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Consultation document: changes to Human Medicine Regulations to support the rollout of COVID-19 vaccines

Published 28 August 2020

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This publication is available at https://www.gov.uk/government/consultations/distributing-vaccines-and-treatments-for-covid-19-and-flu/consultation-document-changes-to-human-medicine-regulations-to-support-the-rollout-of-covid-19-vaccines

Introduction

COVID-19 is the biggest threat this country has faced in peacetime history, which is why the UK government is working to a scientifically led, step-by-step action plan for tackling the pandemic – taking the right measures at the right time.

Effective COVID-19 vaccines will be the best way to deal with the pandemic. Any vaccine must first go through the usual rigorous testing and development process and be shown to meet the expected high standards of safety, quality and efficacy before it can be deployed.

The independent Joint Committee on Vaccination and Immunisation (JCVI) will advise the UK government on which COVID-19 vaccine/s the UK should use, and on the priority groups to receive the vaccine based on the best available clinical, modelling and epidemiological data. This will depend on the properties of the vaccine, those most at need (including health and care workers) and the particular medical circumstances of individuals.

The preferred route to enable deployment of a new vaccine for COVID-19 is through the usual marketing authorisation (product licensing) process. If a suitable COVID-19 vaccine candidate, with strong supporting evidence of safety, quality and efficacy, becomes available, we will seek to license that vaccine through the usual route. Until the end of December 2020, EU legislation requires biotechnological medicines (which would include candidate COVID-19 vaccines) to be authorised via the European Medicines Agency, and a marketing authorisation granted by them would automatically be valid in the UK. From January 2021, the UK's licensing authority will have new powers to license all medicines, including vaccines. However, if there is a compelling case, on public health grounds, for using a vaccine before it is given a product licence, given the nature of the threat we face, the JCVI may take the very unusual step of advising the UK government to use a tested, unlicensed vaccine against COVID-19, and we need to make sure that the right legislative measures are in place to deal with that scenario.

A temporary authorisation of the supply of an unlicensed vaccine could be given by the UK's licensing authority under regulation 174 of the Human Medicines Regulations (see below). A COVID-19 vaccine would only be authorised in this way if the UK's licensing authority was satisfied that there is sufficient evidence to demonstrate the safety, quality and efficacy of the vaccine. 'Unlicensed' does not mean 'untested': this temporary authorisation process exists to address the possibility that, in certain situations of public health need, the licensing authority may consider that the balance of risk and benefit to patients justifies the temporary supply of the relevant vaccine pending the issue of a product licence. Regulation 345 of the Human Medicine Regulations transposes into UK law a requirement of EU law that key actors in the medicines supply chain cannot generally be sued in the civil courts for the consequences resulting from the use of an unlicensed product, or a new use of a licensed product, that a national licensing authority is recommending in order to deal with certain specific health threats.

The UK government is seeking views on proposals to make changes, in conjunction with the Minister of Health in Northern Ireland, to the Human Medicine Regulations 2012. These changes will support the effective rollout of a COVID-19 vaccine and the upscaling of influenza (flu) vaccination programme in the UK. It is important to emphasise, however, that although some of the measures specifically reference COVID-19 and flu vaccines, the proposed changes will also facilitate the efficient mass distribution of treatments for COVID-19, or for any other disease that poses a serious risk to public health.

Medicines regulation in the UK

The Human Medicine Regulations 2012 (HMRs), which the attached draft Regulations amend, set out a comprehensive regime for the authorisation of medicinal products; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance. They also provide for enforcement powers for the authorisation and supervision of medicinal products.

Medicines regulation is a devolved matter in relation to Northern Ireland and a reserved matter (to the UK Parliament) in relation to Scotland and Wales. This why changes to the UK-wide HMRs are made by the UK and Northern Ireland ministers, acting jointly. The Medicines and Healthcare products Regulatory Agency (MHRA), an Executive Agency of the Department of Health and Social Care, is the body that performs the functions of the UK's 'licensing authority' under the HMRs across the whole of the UK, acting on the authority of the Minister of Health in Northern Ireland and the Secretary of State for Health and Social Care.

