CHECKLIST FOR PRODUCT EVALUATION
- Products in R&D

- ◯ Has the mechanism of action been established?
- ◯ What preclinical evidence exists to support or justify the expected clinical profile?
- ◯ Have all studies *in vitro* and *in vivo* been reviewed?
- ◯ What additional preclinical studies will be required for regulatory purposes or to allow clinical studies to commence?
- ◯ Have all the clinical data (including ongoing trials) been reviewed and are any potential problems apparent?
- ◯ Will any additional clinical studies be required to meet regulatory needs or to gain clinical acceptance for the product at planned dose levels?
- ◯ Is there a robust formulation with an adequate shelf-life, which is suitable for planned dose levels?
- ◯ Do any safety or pharmacokinetic issues remain unanswered?
- ◯ Do safety and toxicity data exist for all the planned formulations?
- ◯ Are the available regulatory data acceptable for the planned markets and indications, and for any existing marketing approvals that may need updating?
- ◯ Is the expected or actual price and level of reimbursement secure – are any changes expected for the target markets e.g. if other products experience patent expiry?
- ◯ Does the approved/expected data sheet profile and indications provide the expected competitive profile?
- ◯ Does an acceptable production process exist?
- ◯ Are QA standards acceptable, both to the regulatory authorities and internally?
- ◯ Is the supply chain secure?

CHECKLIST FOR PRODUCT EVALUATION
- Products in R&D

- ◯ Is any investment required for in-house manufacture included in planned forecasts?
- ◯ Has the proposed deal been cleared with purchasing and production?
- ◯ What are other licensees doing and can, or must, you exchange data with them?
- ◯ Are there any outstanding insurance claims and have the company's insurers cleared the product?
- ◯ Are any trademarks registered and free from dispute in the required markets, and are they acceptable linguistically?
- ◯ Are any patents valid, when do they expire in all required markets, and is there any risk of patent disputes with third parties?
- ◯ Is the licensor planning to introduce any new, upgraded competitor products?
- ◯ Is any market research available to help to evaluate the product's potential?
- ◯ Is the planned market share achievable, and are pricing expectations realistic given the market dynamics?
- ◯ Are generic competitors for the product, or for any of the major competitor products, anticipated that may reduce potential volume forecasts and prices?
- ◯ Who will be the target clinician groups in terms of both opinion leader groups and potential prescribers?
- ◯ How will the product slot into current visit profiles and what additional resources may be required to visit new clinician groups?
- ◯ Will the expected margin support the planned promotional spend?
- ◯ What will be the impact on existing business and product mix?
- ◯ Is seasonality important?