Homecare medicines service: a good practice guide for pharmaceutical marketing authorisation holders (MAH)

Introduction

Please note that a homecare medicines service is only one means of distributing medicines – and may not be the best option in all cases. Recognition/consideration of other models is essential to ensuring that the patient gets the best service/treatment possible.

When a homecare medicines service is chosen as an appropriate means for medicines distribution, it is key that:

- The supply of the services is well thought out in advance
- All parties understand what is required of them
- Contingency arrangements are in place

MAHs take the provision of homecare services seriously. Although practice will vary between companies, in what can be considered a commercial and competitive arena, there are several principles and legislative requirements which can be distilled into a good practice guide. This guide attempts to pull together these principles via a series of issues to be considered by companies.

Although this guide primarily focusses on the needs and actions for the MAH, it may also be of interest to a range of stakeholders involved in homecare medicines services. These may include clinicians, pharmacists, National Health Service (NHS) finance, NHS procurement governance, homecare providers, the commercial medicines unit, commissioners and patients.

However, this guide is not intended as a definitive or comprehensive manual for how homecare medicines services are designed, contracted, or managed by the pharmaceutical industry; therefore, arrangements need to be decided unilaterally by MAHs on a case-by-case basis.

This guide is structured to align with the Royal Pharmaceutical Society (RPS) Handbook for Homecare Services. It also considers the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA), Association of the British Pharmaceutical Industry (ABPI), Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Pharmacovigilance Practices (GVP) Module VI and other regulatory bodies as applicable (see Annex 1 – Useful Links). This guide is to be seen as a living document, recognising the need for future useful documentation to be added and referenced.

The patient experience

Patients remain at the heart of any homecare medicines service. This section aims to highlight the key areas for MAHs to consider in relation to patients when considering the design and establishment of a homecare medicines service.

Whether it is appropriate for an individual patient to receive their medicine and/or additional services, or care, at home must be determined by a healthcare professional (and/or multidisciplinary referring team) in consultation with the patient.

Patients may need to be transferred to, or from, a homecare medicines service, or between homecare providers, at any time during their treatment. Services must be designed to allow this to happen with minimum impact on the patient.

Patients will be asked by their clinical referring centre to give their agreement to receiving a homecare medicines service. The clinical referring centre completes the initiation documentation (e.g., a patient registration/ referral form) which indicates their agreement. After the patient signs, they receive a patient information record form which documents their acknowledgement that they have received appropriate information. More information regarding service initiation is available in the RPS Handbook for Homecare Services and the associated appendices (including Appendix 1 - National Homecare Patients' Charter; see Annex 1 - Useful Links).

Patient choice

Under the NHS Constitution (see Annex 1—Useful Links), patients in England have the right to a certain amount of choice in their care. Patient choice includes whether the patient wants to opt in or out of an available homecare medicines service, and to some extent, what date, time and location their medicines and/or services will be delivered.

A patient may receive more than one medicine from multiple MAHs, either under a MAH sponsored homecare medicines service or under an NHS funded homecare medicines service. In these circumstances, every reasonable attempt should be made to enable the prescriber to use one prescription template if appropriate and for the homecare provider to consolidate deliveries.

It is the responsibility of clinical referring centres that patients should be made fully aware of their rights. Ideally they should be provided with a copy of the patient information record form and the homecare medicines services patient charter which can be found in the RPS Handbook for Homecare Services in England (see Annex 1—Useful links).

MAHs may also wish to assure themselves that patients:

- **Are made aware of how the homecare medicines service is likely to operate**
- **Are provided with appropriate information about their medicines (e.g., patient information leaflets)**
- **Understand their own responsibilities**
- **Are given details of how they can opt out or make complaints**

Patient group engagement

The engagement of MAHs with relevant patient groups or third sector organisations should be considered on an ongoing basis, to ensure any homecare medicine service is fit for purpose.

MAHs may seek assurances that patients receiving a homecare medicines service are regularly consulted via patient satisfaction surveys from the homecare provider, to ensure the quality and consistency of any service. A patient satisfaction survey template can be found as an Appendix to the RPS Handbook for Homecare Services.

Patient Information and access to Apps

Each clinical referring centre is obligated to review all patient materials relating to each service. Therefore, each clinical referring centre should be provided with all MAH-designed patient information relating to their service(s) and given the opportunity to approve the information that is to be sent to their patients. Any links to micro sites or Apps will require Digital Technology Assessment Criteria (DTAC) approval as well as sign off by each clinical referring centre.