Policy objectives

The main policy objectives of these proposals are to:

1. In the interests of patient safety and providing clarity to the supply chain, clarify our approach to a pre-existing provision (regulation 174) in the HMRs, that enables the licensing authority to temporarily authorise the supply of an unlicensed medicinal product for use in response to certain specific types of public health threat, including the suspected spread of pathogens. We propose to clarify that this temporary authorisation can be permitted with specified conditions attached. That will allow, for example, the licensing authority to attach conditions to ensure product safety, quality and efficacy.
2. Clarify the scope of immunity from civil liability which regulation 345 of the HMRs puts in place for certain products whose unlicensed use is recommended by the licensing authority in response to certain specific types of public health threat, so that it clearly applies not just to manufacturers and healthcare professionals but also to the company placing an unlicensed medicine such as a vaccine on the market with the approval of the licensing authority – and to clarify the consequences on immunity, should there be a breach of the conditions imposed by the licensing authority.
3. Ensure that the UK has the available workforce to administer the COVID-19 vaccine and influenza vaccine.
4. Ensure that the vaccines and treatments used in response to certain specific types of public health threat, such as a COVID-19 vaccine, can be promoted as part of national vaccination or treatment campaigns.
5. Make short-term provisions for wholesale dealing of COVID-19 and flu vaccines, and treatments for pandemic diseases, in the case that the vaccine/treatment needs to be moved under NHS or armed services' authorised arrangements between premises at the end of the supply chain by NHS and armed services' providers of care that do not do not hold wholesale dealer's licences.

Nature of the consultation

It is important to explain at the outset the relatively limited nature of this consultation exercise. Therefore, the following 3 limitations should be borne in mind:

1. Timing

At the time of publication of this document, it is not clear what the earliest date is that it might be possible to deploy a COVID-19 vaccine in the UK. In the circumstances, the UK government is moving as quickly as possible to put in place a package of legislative measures that would support the delivery of a safe and effective vaccine, for whenever the measures are needed.

Any successful steps to fight COVID-19, including the deployment of a safe and effective vaccine or therapeutic product, will of course have a beneficial impact for all parts of UK society. These legislative changes will also ensure that businesses who may be supplying vaccines and organisations that may be administering them can have as much confidence in the nature of the legal framework they will be operating under as we can reasonably give them – while also ensuring patient safety remains central to any proposal. However, having to move quickly means having less time than we would like to consult on these proposals – indeed, we are asking for comments by the end of Friday 18 September 2020.

However, even after the consultation has finished and amendments have been made, the UK government will remain open to the possibility of making further changes – very rapidly, if need be.

Therefore, please do not refrain from commenting simply because the official period for receiving comments is at an end. If you have something that you want to say about these proposals, the UK government wants to hear it.

2. Targeted discussions

Even though we are happy to receive comments from anyone, the purpose of this consultation exercise is to engage directly with specific stakeholders that we have identified. The UK government will be holding discussions with those stakeholders, at which it will be going into further detail about the proposals. This consultation document has been produced to support those discussions.

What that means, in practice, is that the consultees to whom this document is addressed are a specialist audience, made up of people and organisations that we would expect have a detailed knowledge of the legislative and practical context in which these proposals sit – and also of the likely impact of the measures. It is also an audience generally used to discussing draft legislation without having all of the detail explained.

That means providing in this document less detail than the general reader might like – but a level of detail that is proportionate to the exercise. We do appreciate that some people may prefer us to have undertaken a different sort of consultation exercise, even in the limited time available. This is one of the reasons why some of the provisions are time limited or have review provisions built into them. Some debates will necessarily be renewed, whatever the outcome of this consultation exercise.

3. High-level nature of the proposals

This consultation is about the changes to the UK regulatory framework for human medicines, which are being introduced to clarify the regulatory context that is relevant to mass vaccination. Decisions of detail regarding deployment will be taken in most cases by the NHS in each of the 4 nations of the UK, as they decide the best way to roll out any COVID-19 vaccination programme in each nation – as they do for their national flu vaccination programmes, and would do for any future national distribution campaign for treatments for a pandemic disease.

What this consultation exercise is definitely not about is who would, or would not, be vaccinated as part of a COVID-19 or flu vaccination programme, or how the NHS in each UK nation would commission or run it. For example, just because one UK nation might want to train student nurses and doctors to administer COVID-19 vaccines or flu vaccines, that does not mean another UK nation would also want

to do it. What the proposals do is give them all the option of doing so within a clear and supportive legal framework, should they want to use it. To a great extent, these proposals are enabling, essentially supporting a range of options that the NHS in each UK nation will have available to them.

