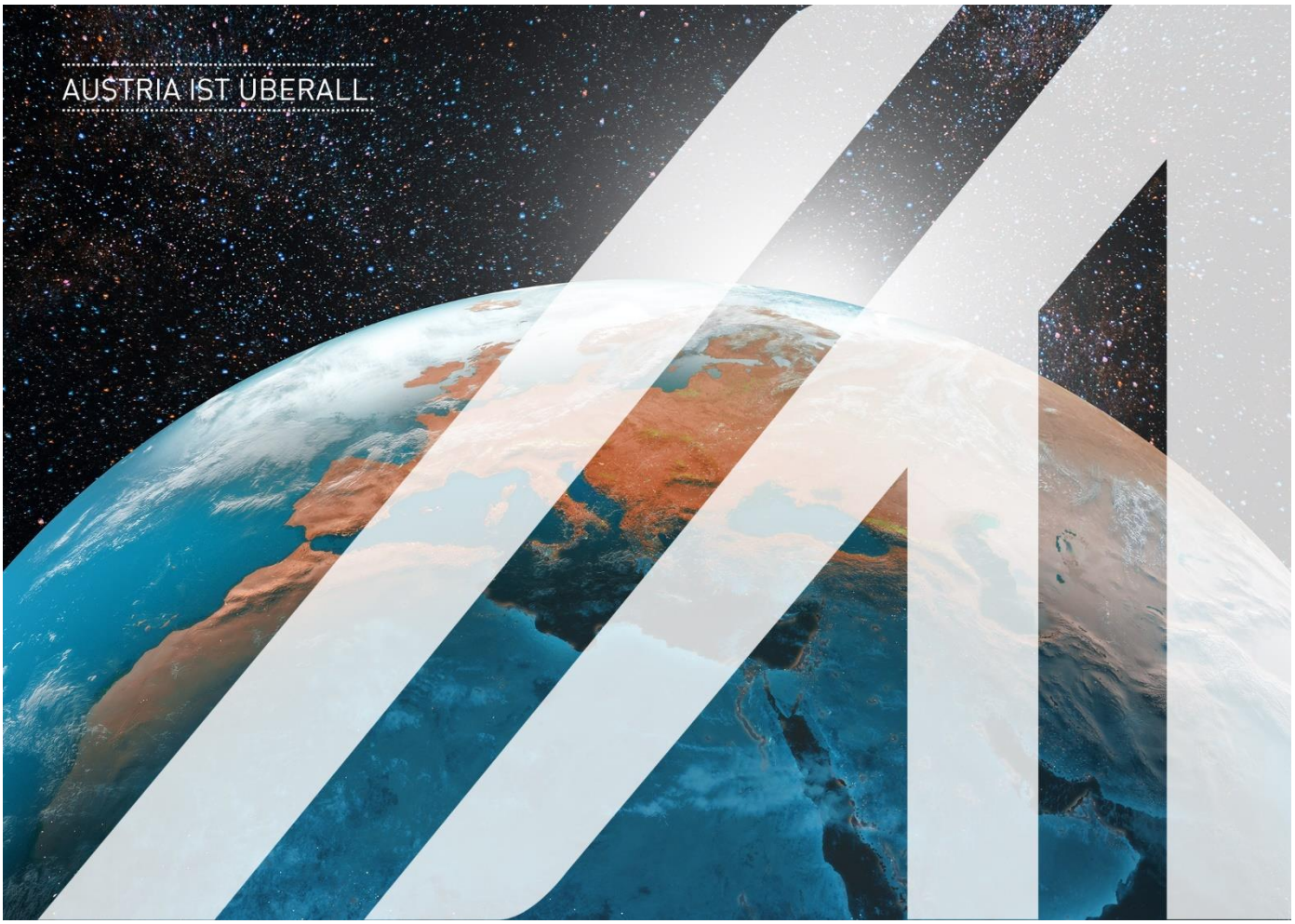
AUSSENWIRTSCHAFT AUSTRIA

AUSSEN WIRTSCHAFT BRANCHENREPORT VEREINIGTES KÖNIGREICH

HOW TO ENTER THE UK NHS MARKET
A GUIDE FOR AUSTRIAN MEDICAL TECHNOLOGY, DEVICE MANUFACTURERS & INNOVATORS

AUSSENWIRTSCHAFTSCENTER LONDON
JÄNNER 2024

go international
Bundesministerium Arbeit und Wirtschaft
WKO AUSSENWIRTSCHAFT AUSTRIA



Unser vollständiges Angebot zum Thema **Gesundheitheitssystem & Einrichtungen** (Veranstaltungen, Publikationen, Schlagzeilen etc.) finden Sie unter wko.at/aussenwirtschaft/gesundheitssystem.

Eine Information des

AußenwirtschaftsCenters London
T +44 20 7584 4411
F +44 20 7584 7946
E london@wko.at
W wko.at/aussenwirtschaft/gb

In Zusammenarbeit mit

Jon Wilks, UK HealthGateway Ltd
T +44 20 7664 8711
F +44 20 7664 8746
E info@ukhealthgateway.com
W http://www.ukhealthgateway.com

Dieser Branchenreport wurde im Rahmen der Internationalisierungsoffensive go-international, einer gemeinsamen Initiative des Bundesministeriums für Arbeit und Wirtschaft und der Wirtschaftskammer Österreich, erstellt

Herausgeber, Medieninhaber (Verleger) und Hersteller:
WIRTSCHAFTSKAMMER ÖSTERREICH / AUSSENWIRTSCHAFT AUSTRIA
Wiedner Hauptstraße 63, 1045 Wien
Redaktion: AUSSENWIRTSCHAFTSCENTER LONDON T +44 20 7584 4411.
E london@wko.at W wko.at/aussenwirtschaft/gb

Ein Service der AUSSENWIRTSCHAFT AUSTRIA

TABLE OF CONTENTS

INTRODUCTION

The United Kingdom's National Health Service (NHS) is the largest state-run, free at the point of access health system in the world. It covers every facet of health from hospitals to family doctors and community nursing and is a cherished national institution.

The United Kingdom is, of course, 4 different countries (England, Wales, Scotland, and Northern Ireland) all of which have their own elected government assemblies and all of which have devolved responsibility for health. In effect this means that the National Health Service is 4 national health services – and each is different in organisation, size, scope, and focus.

It is generally acknowledged that each has the same principal challenge – how to continue to provide a 'free' (fully taxpayer funded) health service where demand is growing and funding is tightening, whilst at least maintaining outcome standards.

As an export market for Austrian health and medical technology and service companies, the NHS offers a huge opportunity. It is open to innovative ideas, has the largest budget in government and needs technology to help with a long list of current issues.

