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Enabling Advanced Therapies in NHS Wales

A National Review of Pharmacy Aseptic Service Readiness for ATMPs

September 2026

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for the Chief Pharmaceutical Officer for Wales, with support from Advanced Therapies Wales

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Foreword

The emergence of Advanced Therapy Medicinal Products (ATMPs) represents one of the most significant developments in modern medicine, offering new possibilities for patients with rare, complex or life-limiting conditions. As more of these therapies move from research into routine clinical care, NHS Wales must ensure that patients can access them safely, consistently and equitably.

The Welsh Government's Statement of Intent and the Delivery Plan for Advanced Therapies in Wales set out a clear national ambition to adopt and deliver advanced therapies. Achieving this will require coordinated action across NHS organisations, academia, commissioners, manufacturers and the Welsh Government, supported by a pharmacy workforce and estate ready to prepare and handle these therapies safely.

Pharmacy aseptic services' expertise in the preparation, quality assurance, safe handling and governance of complex injectable medicines provides a strong foundation for supporting gene therapies and other advanced therapies as they become part of routine care, and they will be central to realising our ambition. This review assesses the readiness of aseptic services to support the delivery of advanced therapies. It identifies important strengths, expertise, enthusiasm, and examples of successful, and in some cases UK-leading, delivery by pharmacy teams in Wales. It also highlights areas requiring further work, including workforce development, training, estates, strategic planning, quality assurance support and the need for a consistent national approach.

The central message is pharmacy aseptic services must not be seen as a barrier to advanced therapy delivery, but as an essential partner in making treatment possible. Their skills in risk assessment, validation, quality systems and medicines governance are directly relevant to the safe introduction of ATMPs.

The report's 23 recommendations provide a practical route to strengthen capability, improve governance, share learning and align future service models, including the Transforming Access to Medicines programme, with the requirements of delivering advanced therapies. They require action at local, regional and national level and progress will depend on continued collaboration between health boards, NHS trusts, the NHS Wales Shared Services Partnership, Advanced Therapies Wales and the Welsh Government.

By acting now, Wales can build on existing strengths and provide safe, sustainable and equitable access to advanced therapies for patients across the country. We are grateful to the pharmacy aseptic services leads, clinical teams and stakeholders who contributed to this work. Their contribution and insight have the potential to make a very real difference to people in Wales.

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Executive summary

Advanced Therapy Medicinal Products (ATMPs) are becoming an increasingly important part of modern healthcare. These therapies have the potential to transform outcomes for patients with rare, complex and previously unmet clinical needs, often through single-dose or time-limited interventions that may deliver long-lasting therapeutic benefit. As an increasing number of ATMPs are granted a marketing authorisation by the Medicines and Healthcare products Regulatory Agency and are recommended by the National Institute for Health and Care Excellence, NHS organisations in Wales must ensure the infrastructure, workforce, governance and service models needed to support safe and equitable access to treatment, are in place.

This report commissioned by the Chief Pharmaceutical Officer for Wales, is a Wales-wide assessment of the current state of readiness of NHS pharmacy aseptic services to support the preparation and delivery of ATMPs, with a primary focus on *in vivo* gene therapies.

These products have a direct interface with hospital pharmacy aseptic services, frequently requiring specialist storage, aseptic manipulation, release and safe and timely transfer to clinical areas for administration. The report was commissioned in response to the growing number of ATMPs both in development and already approved, the Welsh Government's policy commitment to advanced therapies, the strategic priorities of Advanced Therapies Wales, and the introduction of UK legislation enabling decentralised manufacture of ATMPs within healthcare settings.

The review found a high degree of interest, enthusiasm and willingness to be involved in delivery of advanced therapies, across pharmacy aseptic services, together with important examples of existing good practice from within the NHS in Wales. Experiences within Cardiff and Vale University Health Board and Velindre University NHS Trust, demonstrate that complex licensed and investigational gene therapies can be supported safely through early multidisciplinary planning, targeted training, clear operational procedures and close coordination between clinical and pharmacy teams. These experiences provide a valuable foundation for wider national learning.

However, readiness across Wales is variable. The review identified inconsistent knowledge and confidence in relation to ATMP preparation, limited formal training for pharmacy aseptic staff, inconsistent exposure to Advanced Therapy Investigational Medicinal Product (ATIMP) clinical trials, and a lack of consistent organisational roadmaps for ATMP service development. Workforce capacity, ageing or constrained infrastructure, access to ultra-low temperature storage, and uncertainty about future demand were also identified as common barriers. These issues are not evidence of unwillingness within pharmacy services, but reflect the need for clearer strategy, practical support and earlier integration of pharmacy expertise into clinical and strategic planning.

A key conclusion is that many of the risks and practical requirements associated with *in vivo* gene therapy preparation align closely with established pharmacy aseptic practice. Pharmacy aseptic services already operate within highly regulated, assurance-led systems for complex and high-risk injectable medicines. With appropriate product-specific risk assessment, staff training, environmental controls, quality assurance and governance, existing aseptic expertise can be applied to ATMP preparation. The priority is therefore to build capacity, confidence and capability, rather than assume that entirely new service models are always required.

The report recommends a coordinated programme of local and national action by pharmacy services and NHS organisations, overseen by Advanced Therapies Wales. In the short term, there is a need to improve awareness and knowledge of ATMPs amongst those working in pharmacy aseptic services, to build a network of pharmacy ATMP champions across NHS organisations, to reflect on and develop plans to improve the readiness of each organisation's pharmacy aseptic workforce and facilities, and to improve the level and timeliness of engagement with clinical, research leaders and executive teams. There is also a need for more coordination at a national level and the report recommends establishing a Wales-wide ATMP pharmacy group supported by experts in quality assurance in pharmacy services, and the development of once-for-Wales resources to support consistent product assessment, decisions on where ATMPs should and must be prepared, and to improve governance around near-patient preparation.

The report also recognises the strategic importance of the Transforming Access to Medicines (TrAMs) programme. Once operational, TrAMs hubs should be considered the default preparation location for licensed *in vivo* gene therapies where product stability, and transport times allow. Where hub-based preparation is not feasible, experts from the regional hubs should support local or near-patient preparation through quality assurance, training, risk assessment and in some cases provision of operational expertise. This balanced approach will help maximise consistency while preserving flexibility for products with very short shelf lives or specific clinical requirements.

Positively, the report is clear that the NHS in Wales has a credible foundation on which to improve its readiness to deliver ATMPs, however action is needed now to avoid future inequities, duplication and avoidable delays. By making pharmacy aseptic services trusted and essential partners in ATMP planning, sharing learning across Wales, and with national oversight through Advanced Therapies Wales, NHS pharmacy teams can strengthen their ability to provide safe, effective and equitable access to advanced therapies for patients in every part of Wales.

Recommendations

	Action timescale	Responsible Person / Organisation
1 All pharmacy aseptic services staff should complete the following ATMP training modules, available through NHS e-learning for Health: • *Introduction to Advanced Therapy Medicinal Products* • *Considerations for hospital pharmacy staff in delivering ATMPs* • *In vivo gene therapy* • *Gene Therapy Medicinal Products, GMOs and Bio-containment*	within 9 months	**Director of Pharmacy** at each health board (HB) & trust
2 Working with the National Lead for Pharmacy Quality Assurance in Wales, training sessions should be developed and delivered for pharmacy aseptic services leads on the key principles of preparation of *in vivo* gene therapies with the objective of 'demystifying' aseptic preparation requirements for ATMPs.	within 9 months	**National Lead for Pharmacy Quality Assurance** **Health Education & Improvement Wales**
3 Pharmacy quality assurance expertise should be available to provide advice and support to aseptic units in establishing preparation processes and procedures for ATMPs.	within 9 months & ongoing	**National Lead for Pharmacy Quality Assurance**
4 Pharmacy aseptic services leads must approach health board/Velindre NHS University Trust clinical leads and executive teams to understand and support the development of organisational plans for ATMPs. *Pharmacy teams must approach the relevant senior clinicians to identify which ATMPs there is interest in providing to patients in their speciality. Organisations should maintain a rolling 24-month plan. Ensure pharmacy services are included at the earliest stages in any planning to deliver ATMPs in the health board or NHS trust.*	within 9 months	**Director of Pharmacy** at each HB & trust
5 The pharmacy service must be represented on every organisation's Genetic Medication Safety Committee, where one is established.	12 months	**Director of Pharmacy** at each HB & trust
6 Each health board and Velindre NHS University Trust must identify a suitably senior member of the pharmacy team to be responsible for ATMPs planning from a pharmacy perspective.	within 3 months	**Director of Pharmacy** at each HB & trust
7 An All-Wales ATMP Pharmacy group to be established to support sharing best practice between services. The group should report to both the Directors of Pharmacy Seamless Pharmaceutical Care Delivery Assurance Group and to the Advanced Therapies Wales programme. The group should also connect with the Pharmacy ATMP Network UK and ensure Welsh representation across its three subgroups: Regulatory, Governance and Technical Services, Clinical Trials and Clinical and Education.	within 9 months	**Director of Pharmacy** at each HB & trust **Advanced Therapies Wales**
8 Pharmacy aseptic services should consider *in vivo* gene therapy products as injectable medicines that fall under their remit and perform a gap analysis for delivery.	within 9 months	**Director of Pharmacy** at each HB & trust
9 Directors of Pharmacy should consider how existing pharmacy resource is allocated to support the initial set-up work required for pharmacy ATMP preparation and allocate additional resource if necessary.	within 9 months	**Director of Pharmacy** at each HB & trust
10 Organisations should ensure the pharmacy resources dedicated to ATMP delivery is appropriate to the level of demand for *in vivo* gene therapy in each organisation	12 months	**Director of Pharmacy** at each HB & trust

