Response to NHS Chief Executive’s Open Call for Evidence and Ideas

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Call for evidence and ideas

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1) Introduction

Novartis welcomes the Government’s recognition that the adoption and diffusion of innovation in the NHS is key to dealing with the challenges facing the NHS, to the growth of the Life Sciences Industry and to the economy. We are delighted to have the opportunity to outline the company’s views and experiences on the current environment and how this could be improved, alongside examples of best practice. We are keen to collaborate with the Department of Health and the NHS – both nationally and locally – in order to support better adoption and diffusion of innovation at all levels.

Innovation benefits patients by extending life and improving care through technological advances. It benefits the NHS through improvements in productivity and patient outcomes. For Novartis, innovation not only means developing effective, targeted medicines and devices quickly, but also ensuring that these products get to the patients who need them. As such, Novartis believes that the definition of innovation should be broad and should include medicines, products and devices, innovative service delivery solutions, as well as new funding models and access schemes which enable better patient access to technological advances. Overall this delivers therapeutic, quality of life and socio-economic benefits.

We welcome the recognition within the call for evidence that innovation can be incremental or radical or revolutionary. Novartis continues to have concerns, however, that there is a presumption towards valuing only breakthrough innovation. In reality, breakthrough innovation is generally the product of a series of incremental innovations that can be of value in their own right by improving the lives of patients. Failure to recognise this, and to reward innovation of value to patients, will act as a direct disincentive to innovation.
2) Executive summary

There are six key areas where Novartis believes action can be taken by both the Government and industry to improve the quick adoption and diffusion of innovation in the NHS:

- **Enhancing the clinical research environment** – streamlining the system and incentivising Trusts to deliver trials more efficiently will attract greater clinical research from industry, which in turn will lead to faster adoption and greater uptake of new medicines in the NHS
- DH, NICE and industry working together to **negotiate innovative and confidential pricing schemes** which have been shown to successfully drive patient access to new medicines, spreading innovation and providing value to the NHS
- NICE should take a **broader view of value and innovation** to avoid blocking innovation that has genuine value for patients and society
- **National treatment guidance**, with appropriate incentives and sanctions attached for CCGs to ensure proper implementation, should replace lengthy, complex local decision-making processes around new technologies
- **Silo-budgeting and short-termism** should be tackled through the appointment of an individual with responsibility for overseeing integrated pathway management and incentives for CCGs to deliver savings to the local social care budget
- National guidance should be issued with appropriate incentives attached to **drive greater use of licensed biosimilars** to drive efficiencies, which in turn can help fund innovation

3) Novartis UK – How do we innovate?

Our research focuses on areas of unmet medical need, connecting science with patient insights in order to develop new treatments and drive industry standards. Now the world’s biggest industry investor in research and development (R&D)\(^1\), globally Novartis invests $8bn annually, representing 17% of sales and 89% of profits\(^2\). Novartis UK employs over 3,200 people across eight sites responsible for the research, development, manufacturing and sales of pharmaceuticals, generics, biosimilars, vaccines, over the counter (OTC) and eye care products, as well as medical devices.

This extensive portfolio of products and treatments enables Novartis to provide a distinctive perspective on the current levels of adoption and diffusion of innovation across the NHS from early research through branded products, to generics, over the counter medicines and devices. The breadth of the Novartis portfolio also enables the company to offer significant cost-savings to the NHS through lower cost generics, biosimilars and OTC products which facilitate self-care, to counter-balance the higher cost of innovative branded medicines, for which Novartis needs to recoup its significant investment. We are also well placed to identify a wide range of political, cultural, regulatory and budgetary barriers within the NHS, given the breadth and depth of our portfolio.
4) Adoption of innovation

Enhancing UK clinical research will speed adoption and diffusion of innovation

Patients who enrol in clinical trials have better outcomes. These trials provide an early opportunity for the NHS to adopt innovative medicines, whilst also creating a highly skilled NHS workforce and positioning the UK as a leading centre for the life sciences sector. Clinical trials contribute to a strong and vibrant research base and could once more position the UK at the forefront of the delivery of innovation. In turn, this stimulates greater investment in research and development, boosting the capabilities of the UK’s academic and collaborating centres. In our experience, clinicians are more likely to adopt innovations into clinical practice to which they have had exposure through trials – this is particularly important for patients who want to access the most up to date treatment options.

