PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Third Delegated Legislation Committee

DRAFT HUMAN MEDICINES (CORONAVIRUS AND INFLUENZA) (AMENDMENT) REGULATIONS 2022

DRAFT HUMAN MEDICINES (AMENDMENTS RELATING TO THE EARLY ACCESS TO MEDICINES SCHEME) REGULATIONS 2022

Tuesday 8 March 2022

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not later than

Saturday 12 March 2022

The Committee consisted of the following Members:

Chair: †Christina Rees

† Argar, Edward *(Minister for Health)*
† Bonnar, Steven *(Coatbridge, Chryston and Bellshill)* (SNP)
† Bradley, Ben *(Mansfield)* (Con)
Bryant, Chris *(Rhondda)* (Lab)
† Davies, Dr James *(Vale of Clwyd)* (Con)
† Double, Steve *(St Austell and Newquay)* (Con)
† Fletcher, Katherine *(South Ribble)* (Con)
† Gwynne, Andrew *(Denton and Reddish)* (Lab)
† Hall, Luke *(Thornbury and Yate)* (Con)
† Jenrick, Robert *(Newark)* (Con)
† Levy, Ian *(Blyth Valley)* (Con)
† McCabe, Steve *(Birmingham, Selly Oak)* (Lab)
Osamor, Kate *(Edmonton)* (Lab/Co-op)
† Richardson, Angela *(Guildford)* (Con)
Russell-Moyle, Lloyd *(Brighton, Kemptown)* (Lab/Co-op)
† Simmonds, David *(Ruislip, Northwood and Pinner)* (Con)
† Twist, Liz *(Blaydon)* (Lab)

Seb Newman, Jack Edwards, *Committee Clerks*

† attended the Committee

Third Delegated Legislation Committee

Tuesday 8 March 2022

[Christina Rees *in the Chair*]

Draft Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022

2.30 pm

The Minister for Health (Edward Argar): I beg to move,

That the Committee has considered the draft Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022.

The Chair: With this it will be convenient to consider the draft Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022.

Edward Argar: It is a pleasure to serve under your chairmanship, Ms Rees. It is also a pleasure to be here today. It is right that we debate these important provisions.

I would like to take the opportunity, as we often do at the start of such sittings, to pay tribute to every individual who has been involved, in the UK and beyond, in the development and the roll-out of an unprecedented vaccination campaign, not just in this country, but around the world, from the people who have received their jabs, to the professionals and volunteers who have made this happen and those who have continued to keep our NHS running.

The purpose of the provisions in the draft Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022, which, for convenience, I will refer to as the human medicines regulations, is to amend the temporary provisions that cease to have effect on 1 April 2022. The provisions support the continued deployment of safe and effective covid-19 and flu vaccinations at the pace and scale required both now and potentially in the future, while safeguarding patients and limiting disruption to other NHS services.

The SI amends provisions in the Human Medicines Regulations 2012—SI 2012/1916, originally amended by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020—SI 2020/1125—and the Human Medicines (Coronavirus and Influenza) (Further Amendments) Regulations 2020—SI 2020/1594—either to make permanent or to extend by a further two years those key regulatory flexibilities.

In summary, the regulations before us make three key provisions permanent. First, they enable injectable, prescription-only medicines, which include vaccines, to be given under a patient group direction commissioned by the NHS or a local authority. That effectively expands the workforce of available vaccinators. Secondly, they enable pharmacy-led covid and flu vaccination services to operate outside their normal registered premises, thereby enabling, for example, pop-up vaccination clinics to be run by pharmacists at convenient locations for patients. Thirdly, they add several additional groups of healthcare professionals to those who can administer vaccines under occupational health schemes, thereby expanding the workforce to vaccinate health and care staff. The final two provisions relate to a further temporary exemption of easements to licensing requirements for the end-stage preparations of vaccines prior to use and the sharing of vaccines between sites.

The mass vaccination roll-out on the scale and pace that has been possible to date would not continue to happen if the regulations are not approved, and the covid-19 and flu vaccination programmes would not be able to continue running as they currently do. Nor would they be able to be re-established at the pace and scale that has been so vital to our recent success. It is therefore crucial that I provide the rationale in support of these important provisions, which I hope will enable members of the Committee to support them.