11 Health boards and Velindre University NHS Trust should draw up plans to utilise unused/underutilised cleanrooms or isolators to make them suitable for gene therapy preparation	12 months	**Director of Pharmacy at each HB and trust**
12 Pharmacy aseptic service leads should develop a plan to flexibly use their facilities on a sessional basis to prepare ATMPs	within 9 months	**Director of Pharmacy** at each HB & trust
13 Aseptic units should consider whether storage requirements (e.g. ultra low temperature freezers) for receipt and storage of gene therapies are adequate.	within 9 months	**Director of Pharmacy** at each HB and trust
14 Health boards and Velindre University NHS Trust should develop a list of priorities for capital investment to bring facilities up to the required standards for gene therapy preparation	12 months	**Director of Pharmacy** at each HB and trust
15 Should demand grow beyond existing local capacity, the Welsh Government should consider the allocation of capital resource to support commissioning dedicated ATMP preparation on a local or regional basis	12 - 24 months	**Chief Pharmaceutical Officer for Wales,** Welsh Government
16 All licensed *in vivo* gene therapy to be prepared at a Transforming Access to Medicines (TrAMs) hub, once operational, wherever possible • *If not possible (e.g. very short shelf life), TrAMs, health boards and Velindre University NHS Trust must ensure arrangements are in place to support appropriate preparation closer to the patient*	12 months	**Director of Pharmacy Services**, NHS Wales Shared Services Partnership. **Director of Pharmacy** at each HB and trust
17 Pharmacy aseptic service teams should work with Health and Care Research Wales and local Research and Development departments to proactively seek opportunities to be involved with ATIMP clinical trials	within 9 months	**Director of Pharmacy** at each HB & trust and **Health & Care Research Wales**
18 The All Wales Therapeutics and Toxicology Centre should develop and maintain a dedicated ATMP hub with relevant preparation and storage information for NHS pharmacy aseptic services, informed by its horizon scanning activities	within 3 months and ongoing	**Programme Director,** All Wales Therapeutics & Toxicology Centre
19 All Wales guidance should be developed to provide advice on where and in what circumstances, *in vivo* gene therapies can be prepared safely	12 months	**Advanced Therapies Wales**
20 Nationally agreed minimum standards for the governance and oversight of near patient preparation of ATMPs should be developed	12 months	**Advanced Therapies Wales**
21 All Health Boards/NHS Trusts must develop a plan in response to recommendations in this report	by 31 March 2027	**Director of Pharmacy** at each HB & trust
22 Advanced Therapies Wales should review the Health Boards/NHS Trusts plans in response to the recommendations and monitor progress against them	9 months and ongoing	**Advanced Therapies Wales**
23 Advanced Therapies Wales should provide operational support for implementation of the recommendations	within 9 months and ongoing	**Advanced Therapies Wales**

Background

Advanced Therapy Medicinal Products (ATMPs) represent a significant and transformative advance in the treatment of rare, complex and previously unmet clinical needs. As increasing numbers of ATMPs receive marketing authorisation from the Medicines and Healthcare products Regulatory Agency and are recommended by the National Institute for Health and Care Excellence (NICE), NHS services across Wales must adapt to support their safe, effective and equitable delivery.[1,2]

Many ATMPs, particularly gene therapies, are intended as single administration or time limited interventions with the potential to deliver long lasting, and in some cases curative, benefit. This represents a fundamental shift from traditional models of care based on repeated treatment cycles or long-term disease management. For patients and families, these therapies can be genuinely life changing, reducing or eliminating lifelong treatment burden, hospital attendance and disease progression.[3]

Within this evolving landscape, NHS pharmacy aseptic services are expected to play an increasingly critical enabling role in making treatments available to patients. While ATMPs may be perceived as novel, the technical and governance challenges they present align closely with the core remit of pharmacy aseptic services: the preparation, quality assurance and risk management of high risk sterile medicines.

This report provides a national assessment of the preparedness of NHS pharmacy aseptic services in Wales to support the safe, effective and equitable delivery of ATMPs. Its primary scope is *in vivo* gene therapy ATMPs, as these products are the most likely to require a final aseptic preparation step within a hospital immediately prior to administration. The report therefore focuses on the operational, technical, governance and strategic considerations relevant to pharmacy aseptic services, while recognising that other categories of ATMPs may interface with pharmacy services through different models of supply or manufacture. It considers current service capability, emerging pressures and the implications of an evolving regulatory landscape for local and national planning.

What are Advanced Therapy Medicinal Products?

ATMPs are currently defined in UK and EU medicines legislation as biological medicinal products based on genes, cells or engineered tissues.[1,4]

Collectively, ATMPs represent a step change in therapeutic intent. Rather than providing symptomatic control or slowing disease progression, many ATMPs are designed to address the underlying genetic or cellular cause of disease. This means that clinical benefit may be realised after a single administration or a limited number of doses, with effects that persist for many years.

From a pharmacy aseptic services perspective, *in vivo* gene therapies currently present immediate operational and governance challenges. These products are typically supplied as licensed medicines or investigational products and require aseptic preparation within hospitals prior to administration. Preparation steps may include thawing, dilution, transfer to final containers or mixing of components, in line with Summaries of Product Characteristics or clinical trial protocols.[5,6]

There are four types of ATMPs:

Gene therapy medicinal products: medicines that work by introducing, removing or modifying genetic material within a patient's cells to correct or compensate for an underlying genetic defect or disease process. These may be delivered *in vivo*, where the genetic material is administered directly to the patient and taken up by cells within the body, or *ex vivo*, where cells are removed from the patient, genetically modified outside the body, and then returned as part of the treatment.

Somatic cell therapy medicinal products: therapies based on cells that have been substantially manipulated or used for a different function from their normal role in the body, with therapeutic benefit derived from their biological activity.

Tissue engineered products: products containing engineered cells or tissues designed to regenerate, repair or replace human tissue, restoring lost structure and function.

Combined ATMPs: products that incorporate one or more ATMP components together with a medical device, where the biological component provides the primary therapeutic effect.

Rationale for this report

This report was commissioned in response to four clear drivers:

1. A growing number of licensed and late phase ATMPs and Advanced Therapy Investigational Medicinal Products (ATIMPs) expected to enter routine clinical use within the NHS in Wales in the next five years[7]

2. The Welsh Government's Statement of Intent on Advanced Therapies (2019), which set out a national policy commitment to support the adoption and delivery of advanced therapies within the NHS in Wales[8]

3. The priorities set out in Advanced Therapies Wales' Delivery Plan for Advanced Therapies in Wales, including the need to improve timely and equitable access to advanced therapies, strengthen national coordination and ensure the enabling infrastructure and services required for delivery are in place[9]

4. The introduction of new UK wide legislation in July 2025 enabling the decentralised manufacture of certain medicinal products, including ATMPs, within hospital settings[10,11]

Despite the increasing national focus on advanced therapies, assessment of pharmacy aseptic readiness to support their delivery has been limited and largely undertaken within individual health boards and NHS trusts. Despite much of the planning to deliver and the commissioning of advanced therapies being undertaken nationally, there is no overall assessment of pharmacy services' readiness in Wales. Given the critical role pharmacy aseptic services play in the delivery of ATMPs, the absence of such an assessment risks underestimating existing capacity and capability or overstating barriers to local delivery. These risks may lead to sub-optimal decisions on where care is provided and avoidable delays in patient access. The purpose of this report is therefore to describe current preparedness, identify common gaps and challenges, and provide practical recommendations to inform national and local planning.

The Advanced Therapies Wales Programme

The Advanced Therapies Wales programme aims to provide national leadership and coordination for the adoption and delivery of advanced therapies across the NHS in Wales. The programme brings together strategic planning, horizon scanning, service development and regulatory engagement to support the safe, timely and equitable introduction of ATMPs as they transition from research into routine clinical care.

A central element of the Advanced Therapies Wales programme is its delivery plan, which sets out the actions required to translate national ambition into operational reality.[9] This includes identifying priority therapies, defining appropriate service models, clarifying governance and regulatory responsibilities, and aiming to ensure that enabling services, such as pharmacy aseptic services, are adequately prepared and supported.