The decisions that will be taken centrally and apply across the whole of the UK will be the regulatory decisions which are already, as part of the devolution settlement, taken centrally – such as the conditions in relation to which products are marketed. The UK government is not seeking to change the current balance between what are treated as NHS issues and what are treated as regulatory issues, but to go with the grain of the existing system.

1. Temporary authorisation of the supply of unlicensed products

Background

Development of safe and effective vaccines to minimise the impact of ongoing infections during the COVID-19 pandemic remains one of the best options to protect lives.

The preferred route to enable deployment of a new vaccine for COVID-19 is through the usual marketing authorisation routes. Until the end of December 2020, and as part of the transition arrangements, EU legislation requires biotechnological medicines (which would include candidate COVID-19 vaccines) to be authorised via the European Medicines Agency, and any product licensed by the European Medicines Agency before the end of 2020 will automatically be valid in the UK. Following the end of the transition period, the UK's licensing authority will have new powers to approve medicines, including vaccines, itself.

In the UK, the HMRs contain several existing provisions relevant to the supply of medicinal products under pandemic conditions, regulation 174 (https://www.legislation.gov.uk/uksi/2012/1916/regulation/174/made) being particularly relevant. Regulation 174 of the HMRs allows the licensing authority to permit a temporary authorisation for the supply of an unlicensed medicinal product for use in response to certain specific types of public health threat – the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation.

A COVID-19 vaccine would only be authorised in this way if the licensing authority was satisfied that there was sufficient evidence to demonstrate the safety, quality and efficacy of the vaccine, in the particular context in which the licensing authority was asked to take that decision. At no point does the product itself become 'authorised' in the sense of 'licensed' – it remains unlicensed. However, we should also be clear that 'unlicensed' does not mean 'untested', and that regulation 174 exists to address the possibility that, in certain situations of public health need, the licensing authority may consider that the balance of risk and benefit to patients justifies authorising temporary supply of a medicine such as a COVID-19 vaccine pending the issue of a product licence.

The language of regulation 174 makes clear that the powers are available where there is a suspected or actual spread of pathogens, which would include, but would not be confined to, a pandemic. Regulation 174 is an implementing measure for Article 5(2) of the EU Medicines Directive 2001/83, representing the UK's choice of form and methods for doing so in 2012.

If the need arises, regulation 174, in its present form, could be used to authorise nationwide distribution and supply of an unlicensed COVID-19 vaccine (or treatment) in the UK, as well as other potential products. In practice, this means that, if a suitable COVID-19 vaccine candidate – with strong supporting evidence of safety, quality and efficacy – became available before the end of the transition period but it

had not yet been licensed by the European Medicines Agency, regulation 174 could be used to enable temporary UK-only deployment. For these purposes, it makes no difference whether the vaccine had been developed in the UK, elsewhere in the EU/EEA or completely outside UK/EEA.

Proposed amendments in relation to temporary authorisation

The proposed amendments build on and add to the existing text for regulation 174, which we are not proposing to alter. While it is implicit that under regulation 174, as currently drafted, a decision to authorise the supply an unlicensed medicinal product could carry certain conditions, this is not expressly articulated.

To provide transparency, we propose to amend the HMRs to make it explicit that the supply of products, including COVID-19 vaccines, which is temporarily authorised under regulation 174 may be subject to conditions. The imposition of conditions enables the licensing authority to define the safeguards that are a pre-requisite for the safe supply and use of the product and without which authorisation would not be valid. This can range from specifying whom the product is suitable for, setting batch testing and quality assurance standards, and ensuring that appropriate storage is in place throughout the supply chain. Given its importance, it is appropriate to articulate this element of the licensing authority's decision-making more fully in the legislation.

Decisions to authorise sale or supply of an unlicensed medicine under regulation 174 will be, by their very nature, exceptional – and both the nature of the conditions that might be attached and the process that will lead to an authorisation decision will be dependent on the particular facts of the public health threat in question. As mentioned above, a COVID-19 vaccine would only be authorised in this way if the licensing authority was satisfied that there was sufficient evidence to demonstrate the safety, quality and efficacy of the vaccine, in the particular context in which the licensing authority was asked to take that decision.