The purpose of this report is to explain and analyse the ongoing activity of the National Health Service in 2024 so that Austrian medical technology and device and manufacturers and innovators have a clear, reliable, and accurate understanding of how it works and the opportunities available to them. Perhaps most importantly of all, it provides exporters and manufacturers with the terms and language required for them to successfully engage with NHS institutions.

JON WILKS
For and on behalf of UK HealthGateway Ltd
January 2024
jon@ukhealthgateway.com

HOW THE NHS WORKS

The NHS, founded in 1948, is one of the few tax-funded, socialised medicine models of healthcare in the world. Internationally rated as one of the best value systems, the NHS is as British as roast beef and Yorkshire pudding.

It is also one of the largest employers in the world. A rare example of a dwindling number of nationalised industries, there are over 1.4 million people working in the British NHS. The 'urban myth' is that the NHS is the world's 3rd largest state employer behind only the Indian railways or the Chinese Army!

How does the NHS work?

Government revenue services tax the population with the money being collected through the Treasury. Each year Parliament votes an allocation of taxes to departments of state, including health. The apportionment is then distributed, using allocations formulae, to the component parts of the NHS. It is important to stress that, whilst healthcare is therefore entirely tax-payer funded and free at the point of access to UK residents, social care is means tested. Poorer people receive social care (such as domiciliary nurses or care home accommodation) for free whilst more affluent people must pay for it. This is a huge and growing issue.

Since 1948 the NHS has undergone a number of reforms and changes to the service delivery model, attempting, each time, to move it closer to a less bureaucratic, more business-like system with the aim of greater efficiency and productivity.

The latest of these 'reforms' was the Health and Social Care Act 2012. It was an enormous piece of legislation, running to over 300 pages, and brought about an upheaval so big, as one commentator put it; 'it could be seen from outer space!'.

For the main purposes of this report, we will concentrate on the NHS in England as the largest of the 4 UK regions and the most likely to be an Austrian exporter's initial interest.

In outline the current 2024 structure is as follows:

The Secretary of State for Health & Social Care

The Secretary of State has overall responsibility for the work of the Department of Health & Social Care (DHSC). Additionally, and following a government in early January 2018, the Secretary of State has had the title '& Social Care' added to the portfolio. Whilst the DHSC provides strategic leadership for public health, the NHS and now social care in England, the full nature of the '& social care' responsibility is to be determined and there may well be taxation policy changes planned to bring health and social care funding together.

The current Secretary of State is Victoria Atkins and her role is to:-

- provide national leadership for improving outcomes and driving up the quality of care.
- oversee the operation of Integrated Care Systems (ICS).
- allocate resources to ICSs.
- commission primary care and specialist services.
- oversee the safety of patient care.
- monitor financial sustainability.

The Department of Health & Social Care
The Department of Health & Social Care (DHSC) is responsible for strategic leadership and funding for both health and social care in England. The DHSC is a ministerial department, supported by 23 agencies and public bodies.

NHS England (NHSE)
NHSE is an independent body, at arm's length to the government. Its main role is to improve health outcomes for people in England.

The current CEO of NHSE is Amanda Pritchard, who was appointed on the departure of Sir Simon Stevens in 2021, for whom she had been Chief Operating Officer. The Chair of NHSE is Richard Meddings CBE.

Importantly, NHSE's remit only currently extends to health. Social care has previously been directed by local government through 'health and wellbeing boards', but there is a strong expectation, perhaps even inevitability, that this will change, particularly with the onset since July 2022 of Integrated Care Systems. Certainly, the dynamics and demands of the ageing population, coupled with ageing conditions such as dementia, means that hospitals are frequently simply providing accommodation for elderly people who are ready to be discharged but have no plan of care in place agreed with the local government authority in which they reside.

NHSE introduced the concept of 'Sustainability & Transformation Partnerships' (STPs) in late 2016 whereby health Trusts were required to work with their counterparts in local government social care to design local level solutions by which health and social care could better co-exist.

These have now been superseded by Integrated Care Systems, regional agglomerations of health and social care providers charged with designing and delivering joined-up health and social care across that region. There are 42 of these ICS organisations across England.

Note – there is a similar structure to the NHS in Wales, Scotland & Northern Ireland, all of which have devolved government whereby the health system is part of that devolution. They 'enjoy' the same challenges.

Clinical commissioning groups (CCGs)
Clinical commissioning groups came into being on April 1st 2013 in response to the new legislation pushed through Parliament by the then Secretary of State for Health, Sir Andrew Lansley. CCGs were clinically led, statutory NHS bodies responsible for the planning and commissioning (buying) of healthcare services for their local area and numbered nearly 200. CCGs members include GPs and other clinicians such as nurses and consultants. They were responsible for about 60% of the NHS budget and commissioned most secondary care services such as:

- planned hospital care
- rehabilitative care
- urgent and emergency care (including out-of-hours)
- most community health services
- mental health and learning disability services

CCGs could commission any service provider that met NHS standards and costs. These could be NHS hospitals, social enterprises, charities or private sector providers. However, they had to be assured of the quality of services commissioned, taking into account both National Institute for Health and Care Excellence (NICE) guidelines and the Care Quality Commission's (CQC) data about service providers. These CCGs have now been replaced with Integrated Care Systems, but it is important for you to understand their role and purpose as they are still referred to, albeit in the past tense.

Health and Wellbeing Boards
Every "upper tier" local authority had established a health and wellbeing board (since 2014) to act as a forum for local commissioners across the NHS, social care, public health, and other services. The boards were intended to:

- increase democratic input into strategic decisions about health and wellbeing services
- strengthen working relationships between health and social care
- encourage integrated commissioning of health and social care services.

There were 130 Health and Wellbeing boards across NHSE, but it is fair to say that their influence has waned as new initiatives via STPs and (see below) Integrated Care Systems have been introduced. The well-respected Kings Fund independent think tank published an analysis of their long term future that you can read HERE.

Integrated Care Systems
Under the framework and motivation of the STPs, NHSE confirmed the first wave of Integrated Care Systems (ICSs) in mid-2017. The ICS is a further evolution of the STP into a fully functioning alliance of health and social care funding and service delivery.

There are 42 ICS organisations across England, and it is they who are responsible for organising and delivering health and social care provision regionally. They face an immense number of challenges but are also an opportunity for Austrian medtech companies in that they represent a new approach of integrated health and care.
What is certainly clear is that the idea of the NHS and social care simply continuing to operate as it has for the last 75 years or more is ludicrous. The changing needs of the adult population is forcing the NHS and social care to contemplate any number of fundamental changes and ICS is a major attempt to address the current imbalance.

Public Health England
Public Health England (PHE) provided national leadership and expert services to support public health, and also worked with local government and the NHS to respond to emergencies. At the outset of Covid 19 they were the front-line advisors to government and public but, given their poor funding and limited scope, the job was well beyond them, and they were subsumed into NHSE and, now the ICS structures.