In order to support this process, MAHs can share the patient information relating to the service(s) with the Regional Homecare Specialists at the time of submitting the Homecare Service Proposal (HSP) form. Patient information can be reviewed and commented on as part of the review and comment process. If the DTAC assessments have been carried out prior to the HSP form review, then hospitals will be reassured that the DTAC approval has been gained. Where a hospital expresses the need, all distributed patient materials relating to the service should be shared for review.

MAHs should aim to ensure that clinical referring centres are informed if existing patient materials are amended, or a new App (or other digital support) is offered to patients for existing services. Clinical referring centres will also need be given permission to circulate the new information that has been gained and documented.

Implementation and delivery of a safe and effective homecare medicines service

Contractual framework for a homecare medicines service

Before developing a contractual framework with homecare providers, it may be useful for MAHs to consider the following questions:

Product selection/service design

- Why are these products suited to homecare?
- Has this been discussed/user tested with patients, clinicians and commissioners? Is the service offering appropriate to the patient/NHS?
- How do you meet the requirements of a risk management plan/patient safety?

Type of service – please refer to RPS Homecare definitions of services

What type of service is to be provided?

Examples include:

- Dispense & deliver only
- Dispense & delivery, with nurse training for patients
- Dispense & delivery of a product with strict storage or distribution criteria, or with nurse administration
- More complex additional services, such as infusion at home

Who is the customer?

Clinical referring centre/Commissioner/Primary care/NHS England/Integrated care systems (ICGs)

At what level will the service be provided?

Local/Regional/National

Who will pay for the service?

In general, MAHs cover the cost of this type of service, but other funding models are available—for example, the costs could be shared between a clinical referring centre and a MAH.

Is there already a service/framework provided by the NHS?

Is there an existing homecare medicines service in place?

Is the intention to replace an already-available service, or does the existing service not meet requirements?

Homecare provider identification

Which provider(s) have the capability to deliver the service?

Which provider(s) should be used? Is a sole or multiple provider service preferable?

For most services, the recommendation and preference of the National Homecare Medicines Committee (NHMC) is for the use of more than one homecare provider who has suitable/appropriate capabilities for the service being developed. Please refer to the NHMC Good Practice Principles (GPP) on the Specialist Pharmacy Service website, which explains the NHS' expectation of MAH sponsored homecare medicines services. However, in certain circumstances a sole provider may be selected because the demand is likely to be relatively low and/or to avoid a fragmented supply chain to ensure robust availability and provide a specialist service.

Homecare provider selection

Are you satisfied that the required level and quality of operational capability will be delivered?

Please consider the patient pathway when considering the choice of homecare provider. The patient treatment pathway may involve switching between homecare providers as patients progress through treatment options as their disease progresses. It should be a consideration if maintaining the same homecare provider supports local NHS choice and provides stability to the patient.

Consider, for example:

- Appropriate capacity/capability to service the patient population
- Geographic coverage
- Appropriate necessary professional qualifications and licenses
- Maintaining integrity of the supply chain
- Understanding where legal recourse sits
- Adverse Event reporting capability
- Care Quality Commission (CQC) Registration (if applicable)
- The General Pharmaceutical Council (GPhC)/ MHRA License
- Sustainability
- Business Continuity Practice (BCP)
- Key Performance Indicators (KPIs)
- Data Security and Technical measures

Homecare providers may vary in standards of quality and performance and it is recommended that capability audits are conducted, with tenders being issued for specific services and quality commitments. Recognising that the NHMC encourages new provider entrants to the market, MAHs should satisfy themselves that the homecare provider can deliver the service that the company requires, and that patients and the NHS expect.

Have you conducted an appropriate financial viability assessment?

For example, the risks will be considerable unless due diligence is completed before appointing a homecare provider. MAHs should consider their position if there are reasonable grounds to question the continuity of supply. Consider negotiating the terms of sale to the homecare provider in support of supply resilience/ continuity of supply.

Have you selected the optimal quality thresholds to aid patient compliance and clinical outcomes?

For example:

- Frequency of delivery
- Nurse support
- Patient education/training
- Patient support items to accompany the service provision

Nursing requirement

Will the homecare provider be able to provide nurses to train the patients?

Is there a need for a subcontracted nursing partner?