It is true that we are debating the provisions from a completely different place than at the onset of the pandemic and since the key regulatory flexibilities were first made in late 2020. Where we are now is a place that we can all be proud of—the culmination of a national mission that has helped us to withstand the pandemic and restore more freedoms to people in this country. It is a reminder of what we can accomplish when we all work together and testament to the success of the biggest ever vaccination programme in the history of the NHS. The vaccines remain our best line of defence against the virus and to help us live with covid. That is the reason why it is vital to make some of these provisions permanent or to extend them for a further period.

As the Committee would expect, patient safety is at the heart of any public health vaccination programme, and is therefore at the forefront of the provisions in this statutory instrument. I firmly believe that the provisions to maintain an expanded workforce, able to lawfully administer covid-19 and flu vaccines under occupational health schemes, will ensure that we can continue to provide critical protections to health and care workers, while ensuring that vaccines continue to be administered by highly trained, qualified staff operating under rigorous professional standards.

Similarly, the provisions enabling injectable prescription-only medicines, which include vaccines, to be given under a patient group direction commissioned by the NHS or local authority have been critical to supporting widespread protection from covid-19 and flu among the general public. By making the provisions permanent, I strongly believe that we can ensure that public health benefits are maintained through the roll-out of covid-19 and flu vaccination, while striking the right balance of maintaining the rigorous standards of oversight for vaccines to be given safely and effectively.

The provisions to enable a pharmacist to offer vaccinations at sites other than their registered premises have already supported improved patient access for underserved communities. For example, faith leaders at a mosque in Blackburn in Lancashire worked in partnership with NHS Blackburn with Darwen clinical commissioning group and the local council to turn the mosque into a pop-up vaccination clinic. It was successfully able to target and support at-risk groups from all local communities who had potentially been hesitant to come forward for their vaccine. I pay tribute to the work that was done in that setting. Making those provisions permanent will enable that type of crucial activity to continue when and where it is needed.

The provisions relating to the temporary extension of wholesale dealer licences and end-stage vaccine preparation have already supported the swift and safe distribution of covid-19 and flu vaccines, and will continue to be critical to efficiently delivering any necessary future covid-19 and flu vaccination programmes, as well as reducing the wastage of vaccines. We have seen the success that those provisions have allowed. We are therefore prioritising the implementation of them to give health services the certainty that they need to be able to continue to plan and operate any necessary mass covid-19 and flu vaccination programmes on the same basis as now.

The emergence of the omicron variant and our critical ongoing booster campaign have further highlighted why those key regulatory flexibilities cannot be allowed to fall away on 1 April. Last month, the National Audit Office, in its report on the roll-out of the covid-19 vaccination programme in England, highlighted the balance between central command and control structures and wider empowerment locally, and that that was a success factor in achieving more than 139 million vaccinations in the 15 months since the programme began, 71% of which were administered by GPs and community pharmacies. That was against a planning assumption of 56% of vaccines delivered that way.

There can be no doubt that the provisions in the draft Human Medicines (Coronavirus and Influenza) (Amendment) Regulations are vital, as they have supported the safe delivery of the biggest programme of vaccination in our history and have proved their worth. That said, I know that there may be some concern among the public, and indeed in today's Committee, that extending or making the provisions permanent might constitute mass vaccination forever by the back door. I appreciate those concerns, but I categorically put on the record for those who might seek to make mischief with such a suggestion that that is not the case. These are enabling provisions only. There is no requirement to use them, and they will not be used unless they are required; rather, they will be a vital addition to the toolkit for the NHS if mass vaccination campaigns against new variants of covid-19 or flu are necessary in the future.

Turning relatively briefly to the second instrument before the Committee, the Government want patients in the UK to be able to access the most effective and innovative medicines as quickly as possible. We have made real strides in recent years to achieve that, including the launch of the Medicines and Healthcare products Regulatory Agency's innovative licensing and access pathway and reductions in the National Institute for Health and Care Excellence assessment timelines. The early access to medicines scheme is another key aspect of how we deliver on that agenda. The scheme helps to give people with life-threatening or seriously debilitating conditions early access to new medicines that do not yet have a marketing authorisation or licence but where there is a clear unmet medical need.