We have been encouraged by the Growth Review and there has been some progress in the pre-clinical research agenda, including the R&D tax credits and the Translational Research Partnerships. However barriers to clinical research remain which are important as there is a competitive trial allocation process between countries within each Pharmaceutical company.

Barriers to clinical research

- An overly complex market access environment with multiple hurdles and inconsistent decisions, which vary by location and which result in slow and inconsistent uptake of new medicines. There is also a lack of consistency between MHRA & NICE on trial endpoints. In the UK, we are constantly having to justify to our global organisation the merits of conducting research in a country where new product innovations are blocked by reimbursement bodies. The UK performs very poorly in the overall ranking for speed of uptake of new medicines despite having among the lowest prices in Europe.
- Poor access, and the use of unlicensed medicines in place of licensed alternatives, present a major barrier for Phase II-IV trial placement, innovation and investment. This is because we do not believe it is ethical to conduct a trial in a geography where subjects have no post trial access to the treatment.
- A complex, costly and slow clinical research environment, with an historic lack of inter centre collaboration, impedes our investment decisions.
- The widening gulf in the expense of conducting trials in the UK compared to countries in Europe with similar economies, such as Italy, Spain, Germany, France, as well as developing countries with significantly cheaper operating environments such as China, Romania & India.
- There is a lack of accountability for the delivery of commercially sponsored studies at the Trust level.
Overall Industry investment in UK clinical trials has been in steep decline over recent years due to these issues. Novartis is keen to buck this trend – currently Novartis is responsible for 19 per cent of the clinical trials currently run by the top ten pharmaceuticals companies in the UK.

The North West Exemplar Programme (case study below) is a good example of best practice that can be replicated across the country.

**Case Study**  
**North West Exemplar Programme**

The objective of the North West Exemplar Programme was to demonstrate that the English healthcare system could set up and deliver industry sponsored clinical research better and faster than Europe. Novartis had four studies within the programme. One of the studies achieved a global first patient first visit (FPFV) (jointly with Scotland) by delivering FPFV from Final Protocol Package (FPP) in 59 days. Prior to the start of the programme, one study had found it took an average of 621 days from funding agreement to recruitment of first patient, so 59 days was an enormous achievement. The median time for start up (R&D form to first patient first visit) across all trials within the programme was 72 days.

The reasons for this success were many: good teamwork between NHS, NIHR and industry, recruitment to trials being managed by specialist networks, increased accountability for trial delivery from the CEO down, and the fact that the NIHR Networks encouraged industry to work with hospitals they had not collaborated with before. However, to build on this momentum and make it easier for the UK to claim a higher proportion of global trials, we now need to see action on outstanding issues.

**Recommendations**

Novartis believes the UK can be made a more attractive country for investment in clinical research. To encourage greater investment in the UK clinical trial environment, a number of actions should be taken:

a. ACCESS

- *See section 5 - Current barriers to diffusion of innovation*

- The General Medical Council (GMC) should revert to its prevailing guidance in relation to prescribing of off-label and unlicensed medicines. It should be made obligatory for doctors to inform the patient when a medicine is prescribed outside its licence. Provisions need to be strengthened on conflicts of interest so that duties to protect the patient are not compromised by incentives to reduce expenditure on medicines.