The NHS recommends that any nursing, or nurse-led injection training for patients, is carried out either by a homecare provider-employed nurse, or by a nursing partner that is subcontracted to the homecare provider. Depending on the service offered, it may be appropriate for some 'nursing roles' to be fulfilled by phlebotomists and/or nurse associates or other suitably qualified healthcare professionals.

Arrangements that involve the need for separate agreements/contracts (and separate patient referral processes) between the clinical referring centre and the service provider (e.g., homecare provider/nursing partner) are not routinely supported by NHMC. These may involve additional MAH management/governance where there are no alternative consolidated (single provider) service options.

Assessment of proposals

Do you need to establish a cross-functional team to ensure appropriate consideration and inputs from various parts of the organisation?

For example, commercial/legal/marketing/ medical/procurement/supply chain/quality control/regulatory/pharmacovigilance departments may all have views to input regarding each potential supplier's capability to deliver.

Award of the contract

Have the timelines been clearly communicated?

Will the homecare provider obtain supplies from a wholesaler or directly from the MAH?

If contract, Patient Access Scheme (PAS) or other NHS prices are already in place, has the rebate process been detailed in the contract with the homecare provider?

Visibility of arrangements

It is recommended that MAHs work with their homecare provider(s) to understand the process of Service Level Agreements (SLAs) set-up with the NHS, including any regional agreements.

Other agreements

NHMC's Good Practice Principles – Provision of Manufacturer Funded Homecare Services

MAHs are requested to review and provide an intent to comply with the NHMC's GPP-provision of MAH funded homecare services:

NHMC – homecare service proposal form

MAHs are asked to complete a MAH commissioned HSP form 24 weeks prior to the planned service implementation:

National Homecare Medicines Committee (NHMC) Homecare Service Proposal (HSP) Form

The NHMC will then nominate a review group to review the HSP form to provide the MAH with feedback on the proposed service prior to service launch.

Further consideration may be required to progress MAH commissioned homecare services in Scotland and Wales.

Core service specification

The following core services are recommended to be specified in the MAHs over-arching homecare medicines service agreement with homecare providers:

- Patient registration and confidentiality
- Secure transfer of prescriptions
- Compliance/concordance monitoring and active feedback to hospitals to support patients' treatments
- Dispensing and delivery schedule
- Administration of the product
- Annual Product Training and Summary of Product Characteristics (SmPC) notification
- Service key performance indicators
- Individual product agreements should describe in detail the services required for that product
- Reporting of the Clinical evaluation form to referring clinical centre
- Patient Materials
- Clinical waste collection provision
- The right to audit homecare providers' adherence to service specifications, including MAH Good Practice specific audit requirements
- The mechanism by which pharmacovigilance and safety data must be communicated to the clinical referring centre and the MAH
- Management of complaints
- Product recalls
- Adverse Event/Special Situation/Product Quality reporting and management/Product Replacement Process

The NHMC has developed a suite of service specifications for the NHS purchasing authorities to adopt and utilise depending on the service contracted. MAHs may choose to adopt a similar approach, referencing the homecare medicines service template specifications.

Homecare performance management service reviews

It is suggested that MAHs assign appropriate resource to the management of contracted homecare providers, to ensure performance against contracts is optimally managed. It is suggested that MAHs should hold regular service meetings with their contracted homecare provider to review performance against KPIs, tracking trends and following any issues through to resolution. The timing of these reviews would be decided on a case-by-case basis; however, at least quarterly would be advised.

Homecare providers must issue regular patient questionnaires as per NHS requirements. MAHs may request outcomes from the questionnaires and utilise these as part of their review process with the homecare provider. After anonymisation, patient testimonials can also be discussed at service reviews.

Core KPIs

KPIs are recommended to be included in any contracts MAHs have with homecare providers.

These may include, but are not limited to, aspects of:

- Patient service, e.g.
  - Dispensing overview
  - Delivery overview
- Safety and adverse event reporting, e.g.
  - Complaints overview
  - Adverse drug reaction overview
  - Pharmacovigilance and safety training record management
- Data Reporting, e.g.
  - Quality
  - Timeliness

The NHMC has published KPIs for purchasing authorities to adopt and utilise depending on the service contracted. MAHs may choose to adopt a similar approach, referencing the suite of NHS KPIs when published. The NHMC KPIs can be found as an Appendix to the RPS Handbook for Homecare.

Risk management and relevant regulations

There are several potential risks that MAHs should be aware of, and aim to mitigate against, when homecare services are put in place.