The role of pharmacy aseptic services intersects with several Advanced Therapies Wales delivery plan priorities, particularly in relation to:

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- Decisions about the location of preparation for licensed ATMPs and ATIMPs, including the balance between regional hubs and local provision;
- The development of proportionate governance models to support decentralised or near patient manufacture; and
- Workforce capability, capacity and confidence within NHS pharmacy services in Wales.

This report provides a pharmacy specific assessment to support the Advanced Therapies Wales delivery plan. Its findings and recommendations are intended to inform national and local decisions on service configuration, investment and sequencing of activity, including the development of regional and local pharmacy aseptic service models.

ATMP and ATIMP activity in the NHS in Wales

As of September 2026, there are 15 ATMP therapies with a total of 19 positive NICE recommendations (appendix 1) approved for use across the NHS.[2] These therapies span a range of clinical specialties and represent varying levels of maturity, from long established products to more recently recommended treatments entering routine clinical practice.

Of the ATMPs currently recommended by NICE, five are *in vivo* gene therapies. These products are typically supplied as licensed medicinal products and, unlike many ex vivo therapies, commonly require local aseptic manipulation within hospitals prior to administration. For pharmacy teams, there are associated practical considerations which need to be addressed including receipt, storage, scheduling, preparation, release and timely transfer to the clinical area, all of which need to be aligned with the specific requirements set out for each product. As such, these therapies have a direct and immediate dependency on NHS pharmacy aseptic services.

In addition to therapies already recommended by NICE, a further 22 ATMPs are currently included on NICE's horizon. These comprise six therapies in development and 16 classified as awaiting development.

This demonstrates the expansion of research and development in the ATMP field and indicates a sustained flow of therapies that may enter routine NHS use over the next five years.

ATMPs on the horizon include several additional *in vivo* gene therapies, alongside *ex vivo* cell and gene therapies (including CAR-T products) and tissue engineered products. If recommended, a number of these *in vivo* gene therapy products are expected to require aseptic preparation, further increasing the dependency on pharmacy aseptic services for ATMP delivery.

At the time this review was undertaken, NHS pharmacy teams in Wales were supporting a limited range of:

- Licensed ATMPs delivered as part of routine clinical services; and
- ATIMPs delivered within clinical trial settings.

Activity was inconsistently distributed across health boards and trusts, with most product preparation concentrated in the Cardiff and Vale University Health Board and Velindre University NHS Trust, where there is growing experience of the use of both licensed ATMPs and ATIMPs.

Preparation challenges and the role of pharmacy

The preparation of ATMPs, particularly *in vivo* gene therapies, presents a combination of practical, technical and governance considerations that require careful planning and coordination. These therapies are frequently characterised by very short shelf lives, tightly defined preparation and administration windows, and complex storage requirements, including the handling of materials at ultra low temperatures (ULT). In addition, depending on their classification, gene therapies may be subject to enhanced biosafety and environmental controls, including specific cleaning regimes, use of dedicated consumables and clearly defined waste management arrangements, further reinforcing the need for robust and well controlled local systems.[5,6]

From an operational perspective, preparation requirements for *in vivo* gene therapies frequently involve multiple aseptic manipulations undertaken shortly prior to administration. These processes must be carried out reliably, alongside existing aseptic workloads, and may

require flexible scheduling, improved planning and communication with clinical teams, and contingency planning to manage delays or deviations. While these characteristics can appear unique to ATMPs, they are in reality not fundamentally different from challenges already managed within pharmacy aseptic services for other high risk or time dependent injectable medicines.

A key consideration is the need for proportionate risk assessment and clear determination of the most appropriate preparation location for each therapy. National guidance from the Specialist Pharmacy Service (SPS) emphasises that decisions should be based on the characteristics of the product, its regulatory status and biosafety classification, rather than a default assumption that gene therapies require radically new service models. In many cases, existing hospital pharmacy aseptic facilities are well placed to undertake preparation, provided that governance arrangements, staff training and environmental controls are aligned with the specific requirements of the product.[5,6]

Governance requirements for gene therapies may span medicines legislation, local quality management systems and genetic modification and environmental safety frameworks. Pharmacy aseptic services play a central role in integrating these requirements into operational practice, ensuring that preparation processes are authorised, documented and auditable. This includes contributing to local risk assessments, supporting multidisciplinary governance structures and ensuring that standard operating procedures appropriately reflect product specific risks.

Importantly, national guidance consistently highlights the role of pharmacy in supporting safe and proportionate implementation. The expertise within pharmacy aseptic services in validation, change control, operator protection, waste handling and quality assurance is directly transferable to ATMP preparation. The principal challenge lies not in developing entirely new technical skills, but in providing clarity, confidence and capacity to apply existing expertise within an evolving regulatory and therapeutic landscape.

Pharmacy's role in assurance and preparation of non-ATMP sterile medicines

NHS pharmacy aseptic services are responsible for the preparation of injectable medicines where failures in quality or sterility would present a significant risk to patients. Across Wales, this function is routinely delivered through eleven dedicated aseptic units with controlled environments, operating under nationally agreed frameworks that place assurance and patient safety at the centre of practice.[12] Good manufacturing practice guidance on aseptic preparation emphasises that safe supply is achieved through robust system design, clearly defined professional accountability and consistent local and national oversight.

As a result, pharmacy aseptic services already function as highly regulated, assurance led systems for the preparation of complex and high risk sterile injectable medicines. The established governance arrangements, specialist workforce expertise and embedded quality culture within these services provide a strong foundation for supporting newer and more complex products, including ATMPs, where the same principles of risk management, validation and oversight apply.

Regulatory context: decentralised manufacturing

Historically, medicines legislation in the UK was built around a centralised manufacturing model, in which medicinal products were made at a limited number of licensed manufacturing sites before being released, distributed and supplied to healthcare organisations for storage, preparation where required, and administration. This model remains appropriate for many conventional medicines but is less well suited to products that need to be made at, or very close to, the point of patient care because of very short shelf lives or the need for highly personalised manufacture. In July 2025, new UK legislation came into force to address this gap. The Human Medicines (Amendment) (Modular Manufacture and Point of Care) Regulations 2025 amended existing medicines legislation to provide a regulatory framework for decentralised manufacturing models, including modular manufacture and point of care manufacture, that do not sit easily within conventional centralised manufacture and distribution arrangements.[10,11]

Modular manufacture generally refers to manufacture undertaken within a standardised, self-contained unit that can operate across different locations. For example, a deployable manufacturing cleanroom module could be installed within or alongside a hospital to produce a defined medicine. Point of care manufacture refers to manufacture that takes place at, or immediately adjacent to, the clinical setting where the patient will be treated. This may be necessary where a cell or gene therapy product has such a short shelf life that it cannot be manufactured at a distant site and transported to the patient in time for administration.

A central feature of the new legislation is the use of a hub and spoke model in which the control site, or hub, retains responsibility for the pharmaceutical quality system, documentation, training, qualification, validation, audit and regulatory compliance. Manufacturing sites operate as spokes under the governance of the control site. This is intended to allow greater flexibility in where manufacture takes place, while maintaining clear accountability for product quality, safety and regulatory control.

The potential relevance of this legislation to ATMP delivery within the NHS in Wales is considered later in this report.

Current state of readiness

Method of review

A structured qualitative review of pharmacy aseptic service readiness was undertaken across the NHS in Wales, drawing on detailed responses from pharmacy aseptic services leads in the six health boards that currently have pharmacy aseptic services and Velindre NHS University Trust. The review was designed to develop a robust and consistent national understanding of current capability, experience and perceived challenges in relation to ATMP delivery, with a particular emphasis on *in vivo* gene therapy products, reflecting their direct and immediate interface with hospital pharmacy aseptic preparation and release processes.

Data was collected using a comprehensive, standardised question set that was circulated in advance and used to structure follow-up discussions with participants. The question set was deliberately designed to prompt both factual information and reflective assessment, enabling services to describe not only what activity was currently being undertaken, but also their confidence, readiness and perceived ability to expand provision. Questions (appendix 2) were organised thematically to explore readiness across several key domains, including knowledge and engagement with ATMPs, strategic planning and gap analysis, facilities and equipment, workforce and training, operational considerations, governance and compliance, and experience of supporting ATIMPs.

This structured approach supported comparability across organisations while allowing sufficient flexibility for respondents to provide local context, describe differing service models and highlight organisation-specific risks or constraints. In addition to narrative responses, the review captured quantitative indicators, including self-assessed knowledge and confidence scores, access to ULT storage and current levels of clinical trial activity.

Qualitative insights were also sought to explore areas that are less readily captured through metrics alone, such as perceived regulatory complexity, organisational risk appetite, workforce confidence and the practical challenges associated with preparing products with very short shelf lives or multiple aseptic manipulation steps.

Responses were reviewed to identify recurring themes, shared constraints and areas of variation across organisations. The analysis focused on practical and systemic issues relevant to national planning and support, rather than comparing individual aseptic units. The findings therefore reflect common patterns across the NHS in Wales and are intended to inform proportionate planning, targeted support and actions to strengthen readiness for the safe preparation of *in vivo* gene therapy ATMPs within pharmacy aseptic services.

