Northern Ireland Assembly

Windsor Framework Democratic Scrutiny Committee

OFFICIAL REPORT (Hansard)

COM/2023/192 Proposal for a Directive on the Union Code Relating to Medicinal Products for Human Use and Repealing Directive 2001/83/EC and Directive 2009/35/EC; and COM/2023/193 Proposal for a Regulation Laying Down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human Use and Establishing Rules Governing the European Medicines Agency, Amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and Repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006:
Department of Health

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Members present for all or part of the proceedings:
Mrs Ciara Ferguson (Chairperson)
Mr David Brooks (Deputy Chairperson)
Dr Steve Aiken
Mr Jonathan Buckley
Mr Declan Kearney
Mr Peter Martin
Mr Eóin Tennyson

Witnesses:

Mr Sean Curley	Department of Health
Mr Aaron McKendry	Department of Health

The Chairperson (Ms Ferguson): I welcome Sean Curley, principal pharmaceutical officer in the Department of Health, and Aaron McKendry, the Department's senior principal pharmaceutical officer and head of the medicine regulatory group. You are welcome, gentlemen. I invite you to make your presentation.

Mr Sean Curley (Department of Health): Thank you very much, Chair. Good morning, members, and thank you for the opportunity to provide the Committee with some background information on the EU's proposal for a directive of the European Parliament and the Council on the Union code relating to medicinal products for human use, known as "the directive", and its proposal for a regulation of the European Parliament and the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency (EMA), known as "the regulation".

I am a principal pharmaceutical officer in the Department of Health, and my role today is to provide the Committee with background information from a Health perspective on the proposals for medicine supplies coming into Northern Ireland (NI). I am joined by Aaron McKendry, the Department's senior

principal pharmaceutical officer and head of the medicine regulatory group, who leads on the enforcement of medicines legislation in NI.

As members will be aware, the proposed directive relates to medicinal products for human use and will repeal directive 2001/83/EC and directive 2009/35/EC, both of which currently apply in NI via annex 2(20) to the Windsor framework: 'Medicinal products'. The directive lays down the rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use.

The proposed regulation will amend regulations (EC) 1394/2007 and (EU) 536/2014 and repeal regulations (EC) 726/2004, (EC) 141/2000 and (EC) 1901/2006 for all relevant provisions that apply under annex 2(20) to the Windsor framework: 'Medicinal products'. The proposed regulation lays down the procedures for the authorisation, supervision and pharmacovigilance at EU level of medicinal products for human use, establishes rules and procedures for the security of supply of medicinal products and lays down the governance provisions of the EMA. The two legislative proposals are part of an EU reform package and together revise and replace existing general pharmaceutical legislation. It is important to consider the reforms together, as they form a joint package and apply to medicinal products for human use, including those for the treatment of children and of rare diseases.

Members provided questions for the Department to address, and I will provide answers that are based on the Department's current understanding. First, I will discuss the work that the Department has undertaken to understand the interactions between the proposals and the recent EU legislative amendments to ensure the supply of medicines into NI; our engagement with stakeholders; areas of concern or uncertainty; and when an assessment of the proposals will be complete.

There are positive and successful collaborative working relationships between the Department, the Department of Health and Social Care (DHSC) in England and the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). That was demonstrated recently by the successful implementation of Windsor framework arrangements for medicines. The MHRA also hosts dedicated partnership support meetings with industry stakeholders that provide stakeholders with an opportunity to discuss upcoming guidance and legislation. Those channels were used to help to implement the Windsor framework arrangements for medicines. Although the Windsor framework dedicated partnership meetings have been stepped down, engagement with stakeholders has continued to support an analysis of the impact of EU proposals on the whole of the UK, including Northern Ireland.

Regulation 2023/1182, which deals with the Windsor framework arrangements, is a stand-alone regulation and will continue to apply when the EU pharma reforms are introduced. From 1 January 2025, the arrangements for medicinal products under the regulation removed NI from the EU's centralised authorisation procedure for novel and innovative medicines and disapplied EU falsified medicines directive (FMD) safety features on medicines' packaging placed on the NI market. That means that novel and innovative medicinal products are now authorised on a UK-wide basis by the MHRA in line with UK legislation. The disapplication of FMD safety features means that medicine packaging can also be done UK-wide; there is nothing unique to NI.