Where the NHS has tendered for homecare medicines service provision of a particular medicine, the homecare provider(s) should contact the MAH before they submit to the tender, as they can validate that medicines supply under the tender requirements can be met. Subsequent distribution agreements are likely to include terms relating to the provision of anonymised data to allow the MAH to effectively manage their supply chain. The MAH may also need to regularly discuss expected usage volumes and growth with the awardee(s) to ensure accurate demand forecasting and supply chain integrity.

When MAHs are supplying medicines to homecare providers for contracts they have successfully won from the NHS, the MAH is encouraged to ensure that the homecare provider they supply are adhering to the Professional Standards, see Accreditation below.

Before entering into a trading agreement with any 3rd party homecare provider, it is suggested that the MAH check the provider's financial viability by undertaking credit checks. A decision on whether to open a credit account or require the 3rd party to pay up-front on a "pro forma" basis is at the discretion of the individual MAH.

When MAHs are contracting homecare medicines services, they are advised to include in the contractual terms that the homecare provider must adhere to the Professional Standards for Homecare, see Accreditation below.

Where a contract is being developed for a service between the MAH and homecare provider, consideration should also be given to the requirements of a technical agreement if the product is to be in any way altered e.g., infusion services.

The contract should include appropriate payment terms, credit limits and provisions in the event of damage to goods and devices on receipt, and during distribution to the home.

The optimal delivery frequency should be agreed and clearly documented in order to minimise waste, and homecare provider costs should be considered whilst balancing the need for patients or carers to be present to provide proof of delivery.

Where a hospital contract, discount price or PAS applies, the implementation and sharing of information needs to be agreed between all parties, with any applicable non-disclosure agreements signed.

If a MAH encounters a shortage of supply, they should make the homecare provider(s), Commercial Medicines Unit (CMU) and Department of Health and Social Care (DHSC) Medicines supply team aware of the situation at the earliest opportunity. NHS, CMU, DHSC, MAH and homecare providers should work together to ensure patients and clinicians are kept informed of the situation. The NHMC and CMU have produced shortage management guidance—please refer to Annex 1.

Where there are plans to transfer patients between homecare providers, consideration should be given to ensure that arrangements are in place for a seamless transition, to ensure patients experience no interruption in their care and their preferences are considered. It is likely that supporting communications will be needed between the NHS, homecare providers, MAHs

and patients. It should also be recognised that the planned transition takes place at a speed that allows appropriate governance to be set up and patient safety is assured. It is recognised that on occasions, due to pharmacovigilance or contractual concerns, an urgent change in homecare provider is required. In such circumstances, the commissioner of the service, i.e., either MAHs or NHS, is encouraged to develop and implement a proactive and comprehensive stakeholder communications plan.

A risk management approach will safeguard the quality and provision of services to patients. MAHs may benefit from incorporating the principles of quality risk management into all aspects of homecare services in accordance with Quality Risk Management (International Conference on Harmonisation (ICH) Q9).

If concerned with the homecare provider's performance, MAHs may wish to consider, alongside any contractual remedy, engagement with the NHMC, sharing evidence under its homecare medicines service performance management and following the appropriate escalation policy.

MAHs are likely to require homecare providers to have robust business continuity management programmes and systems in place to the appropriate International Standard Organisation (ISO) standard, e.g., ISO 22301:2019.

MAHs should consider requiring that homecare providers operate and maintain a robust quality assurance procedure and methodology to ISO: 9001:2015, including a regular robust self-audit activity. It may be appropriate for MAHs to request visibility of the self-audit plans and activity.

MAHs should ensure contracts clearly outline the homecare provider's responsibility in dealing with product complaints (see governance for service complaints). This may include contracted commitments that homecare providers deal with, and respond to, incidents in a timeframe that supports the NHS. This allows the NHS to respond to complaints within the required timelines and comply with any relevant GDP responsible person requirements; for example the GDP legislation was updated to 2013/C 343/01 in November 2013 to better describe the responsibilities of the responsible person named on the Wholesale Distributor Authorisation (WDA). Section 6.2 of 2013/C 343/01 states 'Any product distribution complaint should be thoroughly investigated to identify the origin of or reason for the complaint.'

MAHs should be clear to communicate and document to providers their responsibilities under the ABPI Code of Practice in providing services. MAHs should consider whether the homecare services fall under the requirements to disclose transfers of value.