- Embed and streamline the process of tripartite scientific advice between MHRA/EMA, NICE and the Pharma company to ensure high level agreements for trial endpoints
b. BUREAUCRACY

- The Government needs to implement fully the commitments in the Plan for Growth, including the formation of a new Health Research Authority, with a smooth transition of powers and responsibilities.
- Novartis would like to input into the new target metrics within Trust/NIHR contracts upon which NIHR funding will become dependent.
- The best model for R&D is seen in countries where there is high enrolment per site as a result of access to large patient populations, hence Novartis’ interest in setting up a Hub and Spoke recruitment model in the UK. We would also like to see the removal of barriers for the referral of patients, such as agreed reasonable referral fee and the abolition of Patient Identification Centres.

c. COSTS

- Ensure all Trusts accept the NIHR costing template.
- There should also be changes to the current coding system and address of the unintended consequences of the Multi Professional Education and Training Review.

d. DELIVERY

- There needs to be proactive issue management and transparent and realistic metrics on deliverables. For example, a top down communication from NIHR via Trust CEOs about accountability and the empowerment of R&D managers to oversee both study feasibility and delivery at Trust level.
5) Diffusion of innovation - existing best practice

Outlined below are examples of where we believe best practice has been effectively delivered to the benefit of both patients and the NHS.

5.1 Patient Access Schemes

Novartis is committed to facilitating patient access to innovative medicines and supporting the NHS in its drive for greater efficiency, through innovative patient access schemes. The ranibizumab reimbursement scheme for wet-age related macular degeneration (wet-AMD) was the second such scheme to be put forward by industry and a good example of how innovative forms of funding can deliver greater access for patients.

CASE STUDY
Ranibizumab reimbursement scheme (RRS)

- Lucentis (ranibizumab) is a licensed, NICE approved treatment for patients with wet age-related macular degeneration (wAMD) (and visual impairment due to diabetic macular oedema and retinal vein occlusion); there are approximately 500,000 people with the condition – 40% of these are over the age of 75.6
- Novartis worked closely with NICE and the Department of Health to develop a patient access scheme (the RRS) where the cost of treatment would be shared.
- A vial of Lucentis costs the NHS £742 and is currently offered to appropriate wet AMD patients through a reimbursement scheme whereby Novartis pays for all vials after the 14th
- This scheme resulted in NICE recommending Lucentis for NHS use.
- Novartis has worked closely with NHS eye units, providing third party consultancy to help them redesign their service pathway which in turn improves capacity and efficiency, supporting the demand for treatment.
- Novartis also provides a team of nurses to conduct the administration of the RRS
- Currently over 50,000 patients are registered on the reimbursement scheme

Recommendation

a. Novartis would like to see the Department of Health and NICE protect the commercial confidentiality of patient access schemes. By protecting confidentiality, industry is able to provide a more attractive offer, without international reference pricing being impacted. The NHS can derive maximum financial benefit, patients can gain access to innovative treatments, and industry is able to rely on strong uptake, in return for investment.

5.2 Industry/NHS partnership and joint-working
As one of the biggest healthcare companies in the UK, Novartis is involved in numerous collaborative initiatives with a range of NHS partners. NHS/industry collaborations offer opportunities to devise innovative service delivery models which improve efficiency and quality of care offered to patients, as well as enabling diffusion of innovative medicines, vaccines and/or other healthcare products. Novartis has long been a major provider of high quality medical education services to clinicians but in recent years has provided a wider range and type of support. This now includes sponsorship for the development of some new services that support NHS priorities.

Below are two examples of successful Novartis/NHS collaborations. The diffusion of such initiatives can be hampered by local cultural barriers in the NHS, where there is resistance to working in partnership with the pharmaceutical sector. As a result, such projects are often rolled out on a piecemeal basis, depending on local relationships and personnel.

**CASE STUDY**
**East Yorkshire Mobile Eye Clinic**

The opening of a new community mobile eye care centre in East Yorkshire in March 2011 is an excellent example of how innovation can be delivered through greater collaborative working, in this case between York Teaching Hospital NHS Foundation Trust, The Eye Site Clinic Ltd, local patient groups and Novartis.

Located at Bridlington Hospital near Scarborough, the clinic enables patients suffering with wet-AMD to receive treatment more regularly and closer to home – elderly patients from Bridlington, Scarborough and Whitby had faced an 80-mile round trip for treatment at York Hospital, with the mobile clinic cutting journey times in half. The mobile unit is capable of treating between 40 and 50 patients per day with Novartis’ anti-vascular endothelial growth factor (anti-VEGF) Lucentis® (ranibizumab), relieving local health services of some of the capacity issues currently being faced.

