PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Third Delegated Legislation Committee

DRAFT HUMAN MEDICINES (AMENDMENT RELATING TO ORIGINAL PACK DISPENSING) (ENGLAND AND WALES AND SCOTLAND) REGULATIONS 2023

Tuesday 5 September 2023

No proofs can be supplied. Corrections that Members suggest for the final version of the report should be clearly marked in a copy of the report—not telephoned—and must be received in the Editor's Room, House of Commons,

not later than

Saturday 9 September 2023

The Committee consisted of the following Members:

Chair: Caroline Nokes

† Ansell, Caroline *(Eastbourne)* (Con)
† Bacon, Gareth *(Orpington)* (Con)
† Bradshaw, Mr Ben *(Exeter)* (Lab)
† Caulfield, Maria *(Parliamentary Under-Secretary of State for Health and Social Care)*
Day, Martyn *(Linlithgow and East Falkirk)* (SNP)
† Fuller, Richard *(North East Bedfordshire)* (Con)
† Fysh, Mr Marcus *(Yeovil)* (Con)
† Henderson, Gordon *(Sittingbourne and Sheppey)* (Con)
† Jones, Andrew *(Harrogate and Knaresborough)* (Con)
† Jones, Fay *(Brecon and Radnorshire)* (Con)
Leadbeater, Kim *(Batley and Spen)* (Lab)
Lewis, Clive *(Norwich South)* (Lab)
† Lord, Mr Jonathan *(Woking)* (Con)
† Simmonds, David *(Ruislip, Northwood and Pinner)* (Con)
† Smyth, Karin *(Bristol South)* (Lab)
† Vaz, Valerie *(Walsall South)* (Lab)
† Wakeford, Christian *(Bury South)* (Lab)

Aaron Kulakiewicz, *Committee Clerk*

† attended the Committee

Third Delegated Legislation Committee

Tuesday 5 September 2023

[Caroline Nokes *in the Chair*]

Draft Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023

2.30 pm

The Chair: Before I call the Minister, I just want to confirm that if gentlemen wish to remove their jackets, they are free to do so.

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 (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023.

It is a pleasure to serve under your chairmanship, Ms Nokes. I will set out the purpose of the draft statutory instrument. The Human Medicines Regulations 2012 set out when medicines need to be prescription only and the requirements of pharmacists selling or supplying prescription-only medicines. This draft statutory instrument makes two amendments to the Human Medicines Regulations. First, it enables original pack dispensing of medicine when original packaging is required. Secondly, it requires whole-pack dispensing of medicines containing valproate.

The first amendment, under proposed new regulation 217B, will enable the pharmacist to dispense 10% more or less of the medicines compared with the quantity prescribed if they can dispense them with the manufacturer's original packaging. Dispensing in the manufacturer's original packaging brings a number of benefits. First, it improves patient safety because original packaging contains clear instructions and information about the medicines. Secondly, it frees up pharmacy time by reducing the amount of time spent splitting packs and counting packs and strips. However, the responsible pharmacist will need to make a judgment as to whether to use this 10% discretion. For example, the flexibility should not be applied to some medicines, such as courses of steroids or antibiotics, and the exact quantity prescribed should be the quantity supplied.

Original pack dispensing will not apply to controlled drugs, where the exact quantity prescribed will continue to need to be dispensed. Nor will it apply where a medicine is already dispensed in a full pack, for example because it is in a form that is not practical to dispense in the exact quantity ordered.

While the flexibility of 10% will not enable all prescriptions to be dispensed in the manufacturer's original packs, it will deal with the issues of whether a month's supply is for 28 or 30 days, and with multiples. For example, if a prescription is for 28 days but the pack has 30 tablets, currently the pharmacist has to remove those two extra tablets. The new flexibility will enable the full pack to be supplied and vice versa. The amendments for original pack dispensing will apply across Great Britain and they are enabling, so pharmacists can decide whether to utilise the original pack dispensing with the flexibility of plus or minus 10%.