Since 2014, the scheme has transformed the lives of patients up and down the country. For example, through EAMS UK patients were among some of the first in the world to access the breakthrough treatment pembrolizumab, which I have hopefully pronounced correctly—I challenge my shadow, the hon. Member for Denton and Reddish, to attempt to do it rather more fluently and smoothly than me—with approximately 500 patients with advanced melanoma receiving that medicine when no other treatment was available to them.

Just one new product made available through the EAMS can benefit hundreds of patients. Putting the scheme on a statutory footing allows us to maximise the benefits it offers to patients, as well as to support the early development of medicines by innovative manufacturers in the UK.

The provisions deliver three key benefits. First, they reduce the regulatory burden on manufacturers supplying EAMS medicines, making it easier to supply and assemble EAMS medicines in the UK. Secondly, they will facilitate the collection of real-world data from EAMS to support patient access to novel treatments in the future. Thirdly, they will reaffirm in legislation the importance of patient safety within the scheme. As a package of changes, this will help more patients to benefit safely from EAMS products and ensure the UK remains internationally competitive in the pre-market medicines access landscape.

I am pleased to bring forward the first instruments using the powers under the Medicines and Medical Devices Act 2021, allowing us to use effective regulation to provide patients and the public with timely access to critical medicines and vaccines. The provisions in the instruments are important; they will be in force if mass vaccination campaigns against covid-19 and flu are necessary to protect the public and our freedoms and will also ensure that patients with serious conditions can be offered new, life-changing treatment options.

2.41 pm

Andrew Gwynne (Denton and Reddish) (Lab): It is a pleasure to see you in the Chair, Ms Rees. I also wish to join the Minister in paying tribute to all those who got us through the last two years in relatively one piece. It has been a remarkable effort on behalf of so many people and serves to show how exemplary our health and care staff and others in public services from local government right the way through to national Government have been in getting us through the pandemic.

The covid-19 pandemic has been the most serious domestic challenge we have had to face in the post-war era. It would be remiss of me not to mention that, in the last two years, we have seen more than 150,000 lives lost. The impact on our own lives and liberties has been totally unprecedented. There were times when it felt like there was no light at the end of the tunnel, on those long lockdown days when we would stay at home, away from friends and loved ones, only to flick on the news and see the numbers of cases rising and rising. A lot has changed since those first few months. Thanks to our NHS, our incredible scientists and the British public, who have been vaccinated in their millions, we have several highly effective covid-19 vaccines. The entire eligible population has been offered a third booster dose and, while the virus is still with us, we are in a much stronger position than back in March 2020. The impact of the vaccination programme cannot be overstated. It has allowed us to reclaim our liberties, which we were forced to forfeit back in 2020, driven down hospitalisations and saved countless lives.

This statutory instrument continues this good work and it will be of no surprise that Labour finds it non-contentious and will support it today. Indeed, it is wholly necessary that the amendments to the human medicines regulations are made. The statutory instrument enables us to continue with mass vaccination campaigns for covid-19 and influenza and extends temporary provisions relating to manufacturing licences and marketing

[Andrew Gwynne]

authorisations. It permanently broadens the healthcare groups that are entitled to administer parenteral vaccines in an NHS or local authority setting and enables community pharmacists to deliver flu and covid vaccines outside their normal premises.

The changes are sensible and will ensure that in any future mass vaccination roll-out, the requisite resources will be available to administer vaccinations. That will be particularly useful over the winter months, when we will need to contend with seasonal influenza alongside a potentially large uptick of covid-19 cases.

As I say, covid has not disappeared and we need to be prepared and ensure that the population remains protected against rising case numbers and possible mutations. That also means ensuring we do more to reduce health inequality in vaccine uptake. The under-30s, some ethnic minority groups and pregnant women disproportionately make up the estimated 8.5% of the 12-plus population who remain unvaccinated. We cannot afford to be complacent, and we need to be doing as much as possible to encourage people to take up the vaccine. It would be helpful if the Minister could set out what further action his Department will take to reduce those inequalities in vaccine uptake and outline how the extension of the provisions will enable his Department to tackle vaccine hesitancy better.