Wet-AMD affects an estimated 500,000 people in the UK and approximately 26,000 new patients are reported each year, with the costs to the NHS amounting to £22bn in the UK.

**CASE STUDY**
**In-Pharmacy Flu Vaccination Programme**

Introduced nationwide in 2008, the Novartis Vaccines In-Pharmacy Flu Initiative provides a comprehensive training and support programme to community pharmacists for the delivery of seasonal influenza vaccinations. Following trials of the concept in Scotland and another programme in City and Hackney PCT (which boosted uptake rates in the over 65s and other high risk groups from the lowest in the country to the highest [65.8%] and increased overall uptake in the over 65s by 16.5% compared to an average of 9.2%\(^9\)). Both schemes partnered with pharmacies including independent pharmacies and the supermarket chain Tesco to provide easier access to seasonal flu vaccination.

The Novartis service was further expanded in 2009/10 with over 1000 pharmacies (including Tesco, Lloyds, Superdrug and AAH Healthwatch members) offering this service throughout England and Wales. The initiative is being further expanded throughout 2011/12 to support and train over 3,000 pharmacists to administer flu and meningococcal (ACWY) vaccines. To date, some 20% of PCTs have commissioned the service\(^10\). Offering a service beyond the traditional GP surgery approach to delivering the Government’s seasonal flu vaccination programme is an
excellent example of how an innovative service can increase convenience and flexibility for patients, whilst also relieving pressure on already stretched GP surgery resources.

**Recommendations**

b. Novartis would like to see the removal of local de facto ‘bans’ or restrictions on industry operating in localities and the embedding of a more entrepreneurial culture to enable discussions around industry collaborations, joint-working and service re-design.

c. We would like to see greater innovation leadership amongst NHS management, with a dedicated member on the new NHS Commissioning Board, as well as local leads for innovation. We would also like to see industry representation on the Board.

**5.3 Clinician-led decision making**

Novartis welcomes the Government’s commitment to putting clinicians at the heart of commissioning in its NHS reform programme. One area where this approach has already shown significant improvement in terms of uptake of innovation is the Interim Cancer Drugs Fund (introduced in October 2010) and subsequent Cancer Drugs Fund (CDF), introduced in April 2011. According to a recent audit by the Rarer Cancers Foundation, some 91% of applications for non-NICE approved cancer medicines to the funds have been approved\(^{11}\). These are clinician-led applications for medicines which were previously largely inaccessible to NHS patients, other than on a piecemeal basis via Individual Funding Requests.

Novartis strongly supports a national approach to sanctioning the use of medicines (via NICE), rather than regional or local assessments. However, the principle of the CDF experience shows that when a dedicated funding stream is provided for a particular purpose, with clinicians at the heart of decision-making, NHS patients are able to benefit from the latest innovative treatments.

**CASE STUDY**

**Afinitor (everolimus)**

Following the launch of everolimus, the only licensed second line treatment in renal cell carcinoma, in September 2009, NHS patient access to the treatment was entirely reliant on individual funding requests (IFRs) submitted by clinicians to their PCTs. The low success rate of IFRs, coupled with the lack of positive NICE guidance, meant everolimus remained inaccessible to the majority of mRCC patients throughout 2009 and 2010. With the launch of the Interim Cancer Drugs Fund in October 2010 and the subsequent approval of everolimus across all Strategic Health Authorities in England, patient access to the treatment dramatically improved. Clinicians were key to promoting the diffusion of this innovation in England, with everolimus reported as the second most prescribed medicine through the Interim Cancer Drugs Fund (from October 2010 to January 2011). Uptake has increased almost five-fold since October 2010, with everolimus establishing itself as the standard of care for all patients who have progressed on a first line tyrosine kinase inhibitor (TKI) agent. Hundreds of NHS patients have benefited from this innovation as a result.
Recommendations

d. Greater clinical involvement, particularly of specialists, in decision-making on access to innovative treatments.

e. Greater use of national commissioning for rare diseases and orphan drugs, to reduce the geographic variation, bureaucracy and delays in accessing treatments which are only accessible through IFRs, as they fall outside the purview of NICE.

