rivaroxaban, and that rFVIIa may be more effective for reversing rivaroxaban than PCC. NICE CG141 for upper gastrointestinal bleeding recommends offering PCC to patients who are taking warfarin and actively bleeding but does not recommend the use of rFVIIa except when all other methods fail[48]. The cost of treating a patient with rFVIIa is estimated as £19,303 for a patient weighing 70 kg[48]. Using the dose of PCC to reverse rivaroxaban documented in Eerenberg and colleagues[47], and cost assumptions from The Dudley Group of Hospitals NHS Trust[49], the ERG calculates a PCC cost for rivaroxaban patients of £1,680 which compares with a maximum cost for a warfarin patient of £1,260[49]. The ERG examines these additional cost assumptions in scenario analysis in Section 4.3.

4.2.8 Consistency/ Model validation

Internal consistency

The MS states that two clinical experts were approached to provide validation on the initial model structure and parameter values tested in the model (MS Section 7.5.4 page 172). Quality control of the model was also undertaken by the model developers (MS Section 7.8 page 267). The MS does not report any checklists used for internal validation.

The ERG has verified that the cost-effectiveness results given in the MS are reproducible and checked the wiring of the model for the key equations and assumptions. The ERG has also verified that the parameter inputs and model results match those reported in the MS. One model input error was found. This relates to PSA and is described elsewhere in this report (Section 4.2.9). This error does not have a substantive impact on model outcome.

As noted in Section 4.2.1, in lifelong treatment the model uses the same probability of recurrent VTE for rivaroxaban and LMWH+VKA for cycles after 36 months. The same probabilities of bleeding events are also used after 36 months for the two treatments. This appears to be an error as the MS notes that all transition probabilities are treatment-specific in the lifelong model. The probabilities after 36 months are not explicitly stated in the MS (MS Section 7.3.2 page 141).

External consistency

The MS compares incidence of VTE and bleeding in the EINSTEIN-PE trial to incidence projected from the economic model by treatment arm and patient group for the 3, 6 and 12