



News release for medical media and national newspapers

Xarelto[®] (rivaroxaban) accepted for use in NHS Scotland

Scottish Medicines Consortium (SMC) accepts Bayer's new oral anticoagulant for the prevention of venous thromboembolism (VTE) in adults undergoing elective hip or knee replacement surgery

London, 8 December 2008 – Bayer Schering Pharma welcomes the Scottish Medicines Consortium (SMC) advice out today, accepting Xarelto (rivaroxaban) for the prevention of venous thromboembolism (VTE) – also known as venous blood clots – in adult patients undergoing elective hip or knee replacement surgery within NHS Scotland (see notes for editors for full SMC advice).¹

The UK NHS performs approximately 160,000 hip and knee replacement procedures annually², over 12,000 of which are undertaken in Scotland.³ Adoption of this recommendation could help prevent unnecessary deaths from blood clots in patients undergoing elective hip or knee replacement surgery – one of the groups at highest risk.⁴ This type of clot is known as hospital-acquired deep vein thrombosis (DVT). Due to the invasive nature of this surgery and lack of mobility it causes, up to half of these patients would go on to develop a hospital-acquired DVT if preventative treatment (thromboprophylaxis) is not given.⁵

In three large phase III studies in patients undergoing either total knee or total hip replacement surgery, oral rivaroxaban was superior to the current standard, enoxaparin a low-molecular weight heparin (LMWH) injection, in reducing the incidence of VTE and all cause mortality in patients while demonstrating a similar incidence of bleeding events.^{1,6-8}

Rivaroxaban is an oral preparation that does not require regular coagulation monitoring and dose adjustment or daily subcutaneous injections, benefits acknowledged by the SMC.¹

Eve Knight, Executive Director of AntiCoagulation Europe, comments “We welcome the SMC’s decision as this will give clinicians more choice to make decisions on appropriate treatment after risk assessment. Current provision of thromboprophylaxis is suboptimal, and

hospital-acquired DVTs continue to cause unnecessary suffering and deaths. Access to effective anticoagulants will hopefully mean more patients will be treated appropriately.”

Current NICE recommendations state that all patients undergoing major surgery should be assessed to identify their individual risk of developing VTE after the procedure and all patients undergoing major orthopaedic surgery of the lower limbs should receive anticoagulant therapy for up to 28 days after surgery in combination with pressure stockings, to reduce the risk of VTE.⁹

Rivaroxaban was launched in the UK in October this year and is currently undergoing appraisal by the National Institute for Health and Clinical Excellence (NICE), who are expected to publish their recommendations early in 2009.

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NOTES FOR EDITORS

Scottish Medicines Consortium advice:

ADVICE: following a full submission

rivaroxaban (Xarelto®) is accepted for use within NHS Scotland for the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.

In three large phase III studies in patients undergoing either total knee or total hip replacement surgery, rivaroxaban was superior to low molecular weight heparin in reducing the incidence of VTE and all cause mortality with patients while having a similar incidence of major bleeding events.

www.scottishmedicines.org.uk

About hospital-acquired DVT

- Venous blood clots, (also known as venous thromboembolism or VTE) can take the form of either:
 - A deep vein thrombosis (DVT) - a blood clot in a deep vein (usually in the leg) that partially or totally blocks the flow of blood¹⁰
 - A pulmonary embolism (PE) - a blood clot blocking an artery in the lungs¹⁰
- Each year an estimated 25,000 to 32,000 people in the UK die from venous blood clots as a result of a hospital stay or surgical procedure (sometimes referred to as 'hospital-acquired DVT'). This is more people than die from breast cancer, prostate cancer, HIV/AIDS and road traffic accidents combined⁴
- Many of these deaths could be prevented⁴
- Effective prevention and treatment of hospital-acquired DVT is a major national public health issue⁴
- People at risk of hospital-acquired DVT include people undergoing major orthopaedic surgery and those who are hospitalised or immobilised over long periods^{11,12}
- The majority (74%) of hospital-acquired DVT cause symptoms after the patient has left hospital¹²
- Hospital-acquired DVT occur in up to 50% of patients undergoing major orthopaedic surgery who do not receive preventative care⁵
- In November 2008, the All Party Parliamentary Thrombosis Group (APPTG) published their second annual report which showed that 70% of acute hospital trusts are now taking steps to risk assess patients for hospital-acquired DVT¹² – compared with only 32% in their 2007 report.¹⁴ These findings demonstrate that more hospitals are now bringing their practices in line with NICE and government recommendations, which are as follows:
 - Current NICE recommendations state that:⁹
 - All patients undergoing major surgery should be assessed to identify their individual risk of developing VTE after the procedure
 - All patients undergoing major orthopaedic surgery of the lower limbs should receive anticoagulant therapy, LMWH (low molecular weight heparin) for up to 28 days after surgery in combination with pressure stockings, to reduce the risk of VTE
 - SIGN guidelines recommend patients undergoing total hip or knee replacement surgery should be considered for both pharmaceutical thromboprophylaxis for up to five weeks following surgery, and mechanical methods of thromboprophylaxis¹⁵

About Xarelto (rivaroxaban)

Xarelto is licensed for the prevention of venous thromboembolism in adult patients undergoing elective hip or knee replacement surgery. It is the first of a new class of oral anticoagulant specifically inhibiting (blocking) Factor Xa, a pivotal step in the coagulation (blood clotting) process.¹⁶

Unlike low weight molecular heparins such as enoxaparin, which are administered daily by injection, Xarelto is an oral, once-daily tablet which is administered six to ten hours after surgery.¹⁷ It is licensed for two weeks following elective knee replacement surgery or five weeks following elective hip replacement surgery. An oral tablet such as Xarelto offers a more convenient, patient orientated treatment option than an injection as it enables patients to more easily continue their anticoagulant therapy at home, providing ongoing protection against the continued risk of developing clots. Further, there are no coagulation monitoring requirements with Xarelto, which is an advantage over traditional oral anticoagulants such as Warfarin.

Almost 50,000 people are expected to be enrolled into the overall development programme for Xarelto. Clinical trials are underway evaluating its use in a wide range of conditions.

About Bayer Schering Pharma UK

Bayer Schering Pharma is a leading, worldwide speciality pharmaceutical company. Its research and business activities are focussed on the fields of haematology & cardiology, oncology, diagnostic imaging, primary care, specialised therapeutics and women's healthcare. With innovative products and using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life of patients.

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