Their original role was to:

- co-ordinate a national public health service and delivers some elements of it.
- build an evidence base to support local public health services.
- support the public to make healthier choices.
- provide leadership to the public health delivery system.
- support the development of the public health workforce.

The fact that PHE has now been subsumed into NHSE is, in our opinion, a cause for regret.

If the NHS is ever to reverse the trend of increasing demand for its services, then concentrating 'upstream' on illness prevention is a clear priority.

Regulators and Watchdogs

NHS Impact
NHS Impact (Improving Patient Care Together) is the body formed by the merger of NHS England and NHS Improvement in 2019. They aim to create the right conditions for continuous improvement and high performance, systems, and organisations for today's challenges, delivering better care for patients and providing better outcomes for communities. Their effect is uncertain at present.

Care Quality Commission
The CQC is the independent regulator for quality in health and social care in England. It makes sure services such as hospitals, care homes, dentists and GP surgeries provide people with safe, effective, compassionate, and high-quality care, and encourages these services to improve.

The CQC monitors and inspects these services, and then publishes its findings and ratings to help people make choices about their care. They also have power to close services they consider do not reach a suitable standard.

There are plenty of critics in regards the methodology and effectiveness of the organisation – one that is focused on finding fault via inspection – which any management source will tell you simply doesn't work as a means of improving quality. But the public have been conditioned to trust in their findings and it would be a brave politician who disbanded them.

Importantly, if your medical technology is directly used to record patient information and use it to inform treatment, then there is a strong likelihood that your product needs to be registered with the CQC.

How NHS services are provided:
Health care provision is through primary care and secondary care, with acute hospitals that are part of an NHS Trust.

There are:

- 42 Integrated Care Systems
- 135 acute trusts
- 17 acute specialist trusts
- 54 mental health trusts
- 35 community providers
- 10 ambulance trusts
- 6,400 GP practices
- 853 for-profit and not-for-profit independent sector organisations, providing care to NHS patients from 7,331 locations.

A good guide to the current structure of the NHS in England can be seen HERE.

NHS Tariff

The 'tariff' is the mechanism by which most NHS service providers are paid for their work. The tariff is like a price list for carrying out procedures, examinations and diagnostics and is set annually. Details of the mechanism can be found on the NHSE website (link).

The Health & Social Care Act 2012 moved responsibility for pricing from the Department of Health, to become the responsibility of NHSE.

Under the terms of the Act, NHSE has a duty to specify those healthcare services for which it thinks a national price should be used and has the duty to set that price. There are also provisions for setting rules governing not only how nationally set pricing will work, but also how local price-setting must operate.

NHS FACTS & FIGURES

NHS funding

- The Department for Health & Social Care budget for 2022/23 is £185.1 billion.
- 86% of this budget (£157.3 billion) is spent on day to day running costs, with the balance for capital expenditure.
- Percentage of GDP spent on health is currently 11.3% (last available figures 2022).
- 37% of the annual budget is spent on workforce.

For a more detailed insight, have a look at the Kings Fund's most recent budget analysis HERE.

NHS staff

In February 2023, across Hospital and Community Healthcare Services (HCHS), the NHS employed (full-time equivalent - FTE): 133,500 doctors; 332,900 nurses and health visitors; 22,342 midwives; 162,539 scientific, therapeutic, and technical staff; 18,605 ambulance staff; 37,381 managers, and nearly 400,000 support staff.

For a full NHS workforce analysis click HERE.

A workforce plan for the NHS has finally been published but promises to be very difficult to fund and deliver, given that training of clinical staff takes a considerable time and the UK's workforce problems are international.

To underline the scale of NHS efficiency, have a read of the most recent Commonwealth Fund report comparing the health systems of Australia, Canada, France, Germany, Netherlands, New Zealand, Norway, Sweden, Switzerland, UK, and USA. You access it HERE.

COMMENT & ANALYSIS

Like all healthcare systems, world-wide, the NHS is facing pressures through demand and funding. Aside from legacy Covid issues, our analysis is as follows:

Unprecedented demand in primary and secondary care is mainly from patients with long-term conditions and the population over the age of 70. The situation is exacerbated by the most recent Conservative Government's approach to public funding. Most public sector providers have seen real term cuts in allocations. This is particularly true of adult social care that, across ten years, up to 2020, will see cuts of 40%. More money has now been promised, but it takes a long time for the effects of this to be reflected in everyday patient experience and there have been repeated government U-turns on commitment to social care funding.

The inability of Social Care to help in the exit of frail elderly patients from secondary care, back into the community means NHS budgets are stretched by patients medically fit for discharge but with delayed transfers of care, some have been known to wait as long as 90 days.

More delayed transfer of care information via NHS Digital is HERE.

For 5 years NHS funding has been slightly above zero; in real terms around 0.1%. Set against increases in demand of (year on year) well over 4%, the predicament the NHS finds itself in is obvious. The next 5-year cycle sees additional funding but there is scepticism around how new any 'new' money really is.

Better joint working between health services and social care has been encouraged by joint pooling of budgets in the Better Care Fund and we expect to see more joint budgeting through the ICS structures, but there is no evidence of this and its effects at present.

Various initiatives have been launched to seek out and share efficiencies and set targets for better NHS performance, 'most recently' in 2015 through an efficiency review Chaired by Lord Carter of Coles. This is pretty important reading for anyone considering entering the NHS market and you can see it, in full, HERE.

In the 2015 – 2020 spending cycle the NHS had a shortfall of funding of £30bn. The gap is to be made by £8bn funding from central funds and £22bn in NHS self-generated economies.

There are few health managers, or commentators, who think this is achievable and it is inevitable the government will have to consider and increase in funding from now onwards. It is clear that the Covid virus emergency has had consequences for the economy which no-one could have accurately predicted. For a right up to date analysis of the budget click HERE.

The principal strategic plan to see the NHS through the next phase of its evolution is the Long-Term Plan, although this is coming to the end of its horizon term.

That said, whatever else you read or do between finishing this report and jumping on a plane to London, you must read it, albeit that its scope is coming to an end.

As the NHS strives for better performance to meet the funding gap, innovations, new technologies and better systems of care take centre stage.

The door is open for manufacturers and suppliers to step forward with the ideas, devices and solutions to help the NHS through a period which is probably the most challenging in its 75-year history.

The 5 priority strategies laid out in the Long-Term Plan are:

• Boost 'out-of-hospital' care, and finally dissolve the historic divide between primary and community health services

• Reduce pressure on emergency hospital services

• People will get more control over their own health and more personalised care when they need it

• Digitally enabled primary and outpatient care will go mainstream across the NHS

• Local NHS organisations will increasingly focus on population health – moving to Integrated Care Systems everywhere.