Sufficient evidence of safety, quality and efficacy is also, of course, the standard by which marketing authorisation applications are judged. Therefore, the conditions imposed on a regulation 174 authorisation for a COVID-19 vaccine are likely to be equivalent to requirements of a marketing authorisation, acknowledging that some flexibilities and pragmatic approaches may be required based on the situation and mode(s) of deployment of the national vaccine programme (and of any future national programme for the roll-out of treatments).

This change, which makes clear the licensing authority's powers to impose conditions, will provide certainty for both the licensing authority and those in the supply chain about the nature of the licensing authority's powers in this area, which are central to an effective system of regulatory control that is in the interests of everyone in the supply chain.

Overall, this change, we believe, would bring clarity and thus strengthen the performance of the supply chain for products whose supply is authorised under this route, which in turn will help to ensure patient safety and is therefore in the best interests of all.

2. Civil liability and immunity

Any decision to roll out mass vaccination programmes for unlicensed COVID-19 vaccines, or indeed any pandemic disease treatments, will be taken nationally, not by the individual companies manufacturing or marketing the product.

The current legal framework already recognises that if manufacturers or healthcare professionals are asked to supply an unlicensed medicine in response to a public health threat, it is unfair also to ask them to take responsibility for the consequences of the use of that medicine in the way that they normally would.

The UK government wishes to clarify some important aspects of the legal regime relating to the civil liability of manufacturers and suppliers in this context.

Who is protected from liability

Article 5(3) of Directive 2001/83 requires that Member States lay down provisions so that marketing authorisation holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of an unauthorised medicinal product, or from the use of a product otherwise than in accordance with its authorisation, when such use is by the licensing authority in response to (among other things) the spread of pathogens. This requirement is implemented into UK law by regulation 345.

What regulation 345 does, therefore, is transpose into UK law a requirement of EU law that key actors in the medicines supply chain cannot generally be sued in the civil courts for the consequences resulting from the use of an unlicensed product, or a new use of a licensed product, that a national licensing authority is recommending in order to deal with certain specific health threats.

The principle of providing immunity from civil liability derives from the Directive. Some of the critical detail, however, is left to individual EU States and countries outside the EU that are implementing this provision.

Although the Directive expressly protects marketing authorisation holders whose products are recommended for use in a manner that is not covered by their authorisation, and the Directive expressly protects product manufacturers of both licensed and unlicensed products, it is silent about pharmaceutical companies whose placing on the market of an unlicensed product is authorised by the licensing authority under the Directive powers. It is however appropriate to treat the person bringing an unlicensed medicinal product to market in no worse a way than the manufacturer who is producing the product on their behalf. This would be entirely consistent with the EU law ‘equal treatment’ principle (that like circumstances should be treated alike, unless differential treatment is objectively justified), and the intention of the EU Directive provision, which is that those responsible for an approved licensed or unlicensed product being on the market as part of the response to the public health threat should be given immunity from civil liability in relation to the consequences of that use.

The UK government therefore proposes to clarify the legislation by putting the pharmaceutical company responsible for placing unlicensed products on the market on the same footing as manufacturers of unlicensed products – and the same footing as marketing authorisation holders of products which the licensing authority recommends are used otherwise than in accordance with their authorisation. This will help to give companies willing to co-operate in the sort of mass vaccination programme under consideration for COVID-19, or mass distribution of treatments in other situations, some assurance that they will not be exposed inappropriately to civil liability.

Extent of the protection

Regulation 345 does not provide complete immunity from civil liability. As Directive 2001/83 requires, regulation 345(4) preserves the application of section 2 of the Consumer Protection Act 1987 (CPA). This means that if a product does not meet the standards set by the Part 1 of the CPA, manufacturers

and marketing authorisation holders are not protected from legal action. A product is defective, for the purposes of the CPA, "…if the safety of the product is not such as persons generally are entitled to expect…", taking all the circumstances into account.

If there is an intrinsic problem with the nature of the product that renders it unsafe, the producer has to be able to show that the objective state of scientific and technical knowledge at the time it was put on the market, including the most advanced level of such knowledge, was not such as to enable that defect to be discovered. By putting the most advanced state of scientific knowledge at the time the product is made available at the heart of the protection that is offered, the CPA does not provide a warranty of performance, i.e. that the product will work or (in the case of a medicine) will not have side effects. However, issues of liability could arise under the Part 1 of CPA if, for example, a medicine was significantly less well tolerated or had significantly greater side effects than other equivalent medicines.