Directive 2022/642 was published in April 2022 and is significant legislation for supplying medicines from Great Britain to NI. The directive permits regulatory requirements, such as the location of a qualified person and batch testing, to be recognised in GB when supplying the NI market, thereby removing additional regulatory importation controls. It also permits the MHRA to issue a national licence in NI for a medicinal product, even when a corresponding product authorised under the mutual recognition or decentralised (MR/DC) procedure is available in the EU. Those amendments have been included in the proposed directive under chapter XVII.

The reassurance that those two significant amendments will continue to apply in NI under the proposed EU pharma reforms should provide some assurances to the Committee on the long-term supply of medicines into NI. That means that the MHRA will continue to authorise medicines in NI and that supplies can continue to be supplied from GB without additional regulatory importation controls. Additionally, aspects of the interaction between the two pieces of legislation and EU proposals are unchanged or will have no impact on NI. For example, any changes to the access to novel and innovative authorised products within the EU or changes to EU authorisation times for those products will not apply in NI because of the amendments under regulation 2023/1182. That relates to the EU proposals on getting quicker access to those types of medicines, so they do not apply to Northern Ireland.

It is important to understand how the amendments will interact with other aspects of the new proposals, including the reclassification of antimicrobials as prescription-only medicines (POMs). It is equally important to note that member states are still discussing the proposed EU pharma reforms, so the final proposals may differ from the current published drafts. There are, for example, ongoing discussions in the EU on the period of data exclusivity for novel and innovative medicines. Although any outcomes of those negotiations will not apply in NI, due to the arrangements under the Windsor framework, it is an example that demonstrates that proposals are not finalised. Therefore, the Department cannot provide an assessment date at this stage, but it will continue to support the MHRA, which is the competent authority for the whole of the UK, as it continues its ongoing work on the technical details of the reforms.

The Department will also continue to work closely with DHSC and all partners as further details of the proposals emerge, including with colleagues from the NI Executive Office in Brussels. I am sure that any members who have been out to that office will recognise the excellent job that our colleagues there do, and they keep us regularly updated.

Members raised queries about any potential actions and negative impacts identified at this stage. As stated, there is some uncertainty concerning the reclassification of antimicrobials as prescription-only medicines. The reclassification would mean that antimicrobial medicines could no longer be sold or supplied under current provisions as general sales lists or pharmacy-only medicines. Therefore, they would need to be supplied or sold under the provisions permitted for prescription-only medicines. Failure to apply the proposals in NI would remove the dual market access that manufacturers in NI currently have when supplying both the EU and UK markets.

Members wanted some information on paediatric medicines. As stated in information provided to the Committee, most regulatory submissions that trigger paediatric requirements will be products that are within the scope of the EU's centralised authorisation procedure, and, therefore, those medicines can be regulated under UK legislation. I am unable to confirm how many submissions would meet those requirements. However, marketing authorisation holders would be able to apply only to the MHRA for UK-wide or NI authorisation. Therefore, the Department does not have any concerns about the authorisation or supply of paediatric medicines. I should also state that, although we cannot give a definitive answer on that, in exceptionally rare circumstances, it may come up that products will not be under the EU's centralised procedure.

At this stage, the Department has not engaged with stakeholders on the financial implications for or potential impact on the pharmaceutical industry. Finally, as members will be aware, any concerns or questions about goods of relevance to the operation of the Windsor framework can be raised by the EU or the UK Government through joint bodies. While the Department has a positive working relationship with DHSC and the MHRA, any queries concerning potential discussions at those joint bodies on the EU pharma legislative package should be directed to the UK Government.

I hope that members are content with the detailed information provided. We are happy to take any questions that members have at this stage.

The Chairperson (Ms Ferguson): Thank you, Sean. Steve Aiken would like to ask a few questions.

Dr Aiken: Thanks very much indeed for the briefing. I have a couple of questions. The explanatory memorandum (EM) states:

> *"New or innovative medicines for the Northern Ireland market must be authorised by the European Commission on the recommendation of the European Medicines Agency (EMA)."*

Is it your understanding that new or innovative medicines are not covered by the European Medicines Agency and are covered only by the UK's MHRA?