REGULATORY REQUIREMENTS FOR AUSTRIAN EXPORTERS

The principal regulatory requirement for selling medical products and services in the United Kingdom **was** that governed by the European Union 'CE' mark before BREXIT and certain changes have been implemented since then.

The full regulatory framework for medical devices being placed on the market in the UK can be seen HERE and is essential reading if you are considering selling a medical device.

Essentially, the new structure is currently very similar to that of the CE classification structure as laid down in the EU's Medical Device Directive (MDD) but uses a UKCA mark instead:

- Class I
- Class II(a)
- Class II(b)
- Class III

Once you believe that you know your appropriate UKCA classification, you need to go through a regulatory process which can have a number of additional steps depending on your classification.

Finally, you will need to write to apply to a notified body which will carry out a conformity assessment to approve your declaration of conformity and issue the appropriate certification. You should also register your device with the Medicines & HealthCare Regulatory Authority which is the overseer of all medical products in the UK and can, for example, coordinate a recall in the event of product issues.

You can find information on notified bodies in the UK here.

As you might expect, there are different rules for medicines and for in-vitro devices and applications. For IVD products, an organisation called BIVDA (British In-Vitro Diagnostic Association) is a splendid first source of information and guidance.

If your product is classified as a medicine, then there are strict national and European Union rules governing development, manufacturing and sale.

In order for any medicine to be sold in the UK it must first be granted a licence (otherwise known as a marketing authorisation). In the UK these are granted by the MHRA (see above) or the European Medicines Agency (EMA) which can process licences for medicines throughout the EU.

If you are at all unsure or uncertain about the processes and mechanisms through which your medical device or medicine should pass prior to sale in the United Kingdom, then you should seek specialist advice from a UK-based regulatory consultancy.

HOW REIMBURSEMENT WORKS

In the United Kingdom, reimbursement is governed by the NHS Business Services Authority. Their role is to govern and control the reimbursement process, part of which is to decide and have governance over which products are eligible to go on the reimbursement list, called The Drug Tariff.

There are a number of key features and rules governing which products are eligible for reimbursement as follows:

The principal reimbursement list for medical devices is Part IXA of the drug tariff. All approved medical devices are listed here with the exception of incontinence products (Part IXB), and stoma care products (Part IXC).

For a medical device to be considered for reimbursement via the drug tariff, it must be identified as:

— Appropriate for prescribing in primary care (family doctors).

— Once prescribed, it will be the sole property of the patient and cannot be transferred. This would include products such as certain bandages and dressings, but not, for example, a blood pressure monitor.

Generally speaking, hospitals are not reimbursed for their purchase of medical devices (they are directly funded by the government via their annual budget) which is why reimbursement is the preserve of primary care medical devices.

If you believe that your product is eligible for reimbursement (first carefully consider the two rules above), then you can apply to the NHS Business Services Authority for your product to be added to the drug tariff.

The forms to be used for this (depending on the UKCA classification of your device) are HERE.

In our experience, you should anticipate a timescale for your application to be considered of around 3-6 months, depending on complexity.

The NHS Business Services Authority will apply 2 key tests to your product application:

1. Does it represent value for money for the NHS at the price that you have requested in the application?

2. Does it deliver efficacy in respect of clinical outcomes at least on a par with products of a similar type already on the drug tariff?

These key tests have clear ramifications for any application.

Firstly, you must ensure that you have rock solid evidence of efficacy available at the time of the application. Ideally this should be a **comparative study** including one or more of the products already listed on the drug tariff.

Secondly, adopting a 'premium pricing' strategy rarely results in successful listing. NHS BSA will only consider premium pricing if the evidence points to premium outcome results and, even then, the evidence will have to be very compelling and extensive.

If your product is highly innovative and doesn't have a natural category within the drug tariff or any existing products against which it can be compared, it can still be submitted for reimbursement consideration. If it is as good as you say it is then they will create a new category for it, but you will still need that **evidence of efficacy**.

Once your application has been considered you will be given 1 of 3 possible responses:

- **Approved** – congratulations! It will be included in the next drug tariff (it is published in updated form every 6 months) and you can start to sell it on the basis of reimbursement approved.
- **Paused** – typically this means that the authority needs more information, evidence or a price review. If you can supply this, then the application will progress accordingly. If you can't (perhaps you need to arrange a study to go and find some newly requested evidence) then you can pause the application indefinitely whilst you do it.
- **Refused** – not good news. You cannot appeal the refusal and your product will not be considered again until such time as you have overcome all of the reasons for its refusal and can prove that you have done so.

KNOW YOUR MARKET – PATHWAYS & NATIONAL REQUIREMENTS

The National Health Service is huge, with over 1.4 million people working within it and a structure advising and governing its activities that has a comprehensive remit.

At the top of the organisation in England is the Government's Department of Health & Social Care (DHSC) which formulates and develops strategy for national priorities. The DHSC works in close collaboration with NHS England to turn those national priorities into practical, deliverable plans, which NHS England is responsible for delivering.

Working alongside NHS England is the Care Quality Commission which is responsible for maintaining standards and quality of care across the NHS, primarily via an inspection process.

Working with the DHSC to formulate and implement plans are the Royal Colleges that elect members for virtually every different therapeutic sector you can name, as well as the General Medical Council (responsible for registering and reviewing the performance of doctors) and the Nursing & Midwifery Council (responsible for the same for nurses and midwives).

As you would imagine, this means that there are thousands of strategies, plans and best practice guidelines published and acted upon across the healthcare spectrum, every year, and that is before we mention the universities and research institutions conducting studies into every imaginable disease, diagnostic and therapy.

One important organisation to understand if you would like more data or you are considering a **digital technology market entry** is NHS Transformation Directorate. They oversee all of the data driven information within the NHS and, often, they oversee procurement of new digital technology initiatives at scale and publish contract framework guidance for same.

You cannot approach the United Kingdom NHS believing that the pathways, requirements and best practices undertaken in Austria are going to be the same as those in the NHS. That is a risk simply not worth taking, so your priority should be to find out what the NHS best practice guidelines are in respect of your product, service or application.

There are several good places where you may wish start:

- **The Academy of Fabulous NHS Stuff** (https://fabnhsstuff.net/) – a website repository submitted by front line NHS staff and covering almost every element of NHS activity. Thousands of searchable pieces of 'Fab Stuff', tagged and open source.
- **NICE Guidance** – the National Institute for Health & Care Excellence publishes pathways and guidance on a huge range of disease sectors.
- **ORCHA** (https://orchahealth.com/) – an evaluation service for medical device apps that the NHS uses to approve / recommend. Essential if you are developing app-based technology solutions.

Key Therapy & Application Areas:

Cancer
In England: The most recent report is Achieving World Class Cancer Outcomes – A Strategy for England 2015-2020, supplemented by the Long-Term Plan section on cancer. A new 10-year plan for cancer is now gathering evidence.