On the second SI before the Committee, the early access to medicines scheme has been place for almost eight years, and it is managed by the MHRA. It aims to provide patients with life-threatening or seriously debilitating conditions access to medicines that are either not authorised generally or for the specific clinical use proposed. It provides necessary regulatory flexibility for medicines that can often be a matter of life or death. More 100 medicines have been granted promising innovative medicine status and more than 40 scientific opinions have been awarded in areas with unmet patient need. The Labour party support that wholeheartedly. Cutting-edge medication and treatment can often take years to receive full approval and in that time lives can be lost. It speaks to the necessity of the scheme that more than 1,600 patients have benefited from EAMS medicines since the scheme's implementation.

An example of the efficacy of EAMS was given in a recent article on it published by the British Liver Trust. It cited Roche's Tecentriq, which helps to treat people with lung cancer. Because of EAMS, 63 patients were able to access the drug after a specialist review, which gave those individuals access to life-saving treatments four months' earlier than expected. Four months is an exceptionally long time when suffering from a life-threatening condition and can make all the difference to long-term outcomes. Pharmaceutical companies have raised concerns that EAMS is not delivering an attractive proposition for the industry and that the scale of early patient access originally envisioned has not been delivered. Given the example cited by the British Liver Trust, however, I do not think such concerns stand scrutiny.

The EAMS independent review, published back in 2016, identified areas for improvement. The SI addresses some of those concerns, but I will seek further clarifications from the Minister in due course. Placing EAMS on a statutory footing will give pharmaceutical companies and patients necessary legal clarity. I am grateful that the SI is clear about the need to continue to protect patient safety and that it aims to simplify EAMS's requirements where feasible.

It is notable that the proposed legislation will support the collection of real-world data, which will no doubt incentivise medical innovation. I am also grateful that the SI makes it clear that patient consent to data collection is not a condition of EAMS supply.

I have a particular keen interest in EAMS as Labour's lead in the shadow health team for clinically vulnerable, extremely vulnerable and immunocomprised people. Recently I heard from a charity about the anti-viral drug Evusheld. It is a preventive antibody treatment for the benefit of people with compromised immune systems, who cannot get a sufficient antibody boost from vaccines. That medication received approval in the United States and France in December last year, but patients in the UK cannot yet access that treatment because the approval process is ongoing.

It has been reported that for some pharmaceutical companies there is a black hole in the system once the marketing authorisation is granted. Once MA is approved, EAMS designation falls away, and that can lead to a gap of several months in which no further patients can gain access to a given drug as it goes through NICE's final assessment. That treatment gap has been recognised in the independent review and by pharmaceutical companies and charities. Can the Minister offer an assessment of that, and say whether the Department is considering a mechanism to ensure smoother transition from EAMS to full Health TechConnect and NICE approval?

The scheme is a great illustration of the fantastic work that can be done when industry works alongside healthcare agencies with the patient's best interests at heart, but we must not take our foot off the pedal. We need to keep working to ensure that cutting-edge research is properly supported and the needs of patients are put first. My apologies to you, Ms Rees, for getting some of my words garbled; it is the long covid. That will be the excuse for evermore, I fear, but we are happy to support the SIs.

2.50 pm

Steven Bonnar (Coatbridge, Chryston and Bellshill) (SNP): It is a pleasure to see you in the Chair, Ms Rees. I thank the Minister for laying out his reasons for introducing the legislation, and why it is required. I echo the comments made by the Opposition spokesperson on our gratitude to our frontline health workers in the fight against coronavirus. They are the real heroes of these nations.

The Scottish National party welcomes moves to ensure that an expanded category of authorised vaccinators who can deliver the coronavirus vaccine is maintained, and to extend the expansion of locations at which vaccines can be prepared and administered. With full authorisation of the coronavirus vaccine still pending, those moves are necessary. The fact that the conditions need to be extended, as laid out by the Minister, is a reminder to us all that the pandemic is still ongoing, and therefore a reminder to Governments that they should be taking a cautious and sensible route out of it. This is one way in which we will be able to achieve that.