When the protection is lost

The Directive's provisions on immunity are predicated on the supply being that which the licensing authority has recommended or required. This is reflected in the language of regulation 345, which provides immunity in relation to the use of the product in accordance with the licensing authority's recommendation.

If the supply does not materially comply with the licensing authority's recommendation, such supply is no longer the supply recommended or required by the licensing authority. Clarifying that the immunity does not apply where the supply is materially inconsistent with the terms of the licensing authority's approval will make clear that legal recourse still applies in these circumstances.

However, if loss of immunity from civil liability was automatic after breach of any condition included in the licensing authority's approval, that might lead to unfairness. The potential exists for a breach of a technical requirement with a relatively inconsequential effect having a disproportionate impact from the point of view of the manufacturer or person placing the product on the market.

The UK government believes that sufficiently serious breaches should lead to loss of immunity from civil liability, but that opens up the question of what should amount to a sufficiently serious breach for these purposes?

Our preference is to make this an objective test – the view of a third party.

That gives rise to the question of who should be the 'objective bystander' whose view the Courts should determine. For consultation purposes, we are proposing (draft regulation 174A(3)(b)) that "…any risk of death or personal injury that is wholly or partly attributable to that breach is such that a reasonable person [with an interest in placing medicinal products on the market] would regard the breach as sufficiently serious to justify the licensing authority setting aside the recommendation…".

Other options will, of course, be considered, but the 2 under particular consideration are the above text, with or without the text in square brackets – one an 'objective bystander' with specialist knowledge and the other an 'objective bystander' without specialist knowledge.

There is, in this type of legislation, a recognised concept of a person who 'places on the market' a product – normally, in the case of a licensed medicine, the marketing authorisation holder – and in the case of an unlicensed product, there will, practically speaking, be a pharmaceutical company that stands in the same position in relation to the product, i.e. the company that manufactured it or ordered its manufacture.

So, the ‘objective bystander’ in this situation could be a reasonable pharmaceutical company who might conceivably be in the same position as the company actually bringing the product to market.

Alternatively, it would be possible to have as the ‘objective bystander’ any reasonable person – the man or woman in the street.

The challenge is whether, in this particular context, it would be better if the ‘objective bystander’ was someone with specialist knowledge of the subject matter in hand – ideally both technical understanding and experience of what may be very difficult issues.

If we do go with the additional words in square brackets, the specialist bystander would however need to be a ‘reasonable’ pharmaceutical company. That again is an objective test. However, the advantage of a ‘reasonable’ pharmaceutical company in this context is that they can indeed be expected to have detailed knowledge about every aspect of the supply chain from manufacture to final supply.

The final decision on what the ‘objective bystander’ would think – whether the ordinary man or woman in the street or the specialist bystander – would of course be for the courts.

We have also made provision to take account of the fact that there may also be cases where someone in the supply chain is responsible for a breach in circumstances where they should lose their liability but others in the supply chain should not. For example, a manufacturer may have done something wrong but the person administering the product is completely blameless.

Because of this, we propose to clarify that only those persons or entities who are ‘wholly or partly responsible’ for a breach of the conditions lose immunity, rather than every operator in the supply chain.

Vaccinators who are not registered healthcare professionals

It will also be apparent in what we say about workforce expansion that someone other than a registered healthcare professional may actually be administering unlicensed vaccines – and as a basic issue of fairness, we think they should benefit from the same immunity from civil liability as a registered healthcare professional who is performing the same role, if the person who is not a healthcare professional is following one of the proposed new protocols.

Routine enforcement

Finally, the amendments will clarify the legal consequences of a breach of conditions for enforcement purposes. We propose that this should be subject to the standard penalties already set out in law for breaches of Marketing Authorisation conditions: a theoretical penalty of an unlimited fine and 2 years in jail. The MHRA works closely with all suppliers and manufacturers to support their compliance and avoid this outcome. All enforcement action has to be proportionate and they only take formal steps where necessary.

The essential point is that, on this particular issue, we are proposing to treat breaches of licence conditions and breaches of conditions of unlicensed supply in the same way, which puts companies marketing unlicensed products for pandemic use in no better, or no worse, position than they would be in if the product was licensed.