In Scotland: Cancer strategy 2023-25.

In Wales: Cancer Improvement Plan 2023-26.

In Northern Ireland: Cancer Strategy for Northern Ireland 2022-32.

Stroke
In England: The National Stroke Programme.

In Scotland: Stroke Improvement Plan 2023.

In Wales: Wales Stroke Delivery Plan of 2017-2020 still applies. New plan awaited.

In Northern Ireland: Stroke Action Plan 2022.

Heart Disease
In England: NHS England Long Term Plan remains the most up to date guide to strategy.

In Scotland: Heart Disease Action Plan 2021.

In Wales: Heart Conditions Delivery Plan was published in 2017.

Obesity & Diabetes
In England: National Diabetes Prevention Programme.

In Scotland: Diabetes Improvement Plan published in 2021.

In Wales: All Wales Diabetes Prevention Programme updated 2022.

In Northern Ireland: Diabetes Strategic Framework published 2016.

Dementia
In England: New 10 Year Plan on Dementia Awaited.

In Scotland: National Dementia Strategy published in 2017.

In Wales: National Dementia Action Plan for Wales published in 2019.

In Northern Ireland: Improving Dementia Strategies in N.Ireland published in 2011!

Diagnostics & Imaging
In England: Transforming Imaging Services report was published in 2019.

In Scotland: Scottish Radiology Transformation Programme published 2016.

In Wales: National Imaging Programme published in 2019.

In Northern Ireland: No recent report published.

Liver Disease
In England: Latest data HERE.

In Scotland: No recent dedicated national plan.

In Wales: Together for Health Liver Disease Delivery Plan published in 2015.

In Northern Ireland: No recent dedicated national plan.

Each of these reports and plans is just a national high-level approach for each. As one drills down to the specifics of a particular diagnostic process or treatment protocol / pathway, then it is almost certain that detailed guidance has been issued via the royal colleges or clinical associations. There is even an Academy of Medical Royal Colleges which is a good place to start if you wish to learn more.

It is also worth mentioning that, due to the challenges being faced by the NHS in respect of burgeoning demand coupled with finite resource, innovation is being explored and even encouraged as never before within the NHS at every national level.

This all starts, though, by you understanding the national priorities and opportunities that they provide for you and your product, service or technology.

PRODUCT EVALUATION – PROCESSES & OPTIONS

If you have an ambition to break into selling to the UK National Health Service, particularly with a medical device or IT product, then you will be required to demonstrate your product's efficacy in a National Health Service environment.

This is not the NHS being Nationalistic – it is simply that one of the first questions that you will be asked in a sales presentation is 'where has it already been used?'. If your answer to this can only be one or other of Vienna, Innsbruck, or Salzburg, then you are at a distinct disadvantage from an answer of London, Birmingham, Leeds, Cardiff, or Edinburgh.

The fact is that a UK-based NHS evaluation is a 'must have'. This is not necessarily a full-blown clinical trial in that you probably have some data around that anyway. This is simply a product evaluation that seeks, from the outset, to prove some key product benefits or even as a comparison against a competitor.

You have several options for undertaking product evaluation, as follows:

1. Local level independent evaluation.

This would be conducted by identifying and recruiting a local NHS site and working with that site to develop and agree an evaluation plan, prior to the evaluation taking place.

Depending on the complexity of your product, it is typical for such a product evaluation to last from 1 to 3 months, depending on the product's nature.

You will be expected to provide your product free of charge for the duration and, given that you are likely to want to use your evaluation site as a future reference point if all goes well, you would be well advised to extend the 'free' for a further period after the evaluation.

You will also be expected to provide staff training in respect of the product and, if of a monitoring, measuring or diagnostic nature, provide on-call service support.

It is very unusual for NHS sites or personnel to levy a charge for undertaking an evaluation. Typically, it is innovation-positive individuals who volunteer to undertake evaluations and they are simply happy for their name to be associated with the product.

There will probably be ethics committees to navigate and the regulatory aspect may need to be covered, but such an evaluation is a great way to get started.

You would be well advised to work with a UK-based partner in order to set up and manage the evaluation to a successful conclusion.

2. National level NICE evaluation.

NICE is the National Institute for Health & Care Excellence. Its primary role is to guide and advise the NHS as to the suitability and affordability of new technologies, including pharmaceuticals, diagnostics and medical technology.

For pharmaceutical products a NICE evaluation is a near-certain requirement.

For medical devices, you should think carefully before committing yourself to what will be a very thorough, but long and resource-hungry process. Additionally, the findings of NICE are non-negotiable. Whatever they conclude in their evaluation recommendation will be followed by NHS institutions.

For medical devices, the usual evaluation process is that governed by the MTEP programme (Medical Technology Evaluation Programme). NICE provide a consultancy service to help you through evaluation activity and more details can be found HERE.

The NICE MTEP programme takes around 48 weeks to complete, and a report is published at the conclusion of the project.

If you are absolutely convinced that your product, technology or device has the attributes, qualities and evidence to fulfil the requirements of NICE then certainly you should explore with them submitting to an MTEP evaluation. If not (or perhaps if you don't feel that you have sufficiently comprehensive evidence) then you would be sensible to carry out an evaluation via a different route. You can read all of the MTEP eligibility criteria here.

3. Professional Association / Royal College evaluation.

For some products or technologies, it is sometimes worth engaging with a professional association or even a Royal College to evaluate your product. At the very least such institutions have member networks and most run annual or monthly events and symposia where you can exhibit your product or service for a relatively small fee and enter into discussions to recruit an evaluation site.

4. Academic Health Science Networks (AHSNs)

Originally set up in 2013 to offer research services to drive health innovations, the AHSNs now number 15 and, in 2018, were re-positioned to be the UK's primary innovation arm.

The AHSNs are ready and set up to conduct detailed product evaluations, offer advice on developing an innovation and providing signposting for such new innovations.

The only issue is that we have observed with AHSNs is that they can, sometimes, elongate the length of time which it may take you to actually make a sale, and there will typically be fees to pay in return for their services (they are partially self-funding). That said, always worth initiating an initial conversation.

Their strength is that they are very well linked into the hospitals and clinicians who might well want to ultimately specify your product or service.

SALES SET-UP & OPTIONS

In any health service market around the world, one of the key considerations for new market entrants is to determine which sales medium to use – a standard distributor model or a direct sales model through a dedicated sales team. The United Kingdom is no different.

Distributor Model:
Distributors serving the National Health Service are generally very strong at taking orders for your product once the market awareness and acceptability of your product is established.

What they are not typically prepared or equipped to do is raise that market awareness or demonstrate the product's performance and acceptability. You will either have to pay them to do so, or pay someone else to do so, or pursue that activity yourself.