Mr Curley: Yes, that is the case now. Under Windsor framework arrangements, from 1 January 2025, all innovative and novel medicines that fall under the scope of the EU centralised authorisation procedure and are authorised by the European Commission are now authorised by the MHRA for Northern Ireland and the rest of the UK under UK legislation.

Dr Aiken: Is there no issue with generic medicines?

Mr Curley: Generic medicines are still licensed by the MHRA. The EU has no say in the authorisation of such. The national licences are authorised by the MHRA. At the moment, there are no concerns about their supply and authorisation. We are letting MHRA continue to look at the technical details of the proposals, but we have no concerns at the moment about authorisation.

Dr Aiken: One of the previous pieces of legislation that it is looking to repeal is Regulation (EC) No 726/2004. In the legislation, it says, "human and veterinary medicine", and then, in the amendment, it changes to "human medicine". Does that mean that some of the things that we are looking at are already covered? You know that one of our big concerns is veterinary medicine and its authorisation: does that take veterinary medicine completely out of the whole human medicine chain?

Mr Aaron McKendry (Department of Health): I may need to take that away and look at it.

Dr Aiken: It just stuck out when I was reading through the documentation. The legislation clearly said "human and veterinary medicine", and then the amendment said just "human medicine". I wonder whether there are any other implications of that.

I quite like your turn of phrase, and I will take this next point up with the Minister when I see him on Tuesday. Your paper states:

> *"the scale and depth of products that fall under the scope of the new arrangements were unknown at the time of publication."*

Is that a bit of Civil Service catch-all meaning that you do not know quite what is going on?

Mr Curley: No. That obviously relates to the UK EM. The UK EM was first published shortly after the Windsor framework had been announced. The details of the Windsor framework and how it would work and interact with medicines were not known at that point. It was not until they looked at the technical details of the legislation and how it interacts with other legislation that they understood the scale and scope. It is not anything untoward; it is just that, when it was first announced, the details, including the technical details were not known.

Dr Aiken: On issues to do with medical trials, trial medicines and that sort of area, there is something about testing and a qualification of medical testing. Have you any concerns about that?

Mr Curley: Directive (EU) 2022/642, which addressed and changed aspects for medicinal products, also altered things known as "investigative medicinal products" (IMPs) for clinical trials. It also allows for them to continue to flow from GB to NI without any additional importation requirements.

Dr Aiken: They will still be licensed under the UK MHRA. OK. Basically, you are content that, even though significant changes are coming through with the legislative process on the European side, we are still covered by the Windsor framework articles, and, for medicines, medical procedures and the rest, we still fall under the UK regulation?

Mr Curley: There are some parts of the proposals that will apply in Northern Ireland. Novel and innovative medicines will be under UK legislation, but things that do not fall under the scope of that will fall under the scope of the EU proposals. As I said, the MHRA continues to look at the technical details of how they interact with the two EU amendments. There are some aspects with some uncertainty, such as the reclassification of antimicrobial prescription-only medicines.

Dr Aiken: Is it only antimicrobial that, you think, will fall out of the scope, or is anything else likely to fall out of the scope?

Mr Curley: Antimicrobials have been added to the proposals. Under the proposals for prescription-only medicines, it mentions medicines that are used parenterally — injected. They are prescription-only medicines but they have added antimicrobial because they are looking at reducing antimicrobial resistance. It is thought that adding antimicrobial medicines to prescription-only medicines and putting more restrictions on how they are supplied will help to bring down antimicrobial resistance. We are working with the MHRA to understand how that would work in Northern Ireland.

Dr Aiken: OK. Will you flag to the Committee any area that is coming out of scope so that we are aware of that?

Mr Curley: If any other uncertainty comes through or there is any uncertainty that we are still looking at, we will be happy to share that with the Committee. During EU exit days, when Cathy Harrison, Chief Pharmaceutical Officer, was trying to get more detail on some of the proposals for the Health Committee, she was not afraid to voice such concerns, because the supply of medicine to Northern Ireland is vital. She was very vocal, and we will continue to be vocal if there is uncertainty about whether there is likely to be an impact on medicine supplies. I reassure the Committee that we will share any uncertainty.