3. Proposed expansion to the workforce eligible to administer vaccinations

Currently, the HMRs require that only 'appropriate practitioners' administer vaccines, as they are a parenterally administered (for example by injection) prescription-only medicine. Appropriate practitioners are defined under regulation 214 (https://www.legislation.gov.uk/uksi/2012/1916/regulation/214/made) as doctors and other qualified prescribers.

An expanded workforce is required to ensure that the COVID-19 vaccine can be safely deployed widely as soon as it should become available, given the capacity constraints of the current workforce that can administer vaccines.

Furthermore, an expanded workforce eligible for administering the flu vaccine may be required, given the recent announcement of an expanded flu vaccination programme this winter (https://www.gov.uk/government/news/most-comprehensive-flu-programme-in-uk-history-will-be-rolled-out-this-winter). Millions more could receive the flu vaccine than received it last year, so there is a need to ensure the workforce comprises enough people to deliver these additional vaccinations.

There is a possibility that both the flu vaccine and the COVID-19 vaccine will be delivered at the same time, and we need to make sure that in this scenario there is sufficient workforce to allow for this.

We are consulting on making the following 3 amendments to the HMRs to increase the number of persons able to safely deliver licensed and potentially unlicensed vaccinations for COVID-19, in particular to ensure that the COVID-19 vaccine can be rolled out as soon as it becomes available.

1. Expand the scope of patient group directions (PGDs) (https://www.gov.uk/government/publications/patient-group-directions-pgds) to allow the administration of any medicine, including COVID-19 vaccines, the supply of which has been temporarily authorised under regulation 174 of the HMRs. PGDs are usually used to expand the professionals able to deliver prescription-only medicines to individuals. They are used, for example, as part of the annual national influenza immunisation programme by pharmacists working in community pharmacies. However, currently a PGD cannot be used to administer anything that does not have a full marketing authorisation (or one of the currently listed regulatory equivalents) from MHRA. This change will enable the workforce that already operates under PGDs to deliver vaccinations to continue to do so for unlicensed vaccine.
2. Introduce a new type of national protocol, to be authorised by UK ministers and the devolved administrations, which will allow those who are registered healthcare professionals who do not normally vaccinate, and people who are not registered healthcare professionals, to safely administer a licensed or temporarily authorised COVID-19 or influenza vaccine. This protocol would be written similarly to a PGD and would provide the flexibility to define the training and competence requirements of vaccinators, and the clinical considerations they must follow. This will ensure that all measures will be taken to ensure patient safety, including but not limited to clinical treatment of any potential reaction to the administered vaccine, such as anaphylactic shock. The use of the protocol provision will be reviewed after a year, and a report published of the review.
3. Expand the workforce legally allowed to administer vaccines under NHS and local authority occupational health schemes, so that additional healthcare professionals in the occupational health workforce will be able to administer vaccines. Vaccinations for health and care workers are often administered through occupational health schemes, but only nurses are authorised to administer prescription-only medicines under written instruction of a doctor. The proposals would expand the workforce that can administer COVID-19 and flu vaccinations under an NHS or local authority occupational health scheme so that it also includes midwives, nursing associates, operating department practitioners, paramedics, physiotherapists and pharmacists. This will help ensure we have the workforce needed to deliver a mass COVID-19 vaccination programme, in addition to delivery of an upscaled influenza programme, in the autumn. This change is also desirable for

‘business as usual’ in occupational health schemes to better reflect the ability of a broader range of registered healthcare professionals to competently deliver occupational health scheme services. However, the extension just to some occupational health schemes, and just to the additional healthcare professionals mentioned above, will be time limited, to 1 April 2022 (and so to the end of next year’s annual flu immunisation programme) to allow fuller consideration of making a long-term change in this area.

It is important to emphasize that safety is central to any public health vaccination programme. Any additional workforce operating under the national protocol to administer vaccines will be trained and shown to be competent via an NHS and PHE approved training programme to ensure patient safety.

4. Vaccine promotion

Currently there is a prohibition on promoting an unlicensed medicine to healthcare professionals and the public. The UK government is proposing that this prohibition is disapplied to allow (subject to the other restrictions in the HMRs) advertising of any temporarily authorised products under regulation 174, including a COVID-19 vaccine.