Few distributors are willing to sign distributor agreements and invest in stock purchase until that work has been successfully completed, particularly so for new and innovative products that will inevitability need some market introduction effort prior to any sale being contemplated by the customer base.

For most medical devices, UK distributors will operate on a margin of 25-40% from end user price, net of value added tax (VAT). One of your first calculations to make, therefore, is whether you can achieve your market price, be competitive and demonstrate value, and fulfil the margin needs of a distributor.

General full range distributors in the UK tend to operate in primary care, secondary care, tertiary care or specialist sectors (such as emergency services or occupational health). Because of the complexities of these different sectors, there is little cross-over for the big players.

In Primary Care most of the broad range distributors operate via a catalogue and website, depending on the attraction of administrative efficiency (one order, one delivery, one invoice) and a value proposition on price (most operate some kind of a price matching scheme). They will carry as many as 100,000 products ranging from furniture to dressings and cleaning products to clothing. You will typically be asked to pay a fee to a primary care distributor to cover your product's feature in the catalogue and be required to pay a further fee to support any specific promotional requirement that you may conceive.

These broad range primary care distributors are excellent at moving large volumes of popular products. Where they struggle is with very innovative products or highly technical products that require a lot of explanation as to their application.

That said, these distributors cover the 7,500 primary care (family physician) facilities comprehensively and if your product is specific to this sector, then sooner or later you will need to work with one or more.

The **principal distributors** in this regard are:

Williams Medical Supplies (by far the largest and most pre-eminent)

Rocialle Practice Care

Primary Care Supplies

Because of the number of primary care facilities (7,500) it is unusual for suppliers to try to distribute their own products direct to market. The costs of logistics and market engagement are typically too daunting. Perhaps one of the few exceptions to this is in the field of health IT systems and software, where direct to market sales are more popular.

Finally, it is worth mentioning the prevalence of buying groups that emerging in the primary care sector. These are loose, but formalised, collectives of primary care practices which combine their demand to then press for larger discounts. Even with the buying groups, however, it is unusual to deal direct. Examples include the London Buying Group, and LMC Buying Group.

In Secondary Care (hospital sector), the picture in distribution is more varied. Whilst there are broad range distributors operating, primarily across the high-volume consumable sector, there are also a number of niche distributors specialising in particular therapeutic areas or product specialisations.

The situation is further complicated by the activity of NHS Supply Chain, a joint venture between the NHS and DHL Logistics, which aims to provide a comprehensive list of products on contract direct to hospitals.

NHS Supply Chain is not a very large consideration in the primary care sector due to the relatively small value and volume of orders. But in the hospital sector it is a very significant force and, depending on the nature of your product, you will need to give serious and considered thought as to whether to engage with them.

The upside is that they have arrangements in place with virtually every hospital in the country, which includes electronic ordering, invoicing and documentation as well as a regularly updated online catalogue of products feeding directly into local hospitals' procurement and finance systems.

The downside is that they pay huge attention to price (sometimes through a reverse auction process) and rarely offer exclusive supply contracts. In other words, your margins will come under severe pressure, and you will still have to spend considerable effort selling and marketing your products versus near competitors who may also be on the non-exclusive contract.

If you are in the consumable, commodity product sector, then an engagement with NHS Supply Chain is an almost inevitable requirement (though you should be aware that NHS Supply Chain has direct supply arrangements with a number of Chinese factories for OEM supply). If your product is at all innovative and particularly if that innovation necessitates a higher price over a regular commodity product, then NHS Supply Chain is unlikely to suit you.

An NHS Supply Chain contract typically runs for 3 years (during which time you are not permitted to adjust price) with an option to extend for a further 1 or sometimes 2 years.

You can view the latest NHS Supply Chain contracts up for negotiation and renewal HERE.

Many of the niche distributors will undertake the application for and management of NHS Supply Chain contacts for you, assuming that your product would be appropriate.

If your product is genuinely new, innovative, or complex then NHS Supply Chain is unlikely to be an appropriate means of market access. In such cases, you would be well advised to undertake a search for a specialist distributor, assuming that your business model follows that route.

If however, you think that NHS Supply Chain might be a good fit, then you can apply HERE.

There is no central repository or database of UK medical product distributors, and you will probably either do the search yourself or employ a specialist UK service provider to do the work for you, at least to the stage where a shortlist of qualifying candidates has been drawn up.

In terms of broad-spectrum distributors, you might consider the following:

Fannin

Bunzl

Alliance Healthcare (primarily to pharmacy)

Direct Model:
As we have discussed, for many products and services a distributor model may not be appropriate. You may therefore choose to set up an independent company in the UK and employ your own direct sales personnel.

If you are choosing to target the primary care sector, then you will most likely still have to work with one of the big broad-spectrum distributors (see earlier in this section).

For the secondary care, hospital sector, a direct sales model can function perfectly easily without having regard to central supply contracts through NHS Supply Chain, for example.

The most important advice to heed if you are pursuing a direct sales model is to stop thinking about anything happening with the 'National' Health Service. Instead, focus on tackling local level sales leads and opportunities, typically arising out of a successful product evaluation (see section 9).

You should also understand that the NHS moves slowly, particularly so in the case of high or disruptive innovation. It may well take between 6 months and a year before a product, despite having carried out all of the earlier recommendations in this report, starts to make significant sales headway. In this respect recruiting a large number of sales personnel to cover the entire geography of the UK from the outset is rarely a good idea.

Instead, perhaps start with a General Manager appointment operating out of a small unit in a low-cost area outside of London or one of the bigger conurbations. That individual should be charged with:

- Developing a robust understanding of pathways, processes and best practice in the product sector.
- Meeting key opinion leaders and engaging as appropriate.
- Managing an evaluation or evaluations of the product.
- Developing a robust NHS-compliant business case.
- Collecting local level data pertinent to the product and its use.
- Following up on sales leads as they arise.
- Attending symposia, conferences and exhibitions pertinent to the therapeutic sector for the product.
- Overseeing supply logistics and accounts / invoicing.

Once the sales start to come, then consider expanding the sales team activity, though again, the recommendation is to do this gradually, being led by the market's reaction and attraction to your product.

It is relatively easy to set up a UK company and it is undertaken through Companies House.

There may well be tax implications for you, and you should take appropriate professional advice before taking this step.

UK employment law is certainly different from Austrian employment law and, again, you are well advised to take appropriate advice. You can read about UK employment law here.

Finally, one attraction of setting up a UK business with which to enter the National Health Service is that you may qualify for government assistance in the form of grants, particularly if you will be employing people. You can find out more in respect of England HERE.

If you were to consider manufacturing in the UK, then a range of incentives is available depending upon where you might decide to locate the factory. In England, the incentivisation of manufacturing

set up has been reduced, but in Wales, Scotland and Northern Ireland there are a number of schemes aimed at attracting you and your business. Click on any of the links below:

Wales

Scotland

Northern Ireland

DATA & HEALTH ECONOMICS

If you have serious aspirations for entering the NHS market then sooner or later you are going to have to collect, collate and present data. Increasingly, little happens in the health service without data evidence to support it and the breadth and depth of that data is becoming more and more important.

