work is done when a covid vaccination clinic is running. The regulations will make that as efficient as possible. The consultation found that the flexibilities of the arrangements for safe assembly and preparation at the pace and scale required mean that our vaccination programmes are as efficient as they can be.

Again, there was a high level of support for regulation 19, with 91% agreeing that it should be extended. There was a similar level of support for the change to regulation 247A, with 82% agreeing with the proposal to remove condition A so that the regulation can be used outside a pandemic.

The regulations have played an important role in reducing workforce pressures, so we are looking at how that can be made permanent. Work is being done to see how we can use our learning from the regulations and the tools they offer to reduce workforce pressures in the future and increase our capacity to deliver hundreds of millions of covid-19 and flu vaccinations. The regulations have also released qualified healthcare professionals to deliver other care across the system.

There are a range of benefits to extending the regulations. The Government propose to temporarily extend the provisions to 1 April 2026 and, in the case of regulation

247A, to remove the requirement that there should be a pandemic or imminent pandemic when the medicine is supplied while a more permanent solution is developed. Extending the provisions will allow the Government to work with system partners to undertake a fuller consideration of longer-term mechanisms that could be deployed to better support the delivery and administration of covid-19 and flu vaccines.

In the short term, however, given the high level of support expressed in the consultation and at a time when covid-19 and flu continue to be prevalent, there is an ongoing need to support the continued safe and effective supply, distribution and administration of covid-19 and flu vaccines by maintaining the provisions to April 2026. I commend the regulations to the Committee.

9.32 am

**Christian Wakeford:** It is a pleasure to serve under your chairmanship, Dame Maria. The Minister will note that I am not the shadow Minister, but if my hon. Friend the Member for Erith and Thamesmead has any additional questions she will write to the Minister. I will start by wishing the hon. Member for Beaconsfield a happy birthday, though unlike the Minister I do not need to keep up a good relationship with the Whips' Office anymore.

I first want to pay tribute to all those who have done so much to blunt the impact of the unprecedented pandemic that came to the UK nearly four years ago. A remarkable effort has been made by our health and care staff, our scientists and others in public services who have done so much to keep the public safe and vaccinate millions across the country as quickly as possible. The positive impact of the vaccination programme cannot be overstated. It not only undoubtedly saved so many lives and drove down cases of covid-19, but finally allowed us all to end the lockdowns and reclaim our freedoms.

As the Minister set out, today we are considering regulations to update legislation pertaining to the movement and supply of covid-19 and influenza vaccines. The changes seek to extend the sunset clauses of regulations 3A and 19 to 1 April 2026 and alter regulation 247A to extend its provision until 2026, instead of the current restriction on its use to only during a pandemic. Extending the provisions, which includes allowing the NHS to continue to use an expanded workforce, appears to be an important intervention to continue to allow the deployment of safe and effective covid-19 and influenza vaccines at the pace and scale required to keep the public protected.

The draft regulations aim to build on the hard work of the covid-19 vaccine roll-out across the country. It will be of no surprise that Labour finds them uncontroversial and will support them. As shown by the mostly positive responses to the Government's consultation last year, the provisions appear to have proved very beneficial to stakeholders in the health and care sector. Regulation 247A appears to have reduced workforce pressures while increasing flexibility in the workforce and providing opportunities for career progression. The impact assessment highlights the positive expected value of these regulations and shares the conclusion that vaccinations are a powerful and beneficial tool to tackling viruses and diseases like influenza and covid-19.

None the less, we have some questions for the Minister. In the impact assessment, the Department mentions its work to move towards a permanent approach that will likely alter these provisions again in the future. As they will be extended only by two years, there appears to be a need for a long-term solution. Can the Minister provide us with any detail about the progress the Department has made in its planning for a permanent approach and when we should expect the developments to be brought forward?

I also wanted to ask the Minister about the wider issues of vaccine take-up, vaccine hesitancy and vaccine misinformation. They are especially poignant given the recent measles outbreak across the country, where too few of our youth were protected against a potentially deadly virus. The Minister will likely be aware of calls last autumn for the Government to extend this winter's covid vaccination booster programme to the 12 million people in the 50-to-64 age cohort. Can the Minister explain why the provision was not extended to that age cohort and whether the Department is worried that we have left millions without proper protection during this winter?