Moving on to the draft Human Medicines (Amendment Relating to the Early Access to Medicines Scheme) Regulations, the SNP again welcomes moves to support

more patients for whom medicines exist that are not yet authorised for full sale and marketing in the UK medical market. Approval of medicines under EAMS must be followed by the adequate provision of medicines to those who need them. As the legislation around medical marijuana shows, approval does not always translate to availability to those in need. The UK Government should take the opportunity, while reviewing medicine provision, to consider the removal of prescription fees. While people throughout the UK face the consequences of a real cost of living crisis, forcing them to pay for their medicine too is, in our opinion, wrong. I would like to hear the Minister's opinions on that.

2.52 pm

Edward Argar: I am grateful to both the shadow Minister and the SNP spokesperson for the tone and manner in which they have approached this. Often when our activities in this House are looked at from outside, what is seen is the disagreement across the Dispatch Box in the Chamber, but actually there are many things such as today's instruments that are of importance to all our constituents, wherever they are in the UK, and there is a great degree of consensus. I am grateful for that, and it is a pleasure, as always, to serve opposite the hon. Member for Denton and Reddish.

Both hon. Members who spoke were right to highlight the collective effort that has been involved in the vaccination programme. We rightly pay tribute regularly to our health and care workers, but it is equally important that we pay tribute to those in central Government, the civil service, local authorities and local councils up and down the country, to volunteers and others who have given of their time and commitment to make this work, and of course to the great British public, who bore the restrictions under which they lived for two years, on and off, to a greater or lesser degree, with fortitude. They have done the right thing and got vaccinated in their millions, and it is right that we say thank you to them for that.

The shadow Minister rightly touched on a number of points. He talked about health inequalities in the context of vaccination. He is absolutely right, and we continue to focus very much on that issue in terms of driving further uptake of the vaccine. A range of different inequalities manifest themselves in this context. The example that I used of a mosque becoming a vaccination centre is, I think, a powerful one. That took place in similar settings up and down this country, in our towns, cities and rural communities. Using such venues to make it easier for people to engage with the vaccination programme is central. That is why the statutory instrument is so important.

Alongside that, we rightly continue to work with community leaders and others to inform and educate people about the reality of the vaccine and its potential to save lives and prevent serious illness, to try to counter some of the dangerous misinformation that can often be found on the internet or elsewhere, and to encourage people to take up the vaccine if they have not already done so. I reassure the SNP spokesperson—though I do not know that he needs reassurance—that we have engaged fully with the devolved Administrations, including the Scottish Government, who have been extremely helpful and supportive in what we are seeking to do here. Through him, I pass on my gratitude to the Government in Scotland.

The shadow Minister rightly highlighted the success of the EAMS programme and what it has achieved, and the example of a medicine being available four months earlier than it otherwise would be, and just what a difference that can make. It is literally the difference between life and death in many circumstances, so it is hugely important. I share his view of the 2016 review. We have made progress today, and will do subsequently, but there is still more to do on the review, and we continue to look at how we can build on it. He talked specifically about the gap that could occur between the EAMS programme and an MA being granted. It is an important point, because if someone is undertaking a course of the medicine or needs to start it, returning to our earlier discussion about timeliness being important, any delay—be it one month or two—can be a real challenge. I commit that we will look at that, in the context of the other 2016 review recommendations that we need to reflect on to see whether we can go further.

I agree with the shadow Minister entirely that it is vital that we do not let up in our vaccination efforts, because the vaccine has been our route out of this highly dangerous pandemic. Nor must we take our foot off the gas in respect of promoting and enabling access to cutting-edge research and treatments for patients in this country—all of our constituents, should they need it. I believe that the two sets of draft regulations before us help to enable us to achieve that goal, and I commend them to the Committee.

Question put and agreed to.

DRAFT HUMAN MEDICINES (AMENDMENT RELATING TO THE EARLY ACCESS TO MEDICINES SCHEME) REGULATIONS 2022

Resolved,

That the Committee has considered the draft Human Medicines (Amendment Relating to the Early Access to Medicines Scheme) Regulations 2022.—*(Edward Argar.)*

2.57 pm

Committee rose.