MAHs should ensure adherence to the pharmacovigilance requirements:

https://www.abpi.org.uk/publications/guidance-notes-for-patient-safety-and-pharmacovigilance-in-patient-support-programmes-2018/

Northern Ireland (NI)

MAHs need to consider any differentials in homecare provision in NI driven by the European Union (EU) Exit/Northern Ireland Protocol (NIP) requirements. This may include MAH/prescriber liabilities for dispensing of compliant medication as per the NIP requirements.

Homecare service in Northern Ireland (NI)

Recognising the EU medicine regulatory regime applicable in NI under the NI Protocol following Brexit, whilst some medicines are covered by a UK-wide marketing authorisation, the marketing authorisation for other medicines may be specific to NI and separate to corresponding Great Britain (GB) authorisations.

The MHRA have confirmed that import obligations under GDP do not apply once a medicine is dispensed for individual use. Therefore, medicines dispensed in GB and supplied to NI patients, even if the NI/GB marketing authorisations were granted at different times or with different scope, subject to a valid prescription, the authorisation status of the dispensed medicine should not make a difference.

MAHs, however, may choose to review their own regulatory and ABPI Code of Practice obligations, and should consider associated prescriber liability, if medicines being supplied to patients in Northern Ireland under MAH funded homecare services are known to be technically unlicensed within NI.

MAH business and workforce planning

It is recommended that MAHs assign appropriate resource to the management of contracted homecare providers, to ensure performance against contracts is optimally managed.

Governance of Homecare Services

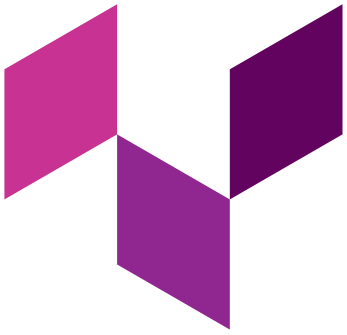
RPS – Handbook for homecare services

In 2011, the DHSC commissioned the report Homecare medicines – Towards a Vision for the Future (also known as the Hackett Report), led by Mark Hackett, formerly Chief Executive, University Hospital, Southampton NHS Foundation Trust. The report identified the Chief Pharmacist as the accountable officer for ensuring the safe and effective provision of homecare medicines services and made a list of recommendations to improve the financial and clinical governance arrangements for patients receiving medicines via the homecare route.

The implementation of this report included the development of national standards for homecare—RPS Professional Standards for Homecare Services, and subsequently the Handbook for Homecare Services. MAHs are strongly encouraged to consider the recommendations and examples of good practice captured in the Handbook. These documents can be found at:

Professional Standards for Homecare Services (rpharms.com)

NHMC continue to be guided by the RPS Professional Standards and review/update homecare policy as relevant.



Regulation and Accreditation

Obligations under GB/EU regulations and law

Homecare medicines services are often selected as the route to fulfil product administration and monitoring obligations from the time a medicine first becomes available for patients. The conditions of licensing a medicine require continued surveillance and data collection to ensure patient safety. In such instances, the homecare provider may be selected by the MAH with a specific service specification in mind. A MAH could have their marketing authorisation revoked if they do not fulfil their post-marketing commitments (see Annex 2). In such circumstances, certain aspects of patient monitoring are not an additional service, but are a legal obligation undertaken at cost to the company.

MAHs are also required under Article 23a and 81 of Directive 2001/83/EC (as amended)—within the limits of their responsibilities—to maintain appropriate and continued supplies of their products, and to notify the Licensing Authority if a product is not going to be available either temporarily or permanently. The legislation requires two months' notice in all but exceptional circumstances. In addition to this requirement, MAHs should ensure that the DHSC Medicine Supply Team is notified as soon as possible of any potential shortages that are likely to have an impact on patient care (via the DaSH Portal):

Login | DaSH | Department of Health and Social Care (dhsc.gov.uk)

MAHs are required to comply with safety regulations outlined in Module VI of the "Guideline on good pharmacovigilance practices (GVP)". Contracts with third parties should clearly document the provider's and MAH's obligations in respect of Module VI.

MAHs are also bound by competition law in their tendering and contractual activities within the NHS. Companies must decide their commercial practices unilaterally. This may result in companies requiring that pricing information, costs or any confidential information is not disclosed in order that competition is not limited or distorted in any way.

Nurse qualification

Where nursing services are included as a component of the homecare arrangement, the MAH's medical departments may consider how best to approve the specification details, including the appropriate qualification of the nurse undertaking the service and the appropriate accreditation from either:

- CQC
- Care and Social Services Inspectorate Wales (CSSIW)
- Care Inspectorate – Scotland
- Regulation and Quality Improvement Authority (RQIA) – NI

Horizon scanning and future considerations

There are likely to be several future policies/considerations that could impact the homecare environment over the next 5 to 10 years that may need to be considered in an MAH's plans.