Dr Aiken: Thank you very much indeed for the quality of your evidence. Sometimes, evidence to the Committee is not quite of the same quality. Also, thank you for answering the questions as well as you have.

Mr Martin: I echo Steve's comments: the evidence has been really sound.

I will start with antimicrobials, which is more or less where Steve left off, particularly antifungals. I understand that the driver behind the EU moving some of those to prescription-only is to mitigate resistance to them. Is it possible at the moment to buy antifungals in Northern Ireland without a prescription?

Mr McKendry: There are three classifications of medicine in Northern Ireland: general sales list (GSL) medicines, which are the least tightly controlled; pharmacy medicines, which are sold only from a pharmacy and might be considered over-the-counter (OTC) medicines; and prescription-only medicines, which, as you say, need a prescription and are, bar some exceptions, supplied from a pharmacy. I think that you are asking whether antifungals fall within that GSL category, and there will be some that do. GSL medicines are ones that you might buy in a garage or large supermarket, so some will fall into that category.

Mr Martin: In the antifungal category, those could be treatments for athlete's foot or yeast infection, for example.

Mr McKendry: Exactly.

Mr Martin: My wife is a pharmacist, so I know a wee bit about this sort of stuff. *[Laughter.]* Let us stay with pharmaceutical sales and talk about the step up from GSL. You might go a pharmacy and ask, "Can I have x or y?". That would probably widen the list of antimicrobials a little, so there might be other things on that list that you could purchase directly from a pharmacist. I understand the driver for the possible tightening — let us call it "tightening" — of the sale of antimicrobials. However, if this goes through and a number of antifungals, antibacterials or whatever are put on to a prescription-only list, which, if I understood your evidence correctly, is what is being considered, will that have an impact on cost, not necessarily for the consumer, because they will then be free, but for the health service? My understanding is that it is a lot cheaper for the health service if someone buys a treatment for athlete's foot over the counter or in a pharmacy. Could the proposed directive have significant cost implications? There is the cost of getting the script down to the pharmacy, the cost involved in processing that script and the cost of issuing the medicine.

Mr Curley: At this stage, I cannot give you an estimate of how much it would cost.

Mr Martin: I am not asking you to.

Mr Curley: What I will say is that it would be counterproductive to the Department of Health's policy, which is for self-care medicines. If a patient can purchase a medicine, we encourage patients to self-care. Incurring costs would be counterproductive to the Department of Health's policy, but I am not able to give you a figure.

Mr Martin: I will not ask you to do that. You have given me a very honest answer.

I have two concerns about the possible move, albeit I understand the underlying rationale for the EU moving in that direction. My first concern is that, as I expected you to say, Sean, it is counterproductive to where the Department of Health is trying to move, which is to self-care and wider access to medicines so that people can treat themselves. Obviously, that is cost-effective for the wider health service. My second concern is the cost to the health service. My understanding is that, as things stand, it is significantly cheaper for someone to go in and pick something up for, say, athlete's

foot off a shelf in a pharmacy or ask a pharmacist, "Can I have this medicine?" whereupon the pharmacist gets it off the shelf behind them and dispenses it to that person. As I said, that is stuff that we can buy ourselves, and it tends to be quite cheap. If we move in the direction proposed and the EU places antimicrobials on a prescription-only list, the cost of those drugs will significantly increase. That will not necessarily be for just the consumer. On account of the supply chain, I imagine that it will also be more expensive for the health service, because everything is shifted way back to the GP, and there is an entire chain of events going all the way to the pharmacists giving out that medicine. Am I right in saying that?

Mr Curley: I need to be careful, because my colleague Aaron is the expert on that. There are ways of obtaining prescription-only medicines other than via prescriptions. There are provisions that could be explored, but I go back to the point about it being counterproductive to exactly what we are trying to do around self-care. In that regard, there will be additional costs to the health service, whatever provisions are in place. It may be, however, that there are private provisions that could still be offered.

Mr Martin: Are you talking about private scripts?

Mr McKendry: Not necessarily. Some of the existing exemptions, such as a patient group direction (PGD), may allow a supply of prescription-only medicines without a prescription. Members may be familiar with private flu vaccines. That is an example of where you can attend a pharmacy and obtain a prescription-only medicine without a prescription. There may be scope to explore some of those things.