There will also be amendments to allow for some easements from the other restrictions in Part 14 of the HMRs – for example the prohibition on advertising prescription-only medicines. Some of these restrictions – which deal essentially with advertisements to the public, are already disapplied in the case of vaccination campaigns, and that approach is extended to all products given temporary authorisations under regulation 174. The disapplications would be restricted to advertising as part of a campaign approved by ministers and would permit the supplier to participate in any public or healthcare professional information campaign relating to the use of the medicine.

These amendments on the easement of advertising restrictions are not limited to unlicensed vaccines only, but are intended to apply to all the public health purposes that would justify temporary authorisation of the distribution of an unlicensed vaccine or other treatment listed in regulation 174 (https://www.legislation.gov.uk/uksi/2012/1916/regulation/174/made).

This means that, in relation to medicines advertising, the permitted campaigns could relate to any medicinal product use in response to “…the suspected or confirmed spread of… pathogenic agents… toxins… chemical agents or…nuclear radiation…”.

A number of changes have also been made to the special requirements for advertisements wholly or mainly directed at qualified prescribers. These have also been adapted to take into account the new arrangements for temporary authorisations.

Overall, the amendments proposed will ensure that the use of the vaccine and treatments that have been temporarily authorised for sale or supply can be promoted as part of national campaigns in each of the 4 countries of the UK.

5. Make provisions for wholesale dealing of vaccines

There are already situations that arise during public health vaccination programmes where there may be excess vaccines in one healthcare organisation and too few in another separate healthcare organisation. The supply from one to the other would be a wholesale distribution supply and, therefore, subject to having a wholesale dealer’s licence under regulation 18 (https://www.legislation.gov.uk/uksi/2012/1916/regulation/18/made) of the HMRs. This can lead to problems and delays with moving the vaccines between such service providers, and runs the risk that patients

cannot access the vaccine that is necessary for public health protection. The current solution would be to return the excess vaccines to the supplier who would then dispatch them to the organisation with too few vaccines, but this is time consuming and inefficient. With the national vaccination campaigns to protect patients against flu in Autumn 2020 and COVID-19 once a vaccine become available, it is essential that vaccines can be moved swiftly and safely within the healthcare system between NHS providers (and between the suppliers of medical services to the armed forces) to meet patient need and avoid wastage.

We are therefore considering providing an exemption from the need for a wholesale dealer's licence to allow the swift and safe transfer of COVID-19 and flu vaccines, and other medicines for treatment of pandemic disease, in response to patient need. The exemption would be available for NHS organisations, NHS contracted service providers, and the medical services of the armed forces only. Vaccines and some other medicines are subject to controlled storage requirements (for example strict temperature limits for vaccines) so the transfer of any medicine should be properly controlled and appropriate records maintained of correct storage and transfers. The detail of this would need to be set out in the NHS (or armed services) arrangements for the provision of the vaccines, but further guidance would also be provided centrally.

These measures would be time limited so that they will cease to have effect on 1 April 2022. This will allow fuller consideration of making long-term changes in this area.

Conclusion

This consultation document has laid out the proposals for changes to the Human Medicine Regulations 2012 to ensure that, in particular, the UK is able to administer a COVID-19 vaccine effectively once it is available, as well as support the upscaling of flu vaccination and providing in the future for the mass distribution of treatments for pandemic diseases.

Although the earliest date by which a COVID-19 vaccination programme could start is uncertain, preparations are underway. Therefore, there is a need to share information on how the necessary changes to medicines legislation to support the vaccination programme might look.

Responding to this consultation

Taking into account the information in this document, you are asked to give general responses.

The consultation period will run until the end of Friday 18 September 2020.

By necessity we are working towards short timelines, but if you miss the date and still want to make comments, contact us at covidvaccineconsultation@dhsc.gov.uk and we will try to accommodate your comment before any changes are made. In any event, we will consider them as part of the ongoing process of making sure we have everything we need properly in place to deal with the challenges of the coming months.

For those organisations with which we will be holding discussions about this document, we will be contacting you to arrange the appropriate meetings if we have not already done so. If you have been expecting to hear from us about such a meeting, but have not done so, please do contact your normal departmental contacts and they will make sure we have the right contact details and have the arrangements for holding discussions with you in hand.