A transitional provision has been included, so pharmaceutical services in England will need to further negotiate with Community Pharmacy England on pricing arrangements following the draft regulations. I understand that in Scotland, however, they are ready to move forward with this, so it will apply immediately.

Valerie Vaz (Walsall South) (Lab): The Minister gave the example of 28 days or 30 days. Will pharmacists be able to explain to patients that they will not necessarily have to take them for 30 days?

Maria Caulfield: Absolutely, and pharmacists are very keen to do this. This will often be used for repeat medication. A GP may prescribe a month's pack—which, depending on the supplier, will be for either 28 days or 30 days—but when dispensing the packs the pharmacist will be able to give advice to patients so that they are absolutely clear on the instructions, which will also be written on the pack.

That goes to my point that by ensuring that patients receive the necessary information that is included in the original manufacturer's packaging, they will be supported in taking their medicines more safely and effectively. The amendments will lead to a reduction in the use of plain dispensing packaging—those little white boxes—so that patients can stop getting lots of small snips from blister strips. When they get full strips, that will make it easier for them to manage the supply and support compliance, because they will be able to identify more easily whether they have taken their tablet that day and how many they have left.

Original pack dispensing also helps pharmacists and their staff to become more efficient, as the number of times they have to snip blisters, repackage medicines and source extra patient information leaflets is reduced, freeing up time for other tasks such as providing clinical services to patients. The benefits of original pack dispensing will be synergistic with the benefits of expanding hub and spoke arrangements, which we are rolling out across the pharmacy sector. The use of hub and spoke dispensing arrangements has been consulted on, and we will publish that consultation in due course. Both today's measures and the expansion of hub and spoke dispensing are a commitment to the community pharmacy contractual framework and are important foundations in transforming community pharmacy.

The second regulation, proposed new regulation 217C, is about the whole-pack dispensing of valproate. "Valproate" is a term for medicines containing sodium valproate, valproic acid and valproate semisodium; it includes various brands such as Epilim. Valproate is an effective medicine prescribed for the treatment of epilepsy and bipolar disorders, but it is associated with birth defects and neurological disabilities in babies exposed to it during pregnancy. The risk to children of mothers who have taken valproate during pregnancy of having neurodevelopmental disorders is estimated at 30% to 40%, in addition to an 11% risk of congenital abnormalities.

A number of measures are already in place to try to prevent pregnancies while women are taking valproate, such as the pregnancy prevention programme, which has already reduced the number of pregnancies exposed to valproate. But the latest data suggests that in England at least three pregnancies a month are still being exposed to medicines containing valproate. More needs to be done.

The regulations will require that patients receive only the manufacturer's complete original packs, with limited exceptions in specific circumstances. The manufacturer's original packs contain specific warnings and pictograms. There is a patient card along with statutory patient information leaflets, which outline the risks of taking the medicine. If patients are concerned about taking valproate, they should talk to their healthcare provider and should not stop taking their medicines without medical supervision.

The provision will be mandatory across Great Britain. There is no transition period and it will apply as soon as the regulations come into force. I hope I have set out the rationale for original pack dispensing for the majority of medicines and using the specific manufacturer's complete original pack when dispensing valproate medicine. I commend the regulations to the Committee.

2.37 pm

Karin Smyth (Bristol South) (Lab): It is a pleasure to serve under your chairship, Ms Nokes. The Opposition are supporting the regulations because they clearly represent the right thing to do for patients and constituents. Not only do they improve patient safety, which must be our priority, but they increase flexibility for pharmacists and patients alike. I am also pleased that valproate has been given due attention in this SI, following the important work by Baroness Cumberlege in the independent medicines and medical devices safety review; it is just a shame that it has taken two years following the Government's own consultation on this matter to introduce this legislation.

Campaigners have long argued that it is key that medicines containing sodium valproate should be dispensed in the original manufacturer's packaging to ensure that women and girls, particularly those of child-bearing age, always receive patient information about taking the medicine while pregnant. As we know from the many tragic impacts of foetal valproate spectrum disorder on our constituents and people around the country, this SI is long overdue. I pay tribute to those campaigners.