A sample of the questions used during interviews with pharmacy aseptic services leads:

- How would you rate your current knowledge of ATMPs and the role of NHS pharmacy aseptic services in their preparation and handling?
- Has your aseptic unit been approached to prepare any ATMPs, either as part of clinical trials or as licensed medicines, and how did the service respond?
- What do you consider to be the main barriers to initiating or expanding preparation of *in vivo* gene therapy ATMPs within your unit (for example infrastructure, workforce, governance or quality assurance support)?
- To what extent are your current aseptic facilities, equipment and environmental controls suitable for supporting ATMP preparation?
- Do you have plans to upskill existing staff or expand workforce capacity to support future ATMP work?
- Have any pharmacists or technical staff received ATMP-specific training?
- What operational challenges would your service face in preparing products with very short shelf lives or tightly defined preparation and administration windows?

The review identified a consistent set of themes across NHS pharmacy aseptic services in Wales, reflecting both current constraints and areas of opportunity for development.

Theme 1 - Variable knowledge base

Knowledge of ATMPs varies across pharmacy aseptic services. Most interviewees recognised ATMPs as an important and developing area of practice, but detailed understanding of the implications for aseptic services was less consistent. Knowledge was generally stronger in relation to the strategic significance of ATMPs than the practical requirements for local implementation, including governance, workforce capability, environmental controls and routine operational processes.

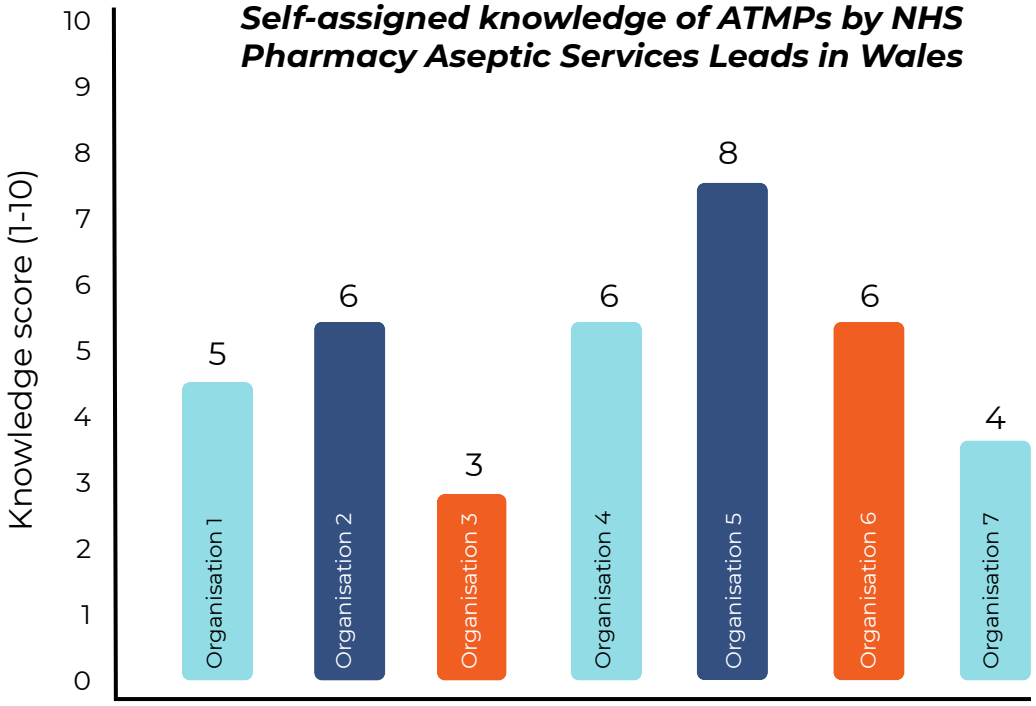
In many services, knowledge has developed through informal routes, including individual reading, professional discussion and opportunistic exposure through attendance at conferences, symposiums or membership of professional networks. This has led to variable levels of understanding and limited evidence of a consistent baseline across teams. Confidence was highest where staff had direct involvement in ATIMP clinical trials, which provided practical experience of risk assessment, product-specific requirements and the application of aseptic process for to gene therapy product preparation.

Participants identified gaps in understanding of the practical requirements and governance arrangements for ATMP preparation in aseptic units. Some requirements appear to be overestimated, leading to assumptions that highly specialised infrastructure or novel processes will always be needed. In practice, many technical and governance requirements align with established aseptic principles and could be managed within existing frameworks, provided there is appropriate risk assessments, processes and quality assurance.

Regulatory knowledge of ATMPs was also uneven across Wales, particularly in relation to gene therapy safety requirements and their application within local service settings. National guidance, including SPS readiness materials, provides a very useful foundation, but services will need support to interpret and implement these consistently. Input from the National Lead for Pharmacy Quality Assurance should provide expert advice and oversight to support a consistent interpretation and implementation of regulatory requirements for ATMP preparation across Wales, reducing uncertainty and helping services develop practical, compliant local processes.

Pharmacy Aseptic Services Leads were asked to rate their knowledge, out of 10, of ATMPs and the role of NHS pharmacy aseptic units in their preparation and handling

(1 = no knowledge, 10 = highly knowledgeable)



Theme 2 - Absence of formal training and dispelling misconceptions about ATMP preparation

A consistent finding was the lack of formal ATMP training for pharmacy aseptic services teams. Pharmacists and pharmacy technicians are not routinely accessing structured, role-specific education focused on ATMP preparation. Current knowledge development appears largely opportunistic, arising through individual reading, attendance at occasional meetings or events, or ad hoc discussion with colleagues already involved in relevant work. As a result, learning is fragmented, with no shared baseline of knowledge across teams and no clear route from awareness to operational competence.

> *"**No pharmacy aseptic services staff have received ATMP-specific training.***
> *No plan currently exists to upskill staff for ATMP work. Our focus has been on managing the increasing systemic anti-cancer therapy workload."*
>
> *quote from interviewee*

ATMP knowledge is also concentrated amongst a small number of senior or specialist staff, with no or limited mechanisms to disseminate learning to the wider workforce. This creates a fragile model of readiness, dependent on individual interest rather than embedded capability. There is a clear need for training aligned for pharmacy aseptic services staff, with content tailored to the practical, governance and quality requirements of ATMP delivery.

Staff confidence is affected by limited familiarity with gene therapies and their associated regulatory, biosafety and operational requirements. For many aseptic services, ATMPs sit outside routine practice and may be perceived as substantially different from established aseptic preparation work. Where teams have had little direct exposure, this can lead to understandable caution before the practical requirements, controls and mitigations have been fully worked through.

> *"**There's a fear factor** among staff when ATMPs are mentioned, and education is key to debunk myths."*
>
> *quote from interviewee*

> *"There's probably **a mystery about ATMPs** for most of our workforce, people can interpret too many things and get quite **scared of the word gene therapy**. There needs to be clarity, it's a staffing issue as well."*
>
> *quote from interviewee*

The interviews indicate that this concern reduces when staff have access to practical exposure, structured training and clear guidance. Services with experience of ATIMPs or early ATMP-related work described improved confidence and a more proportionate understanding of risk. This suggests that the issue is not reluctance to engage, but the need for clearer routes to competence and assurance.

Building confidence will require targeted education, practical exposure and visible professional leadership. Staff appear willing to engage with ATMP work, but confidence is limited by unfamiliarity, service pressures and the lack of opportunities for hands-on experience.

Services will be better placed to respond to future demand where staff understand the practical requirements, have confidence in the controls required to manage risk, and know where to access specialist advice.

Support from the pharmacy quality assurance experts in Wales coordinated by the National Lead for Pharmacy Quality Assurance would provide an important source of specialist advice for aseptic units. This would help services interpret requirements, develop local procedures and address questions relating to validation, safe handling, documentation and governance. Dedicated ATMP quality assurance support provided nationally would also help reduce unwarranted variation between organisations, particularly where local experience of ATMPs remains limited.

Recommendation 1
All pharmacy aseptic services staff should complete the following ATMP training modules, available through NHS e-learning for Health:

- *Introduction to Advanced Therapy Medicinal Products*
- *Considerations for hospital pharmacy staff in delivering ATMPs*
- *In vivo gene therapy*
- *Gene Therapy Medicinal Products, GMOs and Bio-containment*

Recommendation 2
Working with the National Lead for Pharmacy Quality Assurance in Wales, training sessions should be developed and delivered for pharmacy aseptic services leads on the key principles of preparation of *in vivo* gene therapies with the objective of 'demystifying' aseptic preparation requirements for ATMPs.

Recommendation 3
Pharmacy quality assurance expertise should be available to provide advice and support to aseptic units in establishing preparation processes and procedures for ATMPs.

