



Checklist for Selling into the NHS

The NHS wants products and services that are innovative, beneficial and well evidenced, which provide greater health benefit but can also support sustainability or save money. The NHS and its partners, such as universities, alongside many specialist centres and networks, can help companies to develop, test and evaluate their product, technology, or service.

Question

What is your product or service and how, when, where and by whom is it used?

Does your product meet: regulatory requirements & technical/data governance requirements?

Do you know how your product service fits into the care pathway and who will pay for it?

Notes

Products will typically be a bio/pharmaceutical (drug), an advanced therapy (cell/gene product), medical technology including digital technologies or a service. The user may be an organisation, hospital doctor, laboratory scientist, community nurse, GP practice, patient, or citizen.

The Medicines and Healthcare products Regulatory Agency (MHRA) oversees regulatory processes for market all products work and are safe. The Care Quality Commission is the independent regulator of health & social care in England.

A care pathway shows how healthcare is planned and managed for a set of patients with predictable clinical course.

Information and Support

Understand the regulatory frameworks for your product including whether it is a medicine or a medical device or other type of product. See:

https://www.gov.uk/government/organisat ions/medicines-and-healthcare-productsregulatory-agency/services-information

The MHRA Innovation Office provides free and confidential expert regulatory information, advice and guidance. Further industry guidance is also authorisations in the UK ensuring available following EU exit. See also: NHS Digital & Technology Standards and Guide to good practice for the use of digital technology in health and care

> The National Institute of Health and Care Excellence (NICE) provides information about care pathways. The Academic Health Science Networks (AHSNs) support adoption of innovation at regional/national level across care pathways



Have you got clinical support and do patients/users like your product?

Clinicians will trial products with patients through clinical trials and/or evaluations of how they work in practice depending on the product and the regulatory framework it sits in. If a study is done overseas this can be helpful, but UK clinical support is very important for adoption.

The National Institute of Health Research (NIHR) clinical research network has experts across c. 30 specialities and supports clinical trials to achieve time and target. They can find clinicians in the setting in which your product will be used, not just highly cited KOLs. Other NIHR support is specifically available for MedTech and Diagnostics companies including health economic evaluation, input from clinicians, patients, commissioners and funding support

Do you have a strong (relevant) evidence base for efficacy and effectiveness?

To get uptake in the NHS a product or service must have the necessary evidence base. This isn't just about safety and a positive clinical effect as demonstrated in clinical studies but also whether it is effective (works well) in the 'real world' of the NHS system.

See above box for weblinks to **NIHR** support. The **AHSNs** support adoption and diffusion of well-evidenced, beneficial innovations into the NHS and host the Innovation Exchange which highlights needs, signposting, and evaluation support.

NICE produces guidance for health, public health and social care. It reviews innovative technologies (but not all), addressing benefit, value for money and affordability for the NHS. Advice is available from the <u>NICE Office for Market Access</u>

Do you have a good business case (cost/benefit for your product/service) and is it understood who pays (and by what system) and who benefits?

Combined with the evidence base described above, the financial case must be developed to support adoption. Information from overseas health systems may inform, however, the NHS payor needs to be able to consider the full costs of adopting a product or service balanced against improvement in care and/or system efficiency.

See above for links to the AHSN and NIHR MedTech support. A useful resource within the AHSN website is the Atlas of Innovation projects which includes case study examples demonstrating how innovations can save money and improve efficiency alongside improving patient care.

See also the MedTech Early Technical Assessment (META) Tool which can help product developers identify evidence needs for business cases

Companies and innovators can also register their MedTech products on the national HealthTech Connect portal. This raises the profile of transformative innovation and enables support from product development through to adoption. NICE, technology innovation and commissioning groups in the NHS can see all information while other support organisations highlighted above including the AHSNs and NIHR can also review if the innovator so chooses.

Support for inward investors from the Department for International Trade (DIT)

For more information on bringing your innovative productive and services to the UK and to explore the inward investment opportunities alongside this, email DIT at: lifescience@trade.gov.uk