Your being expert in the data surrounding your product and it's therapeutic or diagnostic application is a pre-requisite for sales success. Critically, this data must be reliable and trusted and the more that it is relevant to a local challenge, then the better.

National level statistics from Austria or the UK are not going to serve you well. Making statements such as "research indicates that, on an extrapolated basis, our product can save the NHS £5m per year" is unlikely to endear you to a local procurement manager and their clinical colleagues. What they really want to know is how your product or service will benefit them based on their data, their challenge and their evidence requirements. 'One size fits all' doesn't wash well.

Let's return to the money.

The NHS is financially challenged and every local hospital, primary care centre and community nurse is feeling the pinch. For anybody to stick their neck out in such an atmosphere requires you to protect and reassure them with data driven evidence that demonstrates either:

- Your product will save them £x over x months.

And / or

- Your product will deliver X factor improved outcomes for the same money.

If you can reliably demonstrate both then, to use an English expression that will be recognised, you'll really be "cooking on gas".

How you choose to go about proving this relies on your engaging fully with your target customer and establishing, with them, what the key existing data around their current challenge may be.

Whatever you find out, understand that:

YOU ARE NOT TRYING TO SELL TO THEM. YOU ARE MAKING IT EASY FOR THEM TO BUY.

You make it easy for them to buy through professionally engaging with them and working collaboratively to collect data and make the case for your product or service to be specified.

Beware adopting an aggressive 'sales pitch' mentality. It won't be well received, and you will instantly arouse suspicion and mistrust. NHS people have heard it all from well-intentioned salespeople in the past and, today, nothing happens without a collaborative, data-driven, evidence-based strategy.

DESIGNING YOUR BUSINESS MODEL FOR THE NHS

Your product or service is already being sold and used in Austria to great acclaim. Now it's time for you to start exporting into the UK National Health Service, so your Austrian business model will work fine there. Right? Maybe...

The history of the NHS is littered with discarded products that were a great idea but could not easily be bought (see previous section).

So, before you simply load your existing model into the torpedo tube marked 'NHS', you need to consider the following:

• **Can it be bought outright by the NHS?** If your model relies on a straight cash purchase for the product or service, then consider whether the NHS procurement people whom you are targeting can realistically afford to do so. Money is tight so outright purchase of high capital items is unrealistic. Consider leasing options or bill-per-use option, contracted over a fixed period. Best advice if you are unsure is to ask your procurement contacts what will work best for them.

• **Is purchase predicated on consumables?** Numerous companies have given products for 'free' and then loaded cost into what works out as very expensive, but essential, consumables. The purchase price of the consumables goes up or down depending on forecast and actual usage. It is a sensible idea given the first point here, but the NHS is getting wise to it and will put pressure on you to lower consumable cost and perhaps even provide a contractual annual cap to consumable cost that allows them to demonstrate value /savings over current products or processes. You will need to work through this carefully, and at an early stage, with local procurement staff and, probably, the users of the product.

• **Is purchase based on licensing?** This is often the case with software and IT dashboard systems but, again, the NHS is wise to the often-rapid growth in incremental cost as new licences are required. Furthermore, due to the rapidity of product development and therefore system obsolescence, the NHS is increasingly not prepared to enter into open ended licenses. Could you consider open sourcing and operating on a collaborative management fee instead? Again, talk to your contacts.

• **Have you checked the attractiveness of your end user pricing?** Achieving one and the same price in Austria and the UK might be a challenge. Until you have analysed, compared and contrasted competitor products or services pricing in the UK to your own, you risk everything. It's easy to reduce a price, but you'll invite ridicule if you have already launched and then get forced into it. It is next to impossible to raise a price if you find that you have under called the value. Do the research work. This is particularly important if you are considering reimbursement.

In short, if you are in any doubt, then collaborate with your customer targets to get their input and advice. If your product is attractive enough clinically then they will work with you to set an acceptable price. Don't be tempted to act tough and inflexible. You will be able to repent that all the way back to Austria on the plane with no sales in your order pad.

BUILDING YOUR NHS BUSINESS CASE

If you are to make a sale in the National Health Service then you'll need to create a Business Case for your product or service that will be compelling, convincing and reliable.

Given all that the NHS is going through from a financial perspective, the Business Case acts as a unifying information source, but also as an auditable trail for the decision making and collaboration that will need to take place.

An NHS Business Case template is at the conclusion of this report as a guide to the structure and content that you will be expected to provide.

There are a couple of key elements to consider, as follows:

1**. What is your single, simple truth?** What, precisely and compellingly, will your product or service do that will, at once, seize the interest and imagination of the business case reader? Why should the NHS buy your product or service?

Ideally this is a short sentence that instantly conveys your product's key attraction. This is important because the rest of the business case basically aims to prove this single, simple truth and explain to everybody how it will happen. If it were an elevator pitch it would take the time that the elevator needs to travel 1 floor rather than 20.

2. **What data do you need to prove the single, simple truth?** You'll need to consider this in conjunction with your product evaluation activity and be aware that national level data counts for virtually nothing. It's all about making the case locally.

3. **Who are the key personnel within your target customer whom you need to win over and persuade as to the merit of your product?** Talking to them in advance about the information that they need to be convinced about will help you to construct the content properly so that you achieve project sign off.

Remember that you are trying to make it easy for the NHS to buy. That is the prime purpose of the business case.

FIRST STEPS

If you are an Austrian medtech / life sciences company seeking to sell your product into the United Kingdom National Health Service, then here is your checklist of 10 first steps:

1. Does your product have the necessary UKCA regulatory certification required to sell it in Europe?

2. Have you carried out research to find out how the purpose to which your product is to be put is being addressed in the UK NHS right now?

3. Does your product address the purpose in a better way? How?

4. Who are the key opinion leaders in the UK within your therapeutic / systems sector?

5. Are there any similar products or technologies to your own already being used in the UK market?

6. If so, how are they being used and sold? Is your price competitive?

7. Do you have any evaluation study for your product, particularly versus any comparative competitor product or service? Do you have that evaluation carried out in the UK market? What does it prove?

8. Do you understand how your product will be sold? Will this methodology work in the UK? Is your business model going to be attractive? How do you know?

9. With whom will you need to engage to sell your product? Is it a commodity or a more specialised sale?

10. Do you want to appoint a distributor or sell directly? On what basis have you made that decision? Do you need to review / check it?