Theme 3 - Strategic direction and service planning

There is limited strategic direction being provided for ATMP readiness at organisational level, this is commonly reflected in the absence of a roadmap or service development plans which would support ATMP delivery. While ATMPs are recognised as increasingly relevant to NHS services, this is not always translated into structured planning within pharmacy aseptic services. In practice, this can lead to a largely reactive approach, where readiness work is delayed until clearer demand emerges or a specific request is received. This risks compressing essential activity into shortened timescales, despite the lead time required for infrastructure development, governance design, workforce training and operational validation.

Pharmacy aseptic services' leads described clinician engagement as a key enabler of readiness. Where there are no clear clinical requests, limited trial activity or little clinician interest in ATMP-related work, there is generally very limited local emphasis placed on developing capability within aseptic services. Without visible clinical pathways or an indication of likely demand, it is difficult to justify investment in infrastructure, workforce development, governance and service redesign particularly if doing so would be to the detriment of existing operational capacity.

> *"**The biggest barrier is knowing what's coming**, what trials, what licensed products, and what the uptake will be in our region. Without that, it's like looking into a cloud. We can't plan infrastructure or workforce without clarity on demand and product profiles."*
>
> *quote from interviewee*

> *"In a nutshell, no, we don't have a roadmap at the moment... **it would be great to have a higher-level ATMP strategy for the health board** that then we know where we fit in, rather than reacting to the first ask."*
>
> *quote from interviewee*

Where clinician interest has resulted in use of ATIMPs in clinical trials or planning for licensed products, pharmacy teams are more likely to have practical experience and confidence. This provides a clear basis for joint working between clinical teams, research, pharmacy and governance colleagues, and helps services understand what would be required in practice. Pharmacy teams should therefore take immediate steps to improve their awareness of anticipated clinical demand for ATMPs within their organisations.

Even where there is local enthusiasm for ATMP delivery, there remains uncertainty about the future ATMP landscape, including likely product types, routes of preparation, manipulation requirements and delivery models. This limits forward planning with pharmacy teams finding it difficult to identify which infrastructure, staffing or governance arrangements should be prioritised without clearer national or organisational direction. As a result, readiness is often viewed as dependent on future decisions made elsewhere, rather than as work that can begin now.

Decision making between stakeholders involved in service planning appears fragmented in some areas. Pharmacy aseptic services input is sometimes sought only after important commitments have already been made. This creates avoidable risk, as feasibility questions, infrastructure implications and workforce requirements may only become visible once a service expectation has been established. Crucially, this can mean that when pharmacy services raise often legitimate concerns about capability or capacity, this can be misconstrued as resistance or to pharmacy services being a barrier to delivery. Earlier pharmacy involvement would provide more opportunity to shape realistic delivery models, identify limitations and build sufficient preparation time into organisational plans.

There is clear professional interest in ATMPs across pharmacy aseptic services. Staff are experienced specialists in aseptic preparation, quality assurance, operational delivery and the safe handling of complex injectable medicines, and their expertise will be central to the safe introduction of in vivo gene therapies across NHS Wales. Interviewees described ATMP preparation as a developing area of practice aligned with the established role of aseptic services in enabling access to complex, innovative and high-risk medicines. The findings indicate that pharmacy aseptic service leads are not resistant to ATMPs, rather, they recognise the need for change and are willing to engage with new therapeutic pathways where supported by appropriate training, governance, infrastructure and service planning.

> *"ATMPs are something which we would be keen to try and deliver. They are completely novel and **I think staff would enjoy being involved in something a little bit different and on the edge of research**."*
>
> *quote from interviewee*

More integrated governance routes for ATMP-related activity would help ensure pharmacy aseptic services are involved early in discussions about feasibility, risk and operational delivery. This would support clearer accountability, improved information flow and closer alignment between strategic ambition and the practical requirements of service delivery.

Recommendation 4
Pharmacy aseptic services leads must approach health board/Velindre NHS University Trust clinical leads and executive teams to understand and support the development of organisational plans for ATMPs.
Pharmacy teams must approach the relevant senior clinicians to identify which ATMPs there is interest in providing to patients in their speciality. Organisations should maintain a rolling 24-month plan. Ensure pharmacy services are included at the earliest stages in any planning to deliver ATMPs in the health board or NHS trust.

Recommendation 5
The pharmacy service must be represented on every organisation's Genetic Medication Safety Committee, where one is established.

Theme 4 - Workforce

Workforce capacity was consistently identified as a constraint to ATMP delivery readiness and, for some services, represents the most significant and immediate barrier to progress. Most aseptic services are already operating at or close to capacity, with increasing demands on core activity, including systemic anticancer therapy and other aseptic preparations, limiting the time available for service development, validation and implementation work.

At present, demand for *in vivo* gene therapy preparation in Wales remains low when compared with established aseptic activity. However, this position is expected to change as additional products are licensed and come into clinical use. While current demand is relatively low there is opportunity to define what level of pharmacy input will be required, assess how existing resource can support preparatory work, and identify any gaps in capacity, training, governance or validation ahead of anticipated future demand.

Participants described varying levels of confidence among pharmacy teams in relation to the preparation of *in vivo* gene therapies, largely reflecting limited training and practical exposure. Although these products may initially be perceived as distinct from routine aseptic work, many of the core requirements for manipulation, safe preparation and quality assurance are closely aligned with established aseptic practice. Pharmacy aseptic services leads should therefore not consider *in vivo* gene therapies to be special cases, rather they sit within the wider injectable medicines remit of aseptic services, while recognising that product-specific risk assessment, validation and governance will be required.

Alongside capacity and capability, the absence of a clearly identified pharmacy lead for ATMPs within health boards or trust arrangements was identified as a further gap in organisational readiness. Without a named lead, requests from clinicians, research teams or governance groups may be routed inconsistently, and opportunities for early and appropriate pharmacy input may be missed. A nominated lead would provide a clear point of accountability and support a more coordinated pharmacy response to ATMP-related enquiries and service planning.

> *"**We don't have a designated ATMP lead**. Any requests would probably come through the research and development pharmacists, but there's no formal role or title for ATMP oversight."*
>
> *quote from interviewee*

> *"**Just a designated staff member within pharmacy**, I guess, who could lead on building a health board wide strategy. There's not one currently. So, I think that would be really key to have in place, just so you feel supported and you feel like you've got that necessary governance in place to take on these products which are unfamiliar and new and have a number of regulations to cover."*
>
> *quote from interviewee*

> *"Lots of consultants are aware of these novel products, but whether it actually advances after that because of the lack of current processes and structures to go through in our organisation could be an issue.*
>
> ***Having a designated individual would certainly raise the profile** and make people aware that this could be an option for patients here, not just in a specialist centre or in places with a particular focus on research."*
>
> *quote from interviewee*

The findings also warn that readiness should not be dependent on a single individual within an organisation or on all advanced therapies expertise being centralised in a small number of organisations. Services will benefit from structured approaches to sharing learning and practical experience between organisations and pharmacy teams in Wales, particularly where local exposure to ATMPs has been limited to date. A Wales-wide pharmacy network would support peer learning, reduce duplication, spread emerging good practice and provide a forum for working through common issues relating to workforce, governance and operational delivery.

Overall, workforce readiness will require each service to assess its anticipated ATMP workload against existing capacity, skills and governance support. Staffing should be proportionate to expected demand, but even low-volume activity will require time for planning, training, validation, documentation and multidisciplinary coordination. This supports the need for local gap analysis, clear allocation of pharmacy resource for initial set-up work, and national arrangements to share learning as services develop

Recommendation 6
Each health board and Velindre NHS University Trust must identify a suitably senior member of the pharmacy team to be responsible for ATMPs planning from a pharmacy perspective

Recommendation 7
An All-Wales ATMP Pharmacy group to be established to support sharing best practice between services. The group should report to both the Directors of Pharmacy Seamless Pharmaceutical Care Delivery Assurance Group and to the Advanced Therapies Wales programme. The group should also connect with the Pharmacy ATMP Network UK and ensure Welsh representation across its three subgroups: *Regulatory, Governance and Technical Services, Clinical Trials and Clinical and Education*.

Recommendation 8
Pharmacy aseptic services should consider *in vivo* gene therapy products as injectable medicines that fall under their remit and perform a gap analysis for delivery

Recommendation 9
Directors of Pharmacy should consider how existing pharmacy resource is allocated to support the initial set-up work required for pharmacy ATMP preparation and allocate additional resource if necessary

Recommendation 10
Organisations should ensure the pharmacy resources dedicated to ATMP delivery is appropriate to the level of demand for *in vivo* gene therapy in each organisation

Theme 5 - Infrastructure and facilities

The suitability of existing aseptic service facilities and infrastructure for *in vivo* gene therapy preparation varies across Wales. Some aseptic units are constrained by the age of the estate, limited pharmaceutical isolator capacity, competing aseptic workloads, or essential equipment that is already fully utilised. Other services have access to cleanrooms, isolators and sessional capacity that could be repurposed to support ATMP delivery. This variation means that readiness planning will need to be specific to local circumstances, while remaining aligned to a consistent national approach to quality, governance and patient access.