As the Minister would expect, I have some questions. The Medicines and Medical Devices Act 2021 requires that, when assessing whether regulations would contribute to the objective of safeguarding public health, the appropriate authority must have regard to three factors, one of which is the availability of medicines. It appears to me that the SI misses the opportunity to address the current shortage of medicines, including of those involved in hormone replacement therapy—something that has affected many women across the country.

Section 64(5) of the Medicines Act 1968 prohibits the sale or supply of a medicinal product where that product is not of the nature or quality specified in a prescription—for example, if a pharmacist dispenses two 50 microgram tablets against a prescription calling for a 100 microgram tablet, when the 100 microgram product is in short supply. The SI allows the dispensing of 10% more or less than the quantity prescribed of a medicine. Given that the SI is about flexibility, and given the campaigning on this issue, particularly by women, this could have been an opportunity to look again at packaging; women could then get the drugs that they are prescribed.

The professional judgment of pharmacists will remain a critical part of the dispensing process for all medicines. I am pleased that guidance on whole-pack dispensing of medicines containing valproate will be provided by the Medicines and Healthcare products Regulatory Agency before the instrument comes into force. What other support and guidance will be given to pharmacists to ensure that the SI is implemented effectively? Will the Minister give an indication of the timeline for the consultation on Pharmacy First, given that it is due to be implemented by the end of this year? Can she tell us about the contractual restrictions relating to NHS prescriptions? As I understand it, reimbursement is based on the exact product prescribed. Forgive me if I missed it, but I do not think that she addressed that issue.

Finally, I appreciate the publication of an impact assessment alongside this SI, but the section on reimbursement gives two alternative scenarios: either reimbursement based on the quantity written on the prescription, or reimbursement based on what was dispensed, rather than what was written on the prescription. Those necessarily have different impacts on the cost to pharmacies and the wider NHS. If the Minister could provide clarity on those issues, I would be grateful.

2.41 pm

Maria Caulfield: I thank the Opposition for their support; it is very welcome and appreciated. I, too, pay tribute to Baroness Cumberlege for her work in this area, and to groups including In-FACT—the Independent Fetal Anti-convulsant Trust—which have been campaigning for a long time for better protection and support for women taking valproate.

Let me answer the hon. Lady's questions. On greater flexibility, that is being looked at as a wider piece in community pharmacy by the pharmacy Minister, my hon. Friend the Member for Harborough (Neil O'Brien). There can be flexibility when there is a shortage of medicine; the hon. Lady brought up the example of HRT. When there is a shortage of a product, we issue a serious shortage protocol, which gives pharmacists flexibility when they have a pack on their shelf that is not quite what the prescription says. As she says, the prescription may be for 10 micrograms; if the pharmacist has two packs of 5 micrograms, or a different form of the medicine, there is flexibility under the SSP to dispense that, rather than sticking to the prescription. We are looking at whether that needs to be part of a wider piece of work on medicines overall.

The hon. Lady touched on Pharmacy First. The pharmacy Minister will update the House shortly on that; there is work going on around Pharmacy First and its roll-out. The hon. Lady touched on reimbursement. She is absolutely right: there are cost issues that community pharmacies will rightly want to iron out. That is why we have put a transitional arrangement in the SI: so that discussions with Community Pharmacy England on funding and reimbursement of costs can be hammered out before the SI is put into practice. That is the next

[Maria Caulfield]

stage. Once we have agreed to the SI, we will go into negotiations on pricing and reimbursement, so that the measures meet pharmacy's needs when it comes to costs; the aim is not to put costs on pharmacy by introducing these measures.

I hope that I have reassured the hon. Lady that we are looking at the issues she mentioned. In particular, we issue serious shortage protocols quite regularly when we have a shortage of medicine, and that gives pharmacists a degree of flexibility in dispensing, without the need for further regulation. I thank Members on both sides of the Committee for their support today. I hope that I have reassured them that we are acting with urgency on valproate, and that original pack dispensing will give pharmacists flexibility, which will free up their time, so that they can focus more on clinical activity.

Question put and agreed to.

2.43 pm

Committee rose.