JON WILKS

MANAGING DIRECTOR, UK HEALTHGATEWAY

UK HealthGateway is a specialist NHS market access enabler for international medical and health technology companies seeking to enter the UK.

jon@ukhealthgateway.com

0044(0)7900 570172

APPENDIX

NHS BUSINESS CASE TEMPLATE

OUTLINE:

1 Executive Summary & Single Simple Truth
2 Introduction and Overview
3 Market Analysis
4 Assessment of Benefits
5 Cost / Benefits Analysis
6 Options Appraisal
7 Key Assumptions and Dependencies
8 Risk and Sensitivity Analysis
9 Resource Requirements and Cost
10 Funding Source / Timing / Certainty
11 Timescales
12 Comments / Issues
13 Conclusions / Recommendations
14 Appendices

1. Executive Summary

The Executive Summary should provide a short, informative headline summary of the Business Case document to follow. It should typically be no longer than 1 page and contain:
Your Single Simple Truth.
A short narrative to identify the subject, scope, method of analysis and key results and findings;
A short list of the key objectives of the project.
A summary of the financial metrics (table below, provides a very basic and high-level example of summarizing outlay and ROI) from the investigation, highlighting the most significant;
A brief summary of the conclusions as a result of the study.

	Year 1	Year 2	Year 3	Year ….n	Total Cash Outlay
Investment Value (£) – Capital and Revenue	£x	£x	£x	£x	£x
Available / Committed Funding	£x	£x	£x	£x	£x
Return on Investment (ROI)	£x	£x	£x	£x	£x

2. Introduction and Overview

This section should describe the setting, background and context of the Business Case. It should serve to clarify and elaborate the subject matter of the Business Case. It should clearly state the purpose of the Business Case, e.g.
To obtain financial approval to either commence a project or proceed to the next stage;
To compare alternative solutions, etc…
It should explain the objectives, needs or problems addressed by the requirement. The objectives should be stated in clear and measurable terms with a specified time frame, e.g.:
To have improved communication systems against more competitive cost options from December 2023
To invest £xx in a performance improvement project that will ultimately provide a 10:1 return on the initial investment (spend to save) BY 2025.
It should outline any relevant related initiatives – is the project part of a larger programme? Are there dependencies on the delivery of other projects to realise the benefits?
It should include a statement how the project is 'right-sized'; that is ensuring that the proposed solution is realistically scoped to ensure that the benefits and costs to deliver are in line.

3. Market analysis:

What is relevant to include in this section will depend on the type of investment.
A summary should be given of the main outcome of a full market analysis which should include consideration of the political and economic environment, confidence in likely service providers (systems or consultants), threats from emerging technology etc. Various techniques, e.g. sensitivity analysis can be used to analyse the market. The full analysis may be included as an Annex but the summary should give the degree of confidence in the market and any particular threats.

4. Assessment of benefits:

The benefits to be gained from the investment compared to the alternative of 'doing nothing' should be summarised. Benefits should be identified and quantified, as far as possible, in financial terms: as appropriate, this to include projected cost reduction against investments, impact if no investment,, reduction in risk, improvements in quality, reliability, accuracy and other tangible, non-tangible and consequential benefit i.e. 'what are the real benefits from making the investment?'
A full assessment / explanation of the benefits should be included as an Annex if appropriate.

5. Cost / Benefits Assessment

This will clearly identify the cost benefit against the investment that is being made. This should consist of a simplified presentation of the financial cost/benefit analysis - presented in tables or graphs;
This should include an assessment of, for example:
Investment value – Revenue and Capital
Cost Saving in first 12 months (£)
Cost Saving after first year (£)
Depreciation costs
Total cost (£)
Cash outlay (£)

Additionally, an assessment of unquantified Benefits and Costs, and Strategic Contribution should be considered:
Try very hard to quantify all costs and benefits.
All direct costs should be included.
Indirect costs should be included.
If a non-financial benefit is significant, then define it.
Make the impact of the benefit tangible – describe all likely effects and implication

6. Option appraisal – Recommended option:

When formulating an investment proposal, the options available, including the 'do nothing' option, should be considered and compared. Based on the outcome of the comparison of the options i.e. the option appraisal, a recommendation should be made for one option.
The full option appraisal should include a cost/benefit/risk comparison between the options available to address the business problem / opportunity. Options to include 'do nothing', business and technical options, timing options and, if at all relevant, consideration of 3rd party involvement – contractors, joint ventures partnerships, and funding options. When considering options, relevant strategies, standards, and legal requirements should be taken into account.
Depending on the situation the option appraisal may be simply qualitative or a detailed analysis. It may be done in two stages i.e. a broad sift of a wide range of options followed by a detailed examination of say, 3 of them.

7. Key assumptions and dependencies:

Key assumptions, which, if they turn out to be wrong, may affect the projection for and the eventual success of the investment, should be identified.
Key dependencies, which if not in place may affect the outcome, should also be clearly identified.
Comments about likely inflation rates in the cost and benefit estimates should be included in this section as well.

8. Risk and Sensitivity analysis:

The key business risks associated with the recommended option should be summarised, particularly those which may impact on the financial projections (costs and/or benefits). The summary should include an indication of the probability and likely impact of the risks and the measures being proposed to manage the risk(s) and / or to reduce their impact e.g. business case review prior to major cash expenditure. Political, Operational Economic / Financial and Technical (POET) risks should be considered as they could all contribute to the overall business risk.

The financial projections presented in support of the recommended option should reflect the expected, or most likely, outcome of events. In presenting an analysis of the business risks, the Sponsor should identify the major sensitivities to which the investment could be exposed, typically the impact of cost overruns, time slippage which may result in higher costs and missed opportunities; failure to achieve the development/investment period.

9. Resource requirements and costs:

The resource requirements and costs associated with the recommended option should be summarised i.e. external costs for equipment, external service costs e.g. for consultancy and internal staff costs. The summary is to include investment and running costs.

Resource requirements and costs:	Man years	Capital £	Running costs per annum (range)
External bought-in equipment External services Internal costs			
Total			

10. Funding source / Timing / Certainty:

The source and timing of the funding for the investment, be it required, known or suggested, should be identified and an indication given of the certainty or otherwise of the funding being available when required.

11. Timescales:

The proposed start and end dates should be given together with a list of significant (particularly financially significant) milestones (events with dates). Where relevant, the milestones to include dates on which the investment should be reviewed.		
Main milestones and dates:	Proposed start:	Proposed end:
Tba	date	date

12. Comments / Issues:

This section to be used if needed to draw attention to additional points or issues, which should be taken into account when considering the business case.

13. Conclusions and Recommendations

Bring the document to a close by concluding the findings and making recommendations.

AUSSENWIRTSCHAFT AUSTRIA

AUSSENWIRTSCHAFTSCENTER LONDON
45 Princes Gate
London, SW7 2QA

T +44 20 7584 4411
F +44 20 7584 7946
E london@wko.at
W wko.at/aussenwirtschaft/gb