Where suitable capacity exists, underutilised aseptic facilities provide a practical route to readiness for low-volume *in vivo* gene therapy preparation. This may be particularly relevant where products can be prepared through planned sessions rather than as part of continuous routine workload. However, suitability should not be assumed. Organisations will need to assess whether available rooms, isolators, equipment, storage arrangements and environmental controls are appropriate for the specific products likely to be prepared, and whether any reconfiguration, refurbishment or updated procedures would be required before use.

Given current low volumes of *in vivo* gene therapy activity, there is a strong case for making better use of existing aseptic facilities before assuming that new dedicated environments will be required. A proportionate approach would allow services to test operational arrangements, develop procedures, complete product-specific risk assessments and build staff familiarity while demand remains manageable. It would also help organisations identify where existing infrastructure is sufficient, where targeted local improvement is required, and where future capital investment may be needed as demand increases.

For most services, readiness will depend on flexible use of existing facilities alongside current workload. ATMP preparation is unlikely to justify permanently dedicated aseptic space in the short to medium term in most organisations. Some units may be able to support preparation through planned sessional use, provided this is supported by clear procedures, cleaning arrangements, scheduling discipline and appropriate segregation from other activity.

> *"**Assuming staffing wasn't a constraint, we could allocate up to eight ATMP sessions per week** using the second cleanroom, provided the product is suitable for preparation in a dedicated session."*
>
> *quote from interviewee*

> *"If ATMPs were introduced, **we'd need flexibility in our isolator use.**"*
>
> *quote from interviewee*

Where existing facilities are not suitable, organisations will need to identify and prioritise capital investment required to bring them to an acceptable standard for ATMP preparation. This may include equipment replacement, room reconfiguration or investment in storage and monitoring systems. If demand grows beyond existing local capacity, consideration should be given to additional capital investment from the Welsh Government to support dedicated ATMP preparation facilities on a local or regional basis.

The Transforming Access to Medicines (TrAMs) programme is expected to concentrate NHS pharmacy aseptic preparation in Wales within three regional hub sites, supported by modern preparation facilities and experienced pharmacy aseptic staff. Once operational, these hubs should be considered the default preparation location for licensed *in vivo* gene therapies. This model would support consistent governance, quality assurance and operational oversight, while enabling preparation to be undertaken by teams with established expertise in handling injectable medicines.

The requirements for *in vivo* gene therapy preparation must be considered when finalising the operating models for the TrAMs regional hubs. Product shelf life, transport time, proximity to treatment sites and the reliability of end-to-end logistics will determine whether hub-based preparation is appropriate for individual products. The proposed South East Wales model, in which products with a shelf life of at least four hours are to be prepared by pharmacy aseptic services staff at the hub and transported to clinical sites for administration, provides a practical example of how this model could operate. Learning from this approach should be captured and used to inform future models for *in vivo* gene therapy preparation within the South West and North Wales TrAMs hubs.

Where product shelf life is shorter, or transport arrangements would introduce unacceptable risk, the concentration of aseptic preparation and pharmacy quality assurance expertise in TrAMs means a new model will be required to support health board/trust pharmacy teams to deliver preparation closer to the patient. This support could include product and preparation-area risk assessment, staff training, quality assurance and governance oversight, or direct preparation by TrAMs staff where this is necessary. This will be important to ensure that patients in Wales can access appropriate gene therapies where a regional hub preparation model is not feasible.

Readiness also varies in relation to the infrastructure required for receipt, storage and monitoring of ATMPs. Some services already have established pharmacy-controlled cold-chain arrangements, while others rely on storage capacity outside pharmacy or do not currently have access to the conditions likely to be required for some products. Pharmacy teams should therefore assess current storage arrangements against anticipated ATMP requirements, including temperature range, monitoring, access and business continuity. This should include consideration of whether additional pharmacy-controlled capacity, such as ULT freezer storage, will be required to support safe receipt and storage of gene therapies.

> *"**We don't have any –80°C freezers in pharmacy**, but we do in path lab... we'd have access to that if needed, but I believe we should be storing these drugs inside Pharmacy and within our control. We probably should be looking to purchase a freezer for Pharmacy that we'd temperature monitor ourselves."*
>
> *quote from interviewee*

Recommendation 11
Health boards and Velindre University NHS Trust should draw up plans to utilise unused/underutilised cleanrooms or isolators to make them suitable for gene therapy preparation

Recommendation 12
Pharmacy aseptic service leads should develop a plan to flexibly use their facilities on a sessional basis to prepare ATMPs

Recommendation 13
Aseptic units should consider whether storage requirements (e.g. ultra low temperature freezers) for receipt and storage of gene therapies are adequate

Recommendation 14
Health boards and Velindre University NHS Trust should develop a list of priorities for capital investment to bring facilities up to the required standards for gene therapy preparation

Recommendation 15
Should demand grow beyond existing local capacity, the Welsh Government should consider the allocation of capital resource to support commissioning dedicated ATMP preparation on a local or regional basis

Recommendation 16
All licensed *in vivo* gene therapy should be prepared at a TrAMs hub, once operational, wherever possible
If not possible (e.g. very short shelf life), TrAMs, health boards and Velindre NHS University Trust must ensure arrangements are in place to support appropriate preparation closer to the patient

Theme 6 - Clinical trials and ATMP service readiness

Clinical trial activity provides an important route to building practical ATMP readiness, but access to this experience is inconsistent across Wales. Some services have little or no involvement in injectable clinical trials or ATIMPs, reflecting differences in clinical demand, infrastructure, workforce capacity and local research activity. At present, ATIMPs are only prepared within pharmacy aseptic units in Cardiff and Vale University Health Board and Velindre University NHS Trust. This creates a clear distinction between services that are beginning to develop direct operational experience and those that remain reliant on theoretical knowledge, national guidance or informal discussion. As a result, opportunities to build confidence, test local processes and understand the practical implications of ATMP preparation are not distributed consistently across the NHS in Wales, if not addressed this could result in inequalities of access to ATMPs particularly as new ATMPs are licensed for the treatment of higher prevalence and not just rare diseases.

This has implications for national readiness. Clinical trial activity provides structured, exposure to the governance, quality assurance and operational processes associated with ATMP preparation. It also allows services to test local procedures, clarify roles and develop confidence in a controlled environment before licensed or routine activity emerges. This includes practical consideration of product receipt, storage, chain of custody, preparation controls, documentation, staff training, quality assurance review and multidisciplinary communication. Trial activity can also help services understand the time, resource and coordination required to move from initial feasibility discussions to safe operational delivery.

Where these opportunities are absent, pharmacy teams have fewer practical routes to build familiarity and may be less prepared to respond when clinical demand increases.

Where clinical trial work is established, pharmacy teams gain experience in product-specific risk assessment, governance and process design. This experience can inform future service models and support readiness for licensed or routine treatments by providing a practical setting in which to refine arrangements before wider implementation.

Learning from organisations with ATIMP trial experience should therefore be shared more systematically across Wales, so that services with less direct exposure can benefit from established processes, templates and operational insight. This would help reduce duplication of effort, support more consistent interpretation of product requirements, and enable services to adapt learning to their own facilities and workforce models.

> *"It's been a steep learning curve... every ATIMP clinical trial tends to have different nuances, but* ***in the ones that we've set up we've learned a lot****. It was slow to begin with, but from the knowledge that we gained,* ***we have recently been able to move at a faster pace than we did for those initial trials****.*
> *We can now use knowledge for future trials as well as upcoming licensed gene therapies."*
>
> *quote from interviewee*

Closer working with Health and Care Research Wales and local Research and Development departments would help pharmacy aseptic services identify suitable ATIMP opportunities earlier, assess the implications for local preparation, and build capability before routine demand increases. This would also support earlier pharmacy input into trial feasibility, set-up timelines, facility requirements and workforce planning and growth in clinical trial activity in Wales.

Recommendation 17
Pharmacy aseptic service teams should work with Health and Care Research Wales and local Research and Development departments to proactively seek opportunities to be involved with ATIMP clinical trials

Theme 7 - Negative narrative of pharmacy aseptic services as a potential barrier to ATMP delivery

Some participants identified a risk that pharmacy aseptic services may be perceived as unable or unwilling to support ATMP preparation because of existing pressures relating to capacity, infrastructure or workforce capability. It is not clear how far this perception currently influences clinical planning or decisions about local access, but if left unchallenged it may limit opportunities for early pharmacy involvement in pathway development. This would risk reinforcing a narrative in which pharmacy is viewed primarily as a potential barrier, rather than as a specialist service with the expertise required to support safe and deliverable models of ATMP preparation.

> *"**We need to change the narrative** from 'we can't do this' to 'how can we do this safely and efficiently."*
>
> *quote from interviewee*

Changing this narrative will require earlier and more constructive engagement, as described in recommendation 4, with clinical, management and research colleagues, alongside visible examples of safe delivery. Pharmacy aseptic services should be positioned as active partners in ATMP service planning, rather than as a late-stage operational constraint. This means involving aseptic services leads at the point when clinical pathways, trial opportunities and service models are being considered, so that feasibility, product handling, facility requirements, staffing and governance can be assessed from the outset.

