**From:** (NHS ENGLAND & NHS IMPROVEMENT - X24)
**Sent:** 23 June 2022 11:00
**To:** **Subject:** DOAC patent challenge update

Dear Colleagues

You may be aware that two generic suppliers have challenged the UK patents currently in place for the direct oral anticoagulant (DOAC), apixaban. These court proceedings resulted in one of the apixaban patents and SPC, that was held by patent holder, Bristol Myers Squibb (BMS), being declared invalid. However, implementation of the court decision is stayed (postponed) until either; a) BMS have not appealed prior to the deadline or b) the outcome of any appeal is determined. BMS has filed its application to seek permission to appeal to the Court of Appeal. There are no set timelines for the Court of Appeal to issue a decision and currently an appeal hearing has not been set. Typically, these processes take months to conclude, even if an expedited trial is requested and therefore, we don’t currently expect this to be resolved before mid 2023.  Therefore, this remains an ongoing process and there is significant uncertainty about the timescales and outcome of the appeals process.

You may also be aware that a generic version of apixaban has been made available to wholesalers from the end of May. However, it is important to understand:

a.    the generic version of apixaban has been made available at a small discount against the originator list price (i.e. nowhere near a typical generic discount of 80+%).

b.    the generic version of apixaban has been launched within Category C of the Drug Tariff.

c.    there is limited supply.

d.    the above are not expected to change in the short term.

e.    edoxaban remains the best value DOAC by a considerable margin.

Neither the price at which the generic version of apixaban has been made available nor its limited supply justifies the NHS to change the existing commissioning recommendations that were issued in January 2022 and therefore, consistent with NICE guidance, we continue to recommend clinicians use edoxaban for new patients, where clinically appropriate.

There are still as many as 600,000 extra patients across the country who could benefit from effective anticoagulation. This creates an opportunity to prevent thousands of potentially fatal stroke events over the next three years and therefore our commissioning recommendations for DOACs should continue to be implemented without delay

Thank you for your continued support with the national DOAC framework agreement.

Your sincerely

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