Mr Martin: You might pay £100 for that, though. You do not have to answer that, Aaron.

I will finish by asking this: do you accept that a move from over-the-counter or off-the-shelf medicines to prescription-only medicines for antimicrobials would cost the health service more if that were to be applied in Northern Ireland, given what I outlined about the general process?

Mr Curley: Not having the details, we cannot go into the finances. All that we can say is that it changes the way in which those products are supplied and sold. I am not trying to —.

Mr Martin: I know. I get that.

Mr Curley: It changes how a patient accesses them: whether they go to the GP or use alternative provisions, such as private provisions in a pharmacy or alternative provisions that permit the sale or supply of such products. We cannot provide clarification on what a patient might do.

Mr Martin: Fine. I accept that.

My second question relates to the EM from DHSC on directive 193. I will quote a couple of lines from the paragraph on UK supply resilience:

> *"or have an EU touchpoint in their supply chain, changes that strengthen security of supply for EU member states may have indirect impacts on UK supply resilience."*

I assume that you have read the EM from the Department. Will you comment on that statement, especially on the last line:

> *"strengthen security of supply for EU member states may have indirect impacts on UK supply resilience."?*

I assume that that refers to medicines.

Mr Curley: DHSC leads on the maintenance of medicine supply chains to the whole of the UK. I work closely with DHSC on medicine shortages. Beyond this work, I work on medicine shortages and improving supply chain resilience, so I understand the work that DHSC is doing on this. It is looking at the EU pharma proposals, but, at the minute, I do not think that there is anything of too much concern.

I understand that the EU will also bring forward a critical medicines Act. DHSC is monitoring the UK-wide impact of that as well. I do not believe that much in that is causing too much concern at the moment either.

Mr Martin: OK. I will read paragraph 25, which is on the same area:

> *"However, there may be negative impacts on UK supply resilience if these measures lead suppliers to prioritise the EU market over the UK."*

Do you want to comment on that? It is slightly different from the earlier point that I quoted. I will let you summarise what, you think, DHSC is saying, but it seems to be that there could be negative impacts on UK supply resilience if measures lead suppliers to prioritise the EU over the UK.

Mr Curley: Again, on the basis of the work that I have done, I can say that the UK market is still a very attractive market. I do not know the information on which DHSC based that, but I know that the UK market is still attractive, particularly for innovative and novel medicines and that the number of authorisations for the UK market is still high. I do not have the evidence or anything else that that is based on.

Mr Martin: OK. That is great. Thanks very much, Sean and Aaron.

Mr Kearney: You may already have dealt with this in your previous answer, Sean, but I will go back to a comment that you made earlier. Can you confirm that the Committee should be assured that medicine supplies will continue uninterrupted and that that should not be a point of concern for us at this juncture in light of what is being proposed?

Mr Curley: Based on the proposals that we have seen and what we can see of their interaction with the two significant EU amendments, in the vast majority of cases, there will be no change, or the change will have no impact. Where there is uncertainty, such as on the reclassification of antimicrobials and whether that would impact on supply, I do not know what manufacturers would do or what steps will be taken. If the proposals go through, MHRA and the UK Government will have to look at them and decide what to do. All medicines are authorised on a UK-wide basis, so they will have to make a decision on how those proposals will interact with the whole UK. I cannot give a definitive answer, but I want to reassure you that I can see nothing in the proposals that would disrupt supplies.

Mr Kearney: It is important to place that on the record. We can go only on what we know at this point, and, as you and Aaron assess the situation, there is no concern about disruption to supplies. That is helpful. Thank you.

The Chairperson (Ms Ferguson): No other member has a question, so, on behalf of the Committee, I thank Sean and Aaron for their presentations, which we appreciated. Thank you.

Mr Curley: In response to what you said about our evidence, the quality is on account of our collaborative work with our UK counterparts in DHSC and MHRA. They help us out with that, so I record my appreciation to then.

If Committee members would like a written update on their questions, we can provide that after the session.

The Chairperson (Ms Ferguson): That is much appreciated. Thank you.