Demonstrating capability in practice will support confidence, challenge assumptions about what pharmacy aseptic services can provide, and enable more consistent adoption of ATMPs across the NHS in Wales.

Theme 8 - Shared documentation and once-for-Wales resources

Participants highlighted the need for clear, accessible and nationally prepared documentation to support ATMP preparation. Product-specific information will be needed to inform decisions about preparation location, facility requirements, handling controls, storage, transport and governance. Without a shared resource, individual organisations may duplicate work, interpret requirements differently or delay decisions while seeking information from multiple sources.

*"We need a **shared resource, a once-for-Wales monograph-style database**, so that when we get an approach, we can quickly see whether the product needs a dedicated isolator, a specific facility, or can be prepared in a campaign session."*

quote from interviewee

*"**Logistics and geography are big challenges**. The location where the injectable medicines that we prepare are administered to patients can sometimes be up to two hours of transportation away from our aseptic unit. If a product has a four-hour expiry, it would be very difficult to prepare, check, and deliver in time."*

quote from interviewee

A once-for-Wales approach would support consistency and reduce variation between organisations. It would also help pharmacy aseptic services assess feasibility earlier when approached about a product, particularly where short shelf life, specialist storage or near-patient preparation may affect the delivery model.

Recommendation 18
The All Wales Therapeutics and Toxicology Centre should develop and maintain a dedicated ATMP hub with relevant preparation and storage information for NHS pharmacy aseptic services, informed by its horizon scanning activities

Recommendation 19
All Wales guidance should be developed to provide advice on where and in what circumstances, *in vivo* gene therapies can be prepared safely

Recommendation 20
Nationally agreed minimum standards for the governance and oversight of near patient preparation of ATMPs should be developed

Implementation and oversight

The findings in this report will require local ownership and national oversight if they are to translate into practical change. Each health board and trust will need to consider its current position, identify gaps in readiness and develop a plan for training, workforce, infrastructure, governance and engagement with clinical teams. National monitoring and support from Advanced Therapies Wales would help maintain momentum, support consistency and identify where additional support or escalation is required.

Recommendation 21
All Health Boards/NHS Trusts must develop a plan in response to recommendations in this report

Recommendation 22
Advanced Therapies Wales should review the Health Boards/Trusts plans in response to the recommendations and monitor progress against them

Recommendation 23
Advanced Therapies Wales should provide operational support for implementation of the recommendations

Examples of good practice

The following case studies demonstrate existing experience in the NHS in Wales in preparing and supporting licensed ATMPs and ATIMPs. Together, they show the importance of early pharmacy involvement, proportionate governance and multidisciplinary planning in enabling safe access to complex gene therapies.

Case Study 1: Etranacogene Dezaparvovec (Hemgenix®) for Haemophilia B

In January 2026, Cardiff and Vale University Health Board was among the first NHS organisations in the United Kingdom to prepare and administer etranacogene dezaparvovec (Hemgenix®). Etranacogene dezaparvovec is an *in vivo* gene therapy approved for adults with severe and moderately severe Haemophilia B (congenital Factor IX deficiency) without a history of Factor IX inhibitors.[13] Unlike conventional treatment, which has historically required regular intravenous Factor IX replacement injections, often several times a week, Hemgenix® is given as a single infusion and is intended to enable the body to produce Factor IX itself. For eligible patients, this has the potential to substantially reduce the long-term treatment burden, including the need to return regularly for ongoing prophylactic injections. This single-dose injectable treatment requires preparation in a pharmacy aseptic unit before administration.

Implementation was supported by targeted training, infrastructure development and multidisciplinary planning between haematology, pharmacy and governance teams. Short-term funding from the NHS Wales Joint Commissioning Committee provided additional pharmacy technical staffing capacity within the Cardiff and Vale University Health Board pharmacy aseptic services team, enabling local documentation, workflow and quality assurance arrangements to be developed for safe product handling, aseptic preparation and release.

Cardiff and Vale University Health Board Pharmacy Aseptic Services Team with the first NHS patient in Wales to receive Hemgenix ®

This experience has strengthened Cardiff and Vale University Health Board capability for future licensed *in vivo* gene therapies and provides practical learning that should be shared across the NHS in Wales to support consistent readiness without duplicating local implementation work.

Case Study 2: Cardiff and Vale University Health Board pharmacy aseptic preparation for the AMT-130 Huntington's disease gene therapy trial

AMT-130 represents a groundbreaking development in the treatment of Huntington's disease, a progressive inherited neurodegenerative condition for which no disease-modifying therapy has previously been available. As an investigational *in vivo* gene therapy, it is designed to act at the source of the disease by reducing production of the huntingtin protein within neurons. Early data from the uniQure Phase I/II trial suggest a meaningful slowing of disease progression, marking an important shift from symptom management towards the possibility of altering the course of Huntington's disease.[14]

The UK delivery of the trial was particularly significant for the NHS in Wales. Cardiff was the only UK centre able to undertake the required image-guided neurosurgical administration, bringing together specialist research, neurosurgery, imaging, theatre and pharmacy expertise within the NHS in Wales.

The Cardiff and Vale University Health Board pharmacy aseptic services team provided the sole UK preparation service for AMT-130, translating complex trial requirements into a safe, controlled and quality aseptic process. This included product-specific risk assessment, controlled receipt and storage, validated preparation processes, bespoke documentation and release arrangements aligned to the neurosurgical schedule. This work demonstrates practical capability of the NHS in Wales in preparing complex investigational gene therapies within hospital pharmacy aseptic services. It also reinforces the value of capturing expertise from centres with direct ATIMP experience so that product-specific quality assurance, governance and operational learning can inform wider service planning across Wales.

Case Study 3: Advanced Therapy Investigational Medicinal Products for the ATTEST study

The ATTEST study is a first-in-human clinical trial evaluating TROCEPT-01, also known as ATTR-01, in adults with selected advanced epithelial solid tumours. Delivered in Cardiff through collaboration between Velindre University NHS Trust, Cardiff and Vale University Health Board and the Cardiff Cancer Research Partnership, it provides a further example of the NHS in Wales supporting early-phase ATIMP delivery through coordinated research, clinical and pharmacy expertise.[15]

ATTR-01 is a genetically modified adenoviral therapy designed to selectively infect cancer cells and metastatic lesions while limiting activity in healthy tissue. Once inside the tumour cell, the virus replicates and contributes directly to tumour cell destruction. It also delivers genetic instructions intended to enable local production of a checkpoint inhibitor within the tumour environment, thereby combining direct oncolytic activity with a targeted immune-mediated anti-tumour effect.[15]

The Cardiff delivery model shows how regional research infrastructure can translate academic discovery into early clinical application. The therapy originated from Cardiff University research, while delivery in South East Wales brings together Velindre University NHS Trust pharmacy teams for dose preparation, Cardiff and Vale University Health Board clinical teams for administration and patient care, and regional cancer research infrastructure to support access to innovative trials.

Decentralised manufacturing: Future opportunities for ATMP delivery

The recent changes to the Human Medicines Regulations, set out in section 1.7, provide a framework for innovative manufacturing models that operate outside traditional centralised production arrangements.

At present, there appear to be limited immediate use cases for decentralised manufacture within the NHS. Most currently available licensed *in vivo* gene therapies are supplied as finished medicinal products and require local aseptic preparation rather than full manufacture at the point of care. Horizon scanning undertaken shortly before publication identified limited manufacturer interest in conducting clinical trials using decentralised manufacturing models, although no such trials have yet commenced. As a result, decentralised manufacture is unlikely to represent a routine operational model for ATMP delivery in the short term.

However, the legislation is strategically important because it creates a regulatory route for future models of ATMP manufacture that may need to occur closer to patients. As the ATMP pipeline develops, some products may have manufacturing requirements that make transport from a centralised hub impossible, particularly where shelf life is measured in minutes rather than hours, where administration must be tightly synchronised with manufacture, or where product characteristics require near-patient processing. In these circumstances, decentralised manufacture could support more flexible delivery models while retaining appropriate regulatory control.

One potential future application is the use of mobile aseptic units capable of moving between hospital sites. Such a model could, in principle, allow specialist manufacturing capability to be brought closer to patients without requiring every organisation to develop permanent dedicated facilities. This may be particularly relevant for Wales, where geography, travel time and low patient numbers can make fixed-site models challenging. Mobile provision would still require robust governance, qualified personnel, validated processes, quality assurance oversight, environmental monitoring, cleaning and waste arrangements, and clear accountability under the relevant manufacturer's licence.

Although not specific to ATMPs, the Welsh Blood Service's work exploring drone-enabled transport of blood products and urgent clinical materials provides a relevant example of wider NHS Wales innovation in healthcare logistics.[16] This work demonstrates that new approaches to time-critical transport, infrastructure and service connectivity are already being explored in Wales. For future ATMP delivery, practical factors such as product stability, preparation site, transport time and the reliability of the full logistics pathway will influence whether a hub-based, mobile, local or near-patient model is most appropriate. Learning from emerging logistics initiatives, such as the use of drones for urgent healthcare transport, should therefore inform future planning as decentralised and near-patient models develop.