Diffusion of innovation - current barriers

5.4 National Health Technology Assessment - NICE

Novartis supports the role of NICE in establishing national guidance on the use of innovative treatments within the NHS, by evaluating the cost-effectiveness of medicines and the use of limited resources within the NHS. NICE has enabled widespread diffusion and uptake of innovation in the NHS through the mandatory implementation of positive NICE guidance (as evidenced by the case study in 5.1 above).

However, we have some significant concerns regarding the processes adopted by NICE and, in particular, its approach to valuing innovation. The NICE process is ill-adapted to evaluating medicines for smaller patient populations, where there is limited data available. There is a particular challenge for manufacturers to collect robust outcomes data, particularly against comparators which may no longer be widely used in clinical practice, but which may be used for the purposes of a Health Technology Appraisal.

Innovation has many dimensions, with benefits not only in terms of health outcomes, but also in terms of patient experience, better use of the health system and societal benefits. All these facets should be taken into account when deciding on the adoption and diffusion of innovation across the NHS.

Novartis has some concerns that, in the current tight financial environment, NICE is taking on a role which appears to be overly concerned with cost control rather than cost-effectiveness. There is some evidence that points to NICE becoming more restrictive to new medicines over time – an analysis by Novartis shows that 55% of cancer medicines appraised by NICE since 2009 were turned down, compared to just 28% since the inception of NICE in 2000. This provides one of the biggest barriers to the diffusion of innovation within the NHS, with uptake of non NICE-approved medicines is dependent on piecemeal Individual Funding Requests and, for cancer medicines, access to the CDF. Indeed, if NICE were able to take a more pragmatic and clinician-led approach to appraisals, arguably there would be no need for a CDF.
CASE STUDY
Tasigna (nilotinib)

Novartis was delighted to receive a positive Final Appraisal Determination (FAD) for the use of nilotinib in imatinib-resistant and imatinib-intolerant CML patients in August 2011, after originally being referred to NICE in June 2008. Due to changes to the scope and objective of the appraisal, resulting in changes in the comparators, the appraisal was set back significantly and effectively re-started in October 2010, with strong criticism from clinical experts and patient groups. This has resulted in a lengthy delay to NICE’s final decision. The earliest date at which guidance will be issued on the positive FAD will be October 2011, some four years after nilotinib was licensed and some 3.5 years after SMC approved the treatment for funding in Scotland. Indeed, many PCTs in England have adopted this innovation in the interim, despite the lack of guidance from NICE.

NICE’s revised choice of comparator to treatments no longer routinely used in clinical practice exacerbated the problems in providing robust outcomes data for the submission (which is already challenging for diseases with small patient populations), and an initial negative draft decision at ACD stage. The ACD failed to recognise the innovation in nilotinib, despite meeting a previously unmet clinical need.

Novartis worked closely with NICE and the Department of Health to reverse the decision and secure patient access to this innovative Prix Galien commended treatment. Thanks to a confidential patient access scheme tabled by Novartis which, in our view, undervalues the significant innovation and patient benefit offered by nilotinib, patients in England and Wales will now routinely have access to the treatment.

Recommendations

f. Consideration of additional benefits when assessing cost-effectiveness, such as patient experience, the societal benefits of certain treatments and corresponding savings on social care budgets

g. A more pragmatic approach from NICE to appraisals where gaps in data and uncertainty may exist, together with a more collaborative approach to industry

h. Encourage research and raise awareness both in health sector as well as public domain with respect to clinical trials

i. More account taken of innovation in NICE’s assessment of new treatments

j. Greater specialist clinical involvement in NICE appraisals

k. An independent appeals procedure

l. Consideration of different QALY thresholds for different disease areas.

m. A collaborative approach from Government to co-creating value-based pricing with industry.
5.5 Lengthy and complex local decision-making processes

Even when medicines are deemed cost-effective by NICE, there appears to be a disassociation between national guidance and practice on the ground, with local health economies increasingly developing their own assessment bodies and processes to determine the use of innovative medicines.