This may include:

- Social Value/Sustainability
- e-prescribing
- Value Added Tax (VAT) changes (His Majesty's Revenue and Customs (HMRC))
- NI Supply
- Differential devolved nation homecare policies

Annex 1

Useful links

'Homecare medicines – Towards a vision for the future':

111201-Homecare-Medicines-Towards-a-Vision-for-the-Future2.pdf (publishing.service.gov.uk)

'Towards a vision for the future – Taking forward the recommendations':

towards-a-vision-for-the-future-taking-forward-the-recommendations.pdf (rpharms.com)

The NHS constitution:

http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx

RPS Professional Standards for homecare:

http://www.rpharms.com/unsecure-support-resources/professional-standards-for-homecare-services.asp

RPS Handbook for homecare services in England:

homecare-services-handbook.pdf (rpharms.com)

RPS appendices:

Homecare Handbook Appendices (rpharms.com)

Gain share framework and guidance:

http://www.england.nhs.uk/wp-content/uploads/2014/01/princ-shar-benefits.pdf

Output based specification: System-wide delivery of medicines in homecare (DH Homecare strategy board):

NHMC - System-wide Delivery of Medicines Homecare - Oct 19 v9

NHMC – Homecare TOR, performance management and supply shortage guidance:

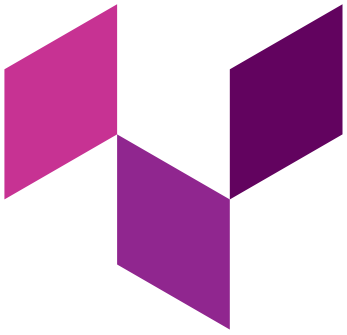
National Homecare Medicines Committee (NHMC) Terms of Reference – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

NHMC - Homecare Provider Performance Management and Escalation - Feb 2022.pdf

NHMC Shortage Management FlowChart - April 2022.pdf

Medicines optimisation Clinical Reference Group:

https://www.england.nhs.uk/ourwork/commissioning/spec-services/npc-crg/medicinesoptimisation



Annex 2

Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance) (legislation.gov.uk)

*Please note—despite the UK leaving the EU at the beginning of 2020, the MHRA has kept a pragmatic approach to legislation, and so the UK has not diverted from the EU GVP legislation (although gradually this may change further).

Furthermore, please note modifications to UK legislation/guidance that no longer apply to the MHRA and UK MAHs on GVP:

Modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders (publishing.service.gov.uk)

* **Three amendments to the Human Medicines Regulation (HMR) 2012 statutory instrument (SI) 1916:**

- The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No.775);
- The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 1385), and;
- The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020 No. 1488)

EU Directive 2010/84 amending, as regards pharmacovigilance, Directive 2001/83/EC

'Article 116

The competent authorities shall suspend, revoke, or vary a marketing authorisation if the view is taken that the medicinal product is harmful or that it lacks therapeutic efficacy, or that the risk-benefit balance is not favourable, or that its qualitative and quantitative composition is not as declared. Therapeutic efficacy shall be considered to be lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product.

A marketing authorisation may also be suspended, revoked, or varied where the particulars supporting the application as provided for in Articles 8, 10 or 11 are incorrect or have not been amended in accordance with Article 23, or where any conditions referred to in Articles 21a, 22 or 22a have not been fulfilled or where the controls referred to in Article 112 have not been carried out.'.

'Article 21a

In addition to the provisions laid down in Article 19, a marketing authorisation for a medicinal product may be granted subject to one or more of the following conditions:

(a) To take certain measures for ensuring the safe use of the medicinal product to be included in the risk management system;

(b) To conduct post-authorisation safety studies;

(c) To comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than those referred to in Title IX;

(d) Any other conditions or restrictions with regard to the safe and effective use of the medicinal product;

(e) The existence of an adequate pharmacovigilance system;

(f) To conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed. Such an obligation to conduct such studies shall be based on the delegated acts adopted pursuant to Article 22b while taking into account the scientific guidance referred to in Article 108a.

The marketing authorisation shall lay down deadlines for the fulfilment of these conditions where necessary.'.

Article 22a refers to similar conditions a competent authority may require after authorisation.

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