For this report, decentralised manufacture should therefore be viewed as an emerging opportunity rather than an immediate solution to current ATMP delivery challenges. The priority for the NHS in Wales remains building confidence and capability within existing pharmacy aseptic services and planned regional hub arrangements. Nonetheless, national planning should continue to monitor the developing product pipeline and regulatory guidance so that Wales is positioned to adopt decentralised or mobile manufacturing models if they become clinically necessary and operationally and legally viable.

Conclusion

This review shows that rather than the NHS in Wales starting from a blank page, there is already good progress towards making health boards and trusts ready to deliver ATMPs at much greater scale. Pharmacy aseptic services already have the professional expertise, quality systems and practical experience needed to support the safe preparation of complex injectable medicines, including *in vivo* gene therapies. The challenge now is to turn existing examples of good practice and capability into a state of consistent national readiness.

The key risk is not a lack of willingness or expertise within pharmacy services, but the absence of a consistent roadmap from awareness of ATMPs in development to a state of operational readiness. Inconsistent training, uncertain demand, infrastructure pressures and fragmented planning risk creating inequalities in access unless services are supported to plan earlier and act in a more coordinated way.

The report sets out a practical response to the gaps identified: stronger leadership, greater staff confidence, a review of infrastructure, equipment and estates, less duplication through national expertise and shared resources, and much earlier involvement of pharmacy aseptic services in pathway, trial and service planning. Together, these actions would improve readiness without necessarily requiring major investment or large-scale service reconfiguration.

The regional TrAMs hubs will be an important part of this future model, but they are not to be viewed as the only answer. Regional hub preparation should be used where product stability and logistics allow, with local or near-patient approaches retained for therapies that cannot safely be managed through a hub-based route.Near-patient preparation will need support from national experts within the TrAMs programme.

Implementing the recommendations will require coordinated across health boards, Velindre University NHS Trust, the NHS Wales Shared Services Partnership, Advanced Therapies Wales and the Welsh Government. Advanced Therapies Wales will provide the national oversight needed to monitor progress, share learning and ensure that local plans translate into practical improvement. Acting now while demand is relatively low, will mean the NHS in Wales can avoid fragmented and inefficient approaches to ATMP delivery ensuring patients can benefit from these therapies without avoidable delay wherever in Wales they access care.

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Pharmaceutical Officer – Clinical Fellow - Welsh Government

Appendix 1

Advanced Therapy Medicinal Products with positive NICE recommendations[2]

Therapy	Brand name	Indication(s)	ATMP type
Etranacogene dezaparvovec	Hemgenix	Moderately severe or severe haemophilia B	*In vivo* gene therapy
Eladocagene exuparvovec	Upstaza	Aromatic L-amino acid decarboxylase (AADC) deficiency	*In vivo* gene therapy
Onasemnogene abeparvovec	Zolgensma	Spinal muscular atrophy; presymptomatic spinal muscular atrophy	*In vivo* gene therapy
Voretigene neparvovec	Luxturna	Inherited retinal dystrophies caused by RPE65 gene mutations	*In vivo* gene therapy
Talimogene laherparepvec	Imlygic	Unresectable metastatic melanoma	*In vivo* gene therapy
Axicabtagene ciloleucel	Yescarta	Relapsed or refractory diffuse large B-cell lymphoma after first-line chemoimmunotherapy; diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after ≥2 systemic therapies	*Ex vivo* gene therapy (CAR-T)
Brexucabtagene autoleucel	Tecartus	Relapsed or refractory B-cell acute lymphoblastic leukaemia (aged ≥26 years); relapsed or refractory mantle cell lymphoma	*Ex vivo* gene therapy (CAR-T)
Tisagenlecleucel	Kymriah	Relapsed or refractory B-cell acute lymphoblastic leukaemia in people aged 25 years and under	*Ex vivo* gene therapy (CAR-T)
Lisocabtagene maraleucel	Breyanzi	Relapsed or refractory large B-cell lymphoma after first-line chemoimmunotherapy when stem cell transplant is suitable	*Ex vivo* gene therapy (CAR-T)
Exagamglogene autotemcel	Aucatzyl	Relapsed or refractory B-cell precursor acute lymphoblastic leukaemia	*Ex vivo* gene therapy (CAR-T)
Obecabtagene autoleucel	Casgevy	Metachromatic leukodystrophy	*Ex vivo* gene therapy
Atidarsagene autotemcel	Libmeldy	Transfusion-dependent β-thalassaemia in people aged ≥12 years; severe sickle cell disease in people aged ≥12 years	*Ex vivo* gene therapy
Strimvelis	Strimvelis	Adenosine deaminase deficiency severe combined immunodeficiency (ADA-SCID)	*Ex vivo* gene therapy
Holoclar	Holoclar	Limbal stem cell deficiency following ocular burns	*Tissue-engineered product*
Chondrosphere (Spherox)	Spherox	Symptomatic articular cartilage defects of the knee	*Tissue-engineered product*

Source: NICE guidance database, accessed September 2026

Appendix 2

Questions sent to pharmacy aseptic services leads ahead of their structured interviews

Introduction

With more and more Advanced Therapy Medicinal Products (ATMPs) receiving product licences and being approved for use by NICE, NHS pharmacy aseptic services are increasingly expected to play a pivotal role in their preparation, handling, and delivery. As these innovative therapies transition from research to routine clinical use, it is essential to understand the current level of readiness across aseptic units. These questions are designed to gather insights into your unit's knowledge, infrastructure, workforce, and strategic planning related to ATMPs. We greatly appreciate your time and expertise, your responses will help inform national planning, identify areas for development, and support the safe and effective integration of ATMPs into NHS services in Wales.

Section 1: Knowledge and engagement

1 On a scale of 1 to 10, how would you rate your current knowledge of ATMPs and the role of NHS pharmacy aseptic units in their preparation and handling?
(1 = no knowledge, 10 = highly knowledgeable)

2 Has your aseptic unit been approached to prepare any ATMPs, either for clinical trials or as licensed products?
If yes, please describe the nature of the request and your unit's response.

3 How would you rate your understanding of the regulatory frameworks relevant to ATMP preparation (e.g. MHRA, HTA, GMO regulations)?
(1 = no knowledge, 10 = highly knowledgeable)

4 Have you or your team received any formal or informal training related to ATMPs?
Have you participated in any cross-sector forums or collaborations (e.g. NHS SPS, NIHR, academic partnerships)?

5 Are you aware of the SPS institutional readiness guides for ATMPs, including those related to GMOs?

Section 2: Readiness, gaps, and strategic planning

6 What do you consider the main barriers preventing your unit from preparing ATMPs? (e.g. infrastructure, workforce, governance, QA support)

7 Do you have a roadmap, service development plan, or business case in place to support future ATMP preparation?

8 Has your unit conducted a gap analysis or risk assessment related to ATMP handling and preparation?

9 Have you identified any potential clinical or research partners within your organisation or region who may require ATMP support in the next 1–2 years?

10 What support or resources would you need to begin delivering, or to expand the delivery of, ATMPs within your aseptic unit?

Section 3: Facilities and equipment

11 Please provide details of your current cleanroom and isolator capacity:

1.Positive pressure isolators:
2.Negative pressure isolators (if applicable):
3.Grade C and D background environments:

12 Do you have access to ultra-low temperature (ULT) storage (e.g. -80°C freezers)? Are these units monitored and validated in accordance with GMP standards?

13 Assuming staffing is not a constraint, how many isolator sessions per week could be allocated to ATMP preparation using your current facilities?

14 What additional facilities, equipment, or environmental controls would be required to routinely support ATMP preparation?
(e.g. isolators, ULT freezers, Grade C/D upgrades)

15 What potential funding sources are available to you to support delivery of ATMPs?

Section 4: Workforce and training

16 Do you have a designated ATMP lead or responsible person overseeing ATMP-related activities within your pharmacy department?

17 Have any pharmacists or technical staff received ATMP-specific training?
(e.g. handling of live vectors, GMOs, tissue-based products)

18 Do you have a plan to upskill existing staff or expand workforce capacity to support future ATMP work?

Section 5: Operational considerations

19 Do you plan to engage with clinical and planning teams to develop a strategy for future ATMP use within your health board?

20 What operational challenges would your unit face in preparing and releasing products with very short shelf lives (e.g. 4-hour stability)?

21 What is the maximum number of aseptic manipulations your unit has validated as part of process validation activities?

Section 6: Governance and compliance

22 What risk rating was assigned to your aseptic unit during your most recent WHC/2024/004 audit?

23 What specific risk score was attributed to your facilities during that audit?

Section 7: Capacity and capability for ATIMPs

24 How many clinical trials are you currently supporting with ready-to-administer injectable IMPs?

25 Are you currently preparing any Advanced Therapy Investigational Medicinal Products (ATIMPs)?

26 In your view, what are the key barriers to initiating or expanding ATIMP preparation in your unit?

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