This proliferation of multiple structural layers within the NHS leads to inevitable inefficiencies, unnecessary duplication and complexity in local decision-making. Repeated value assessments of medicines take place at a local level as formulary and funding decisions are made, often resulting in further barriers to access, such as inconsistent and restrictive guidance, as well as the creation of black and red lists. Wide variations in local funding and affordability further compound the problem of access.

Not only are these regional assessment groups undertaking local cost-effectiveness appraisals, they are increasingly taking on a quasi-licensing role (see case study below). Such appraisals are undermining national regulatory processes, putting patient safety at risk and will ultimately stifle innovation.

CASE STUDY
Lucentis (ranibizumab)

Lucentis (ranibizumab) is a licensed, NICE approved treatment for patients with wet age-related macular degeneration. As outlined in 5.1, ranibizumab has been widely adopted by the NHS since receiving positive NICE guidance. However, this threatens to be reversed as unlicensed bevacizumab (Avastin, licensed for the treatment of certain cancers) is being used to treat patients in place of the licensed treatment in order to save money. In many areas of the country this is being encouraged through the issuing of guidance by some PCTs and regional assessment groups, such as the recent decision by the North East Treatment Advisory Group.

This practice puts patient safety at risk:

- There is emerging evidence that indicates a potential for serious side-effects when bevacizumab is used in the eye, including an increased risk of stroke, when compared to ranibizumab. It is also concerning that there is no formal monitoring process in place to track bevacizumab’s use in the eye.  
- The preparation of bevacizumab for use in the eye is also not standardised and there have been reported issues of infection and change to the drug concentration, related to storage issues.

This practice also undermines the fundamentals of pharmaceutical innovation where manufacturers are rewarded for making the necessary investments to prove the clinical efficacy and safety of their medicines.
**Recommendations**

n. A national communication reinforcing the commitment to the NICE approval mechanism, the mandatory funding direction and the rights of patients to NICE approved licensed medicines, with appropriate sanctions attached.

o. There should be no further qualification, reinterpretation or modification of positive NICE guidance at a local level, in particular in relation to the prescribing of unlicensed medicines. NICE-approved medicines should be automatically included on formularies in primary and secondary care.

p. All regional and local processes for determining medicines use should ultimately be removed. There should not be any re-review of those medicines which have already been approved by NICE and there should be no local tendering of branded medicines. Where time-limited regional processes such as the CDF remain in place whilst the medicines pricing and reimbursement system is being reformed, regional bodies should standardise and be transparent in their processes to limit geographic variability and bureaucracy. Where NICE chooses not to appraise a medicine, clinicians, rather than managers, should be empowered to take a decision on whether the treatment is prescribed.

q. We would like to see an appeal mechanism introduced for both patients and manufacturers when access to nationally approved medicines is inappropriately restricted. Further work needs to be done to identify the route for the appeal mechanism. Potential options could be the NCB, NICE or CQC.

**5.6 Silo-budgeting and short-term decision making**

Innovation in medicines, vaccines, devices and other products often offers an ‘invest to save’ opportunity. However, the current fiscal environment and the demands of the QIPP Programme are leading either to short-term cost cutting or resistance to adopting innovation, at the expense of long-term savings. Novartis would like to see local NHS commissioning organisations take a longer term approach towards funding for innovative treatments, products and services (focusing on all the elements of QIPP, not just ‘Productivity’), rather than focusing on quick fixes.

Cutting back on innovative community-based prevention programmes, such as smoking cessation, will cost more in the long term, leading to a high demand on services down the line. In eye care, cost-saving measures such as delaying cataract operations in the second eye, or investment in innovation such as advanced technology intraocular lenses, fail to recognise downstream benefits like the prevention of costly falls and fractures.
This issue is further exacerbated by a silo-budgeting approach to care. A lack of communication and joined-up working within and between different parts of the health and social care economy discourage an integrated approach to the patient pathway. This silo approach prevents funding flows between therapeutic areas and functions. The silo-budgeting culture prevents uptake of medicines, devices and products where the cost savings are realised in a different part of the NHS budget.