In recent months, it has been proposed that covid-19 vaccinations could be accessed privately, in a similar way to what happens in the United States. Can the Minister share any details about whether and when those vaccinations could be available on the high street? I would also like to raise the issue of health inequalities faced by ethnic minority groups and the most deprived in our society. Last winter, influenza admission rates were 2.6 times higher and covid-19 admission rates 2.1 times higher for individuals living in the most deprived areas than for those in the least deprived. The rate of emergency hospital admissions for influenza was 1.6 times higher for black British people and other minority ethnic groups than for white ethnic groups. I am sure the Minister agrees that the findings emphasise the need to improve vaccine coverage across all ethnic groups and among the least well-off to reduce the risks associated with both influenza and covid-19. What are the Government doing to tackle these inequalities?

Finally, I would like to ask the Minister to explain what the Government are doing to tackle the vaccine misinformation that continues to be widely shared across the country. It remains a large barrier to the delivery of safe and effective vaccines to those who need them and could have a major impact in the future if we face similar health emergencies. While we support the instrument today, I hope the Minister can address the points I have raised. We must ensure we achieve the ultimate goal of sustaining the supply and improving the take-up of safe and effective covid-19 and influenza vaccines at the pace and scale required.

9.37 am

**Maria Caulfield:** I am pleased that we have cross-party support for the regulations. They are important in ensuring that we can deliver an efficient vaccination roll-out, particularly with a potential spring roll-out coming early this year.

In answer to the questions from the hon. Member for Bury South, yes, we are working to look at a more long-term solution. We are engaging with key stakeholders such as NHS England, and proposals will be made.

[*Maria Caulfield*]

There will need to be a consultation, and we will set out the date of that so that everyone can engage with it. It is one thing to put temporary measures in place, but it is another thing to put in long-term, sustainable measures, so it is important that all stakeholders are consulted, particularly those in primary care.

The regulations today extend only to Great Britain. Northern Ireland is not included because health is a devolved matter and there is not a sitting Assembly, but work is going on with Northern Ireland officials and there was positive news today of the potential of the Assembly restarting. We want to make sure that Northern Ireland will be covered by the provisions once there is an Assembly.

**Christian Wakeford:** On that point, it was helpful to have the news today about the Northern Ireland Executive. If, for any reason, they take a long period for this—they have two years to catch up on—will there be a further SI to implement these provisions in Northern Ireland?

**Maria Caulfield:** Ideally, we would not want to do that, because it is for Northern Ireland to determine its own health decisions. However, I can say that Department officials have been sharing draft materials with Northern Ireland officials so, once the Assembly is up and running, that could potentially happen fairly quickly.

On the point that the hon. Member for Bury South made about vaccine hesitancy, it is absolutely true that we are seeing vaccine and immunisation hesitancy across the country. It is very unhelpful that some of these misleading claims are being made, but, when we engage with community leaders, faith leaders and primary care teams that know their communities, we are able to engage.

We had a very successful covid-19 vaccine roll-out, getting to communities that are usually under-represented in vaccination programmes. During covid, that was thanks to the work of the Equality Hub and teams such as the Office for Health Improvement and Disparities. We are now using them again, particularly in London and the west midlands, for the measles immunisation programme, and we should be able to update colleagues about progress on that fairly swiftly.

Although it is not an issue with covid-19 and flu vaccines, there is concern among the Muslim and Jewish communities, and among Seventh-day Adventists and Rastafarians, about the use of pork in some of the measles vaccines. I would just reiterate that there are non-pork-based measles vaccines available, so that should reassure communities on the alternatives. However, there is work to be done in providing reliable information, getting the confidence of communities and making that vaccine as accessible as possible. That is why we are also working with our school teams to ensure that when young children need immunisation, it is as accessible as possible.

The hon. Member touched on the availability of vaccines. We follow JCVI advice and we expect to publish the JCVI advice for the spring roll-out fairly shortly. For those not covered by NHS vaccine programmes—we did not do the over-50s this year—we are looking at the options of a private market for covid-19, as is currently the case for flu. We are having discussions with both suppliers and pharmacies to see what is possible. Again, we will support any moves towards that as much as we can.

The hon. Member's final point, I think, was about ensuring that we can cover as many people as possible with the vaccines. It is down to the JCVI advice. We almost always follow its advice, and it looks at a range of risk factors. That will also change over time; we may move to an annual covid vaccine at some point, compared with the spring and autumn roll-outs, but that will all be guided by the JCVI advice. Obviously, if a variant of concern emerges, that will change things.

The flexibility that these regulations provide really makes a difference, and we have had a positive reception from NHS England—from primary care—about the difference that it has made to the skills mix and career progression of many who administered the vaccines, as the hon. Member pointed out. It has also been a real opportunity to develop the workforce. I hope that that answers hon. Members' questions. I thank them for their cross-party support.

*Question put and agreed to.*

9.43 am

*Committee rose.*