**CASE STUDY**  
**Exjade (deferasirox)**

Deferasirox was launched in 2006 and won the UK 2008 Prix Galien award for innovation. It provided a breakthrough in terms of an iron chelation treatment for sickle cell and thalassaemia patients, many of them children, offering substantial quality of life improvements. The previous standard of care, desferrioxamin (Desferal), involved painful nightly infusions by needle and pump, lasting 8 to 12 hours, five to seven times per week.

Despite acquisition costs for deferasirox being lower than the acquisition costs of desferrioxamin, uptake of deferasirox over the first two years following launch was slow because the costs for desferrioxamin were split across medicines as well as devices budgets. Local commissioners were failing to look at the total cost of desferrioxamin, including the pumps and medicine (£14,350 for a 52kg patient), when comparing it to the cost of deferasirox (£12,761 for a 52kg patient).

Uptake of deferasirox has since improved, following work with commissioners on an individual, local basis, but this problem is likely to persist in relation to other innovations.

**CASE STUDY**  
**Omnitrope**

As branded biologic medicines reach the end of their patent, biosimilars provide significant cost savings to the NHS, which in turn can help fund innovation. Uptake of biosimilars in some disease areas is very slow, mainly as hospitals do not see or have the opportunity to share the benefits accrued to PCTs through the displacement of the more expensive originator drugs.

Omnitrope, a licensed medicine for the treatment of children with growth failure, was the first biosimilar to be reviewed by NICE. However, despite the NICE committee noting the evidence of the equivalence (NICE TA188, 4.3.5) versus the originator product and recommending the least expensive option to be used following a consultation on adherence, uptake across the UK has been poor.

Trusts such as UCLH (BJCP, November 2010) and North of Tyne Area Prescribing Committee (meeting minutes: 08/03/11) have each published estimated savings of £200k per annum through the use of Omnitrope. Whilst these two examples show the efficiencies that can be gained, there is little incentive for many other clinical departments to review their usage of growth hormone therapies, given that the financial gain accrues to the PCT, not the hospital or clinical department.

With some of the largest biologic medicines in the world losing patent protection in the next five years, strong uptake of these initial biosimilars will help drive uptake of future biosimilars, yielding considerable savings for the NHS. Such savings could be reinvested into funding other treatments and enabling greater patient access to innovative medicines.
Recommendations

r. Novartis would welcome the introduction of financial incentives to encourage use of best practice pathways which incorporate innovative medicines and technologies, supporting patient outcomes across primary, secondary and social care. Departments and organisations across health and social care should be able to share the benefits of savings accrued as a result of investment elsewhere. Each clinical senate should have a member responsible for overseeing integrated pathway management. Financial silos must be broken down.

s. The NHS should drive greater efficiencies through more widespread incentivised use of licensed biosimilars to free up funding for more costly innovations.
6) The role of industry in supporting adoption and diffusion of innovation

Novartis recognises the financial and infrastructure challenges which the NHS often faces with adopting and diffusing the latest innovations. We are keen to work closely with the NHS in order to support the use of innovation and deliver value, whilst also maximising patient outcomes, as outlined in 5.2 above.

As well as collaborative partnerships, industry can continue to play its part in ensuring it delivers maximum value to the NHS and patient access to innovative treatments through confidential patient access schemes and risk-sharing agreements.

We are committed to providing the earliest possible access to emerging innovations through clinical trials and are working closely with Government to ensure that, in line with the Plan for Growth recommendations, regulation is streamlined and clinical trials can be set up in the most timely and cost-effective manner.

Recommendations

- Industry should share its extensive data on local prescribing patterns and trends more effectively through a more formalised arrangement of data registry in order to support NHS organisations in the management of local populations and collection of outcomes data.

- Novartis, DH and NICE to work together on patient access schemes and risk-sharing agreements that reward innovation and deliver patient access, whilst maintaining confidentiality (see recommendation e)

- Novartis UK will continue to champion the UK with our Global Headquarters as a centre for clinical trials as recommendations a-d are implemented.
References

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