Institute and Faculty of Actuaries

FRC Risk Reporting Requirements Working Party– Case Study (Pharmaceutical Industry)

Contents

Executive Summary

Actuarial modelling techniques have been applied to 3 key risks faced by XYZ Pharma plc to show the potential variation in profit over the next 5 years that may result from these risks. The risks considered are:

(i) Product pipeline risk
(ii) Product liability risk
(iii) Foreign exchange risk.

The modelling shows that while risk (i) may result in reduced profits if a product launch is more costly and less successful than expected, the combination of this risk with risk (ii) can result in large losses in some extreme scenarios. The addition of risk (iii) adds further variation into the projected results.

This case study is intended to highlight a few of the areas where actuaries could help companies in the pharmaceutical industry to comply with the new FRC risk-reporting guidelines by working with other professionals, including industry experts, to build and analyse suitable risk models.

Background and Scope

The aim of this case study is to demonstrate how the risk management skills and experience of the actuarial profession can be utilised more widely beyond the financial services industry. This report focuses on the pharmaceutical industry and demonstrates how actuarial techniques can be applied to this industry.

A sample risk register was compiled of the potential risks facing a fictional company (XYZ Pharma plc). A simple model was constructed to project its profit and loss account over the next 5 years and to demonstrate how the combination of a few key risks may impact this projection.

Company Background and Highlights

XYZ Pharma plc is a multinational pharmaceutical and biologics company. It is one of the world's largest pharmaceutical companies measured by prescription drug sales and has operations in many countries. XYZ Pharma plc has a diverse portfolio of products for major disease areas.

Key financial highlights:

- Current year sales: £16.28bn (previous: £18.24bn)
- Current year reported operating profit: £2.08bn (previous: £2.44bn)
- Market capitalisation of £50 billion.

Sample Risk Register

The risk register sets out a number of risks faced by XYZ Pharma plc, and classifies these risks by their probability of occurrence and severity of impact. A sample is shown below for illustration.

Description	Likelihood	Impact	Interdependencies /Correlations	Probability	Risk Event Av. Cost	Absolute Cost	Weighted Cost
Insufficient efficacy demonstrated, or side effects	V low	Affects reputation of R&D and operating results		0.5%	V High	100000,00,000	500,00,000
Safety concerns mean no approval given, or extra R&D to spend to get approval.	V low	Affects reputation of R&D and operating results	1	0.5%	V High	100000,00,000	500,00,000
Cost benefit ratio over existing drugs insufficient	Medium	Affects reputation of R&D and operating results	1	10.0%	High	10000,00,000	1000,00,000

Description of Model

The model sets out the "best estimate" profit and loss account for this company over the next 5 years and then applies stochastic simulation to assess how the profit & loss account might vary from the best estimate over this period. For illustration purposes in this case study a five year projection period has been used but if required the modelling approach can be extended to reflect a company's view of the drug development and regulatory approval cycle.

Stochastic simulation is a well-established modelling technique which allows for the variability in potential outcomes due to various risk factors, and can therefore be used to show a range of future outcomes. In this case, 1000 simulations were used to generate the range of results, but in practice, the number of simulations used will depend on the credibility of the data, the type of model used and the potential variability of the outcomes. These are areas of judgement and expertise which actuaries will be able to advise on.

The benefits of using such a model are:

- It provides the management of the company greater understanding of the full range of potential outcomes and the likelihood of the different outcomes
- It provides understanding of risk-adjusted expected values, taking into account asymmetries in the risks
- Quantitative evaluation of risk exposure of each risk driver and of any actions that the management of the company may be able to take

The model has a central scenario which is the 'best estimate' of the profit and loss account over the next 5 years.

Without allowance for risk

Reporting period	1	2	3	4	5
Annual profit (GBP'm)	2019.3	2007.98	1992.33	2412.18	2412.18

Each risk is allowed for by using a suitable statistical distribution to generate values in each simulation. What an appropriate distribution might be is a significant area of judgement. See 'scenarios tested' section for details of statistical distributions used.

In this model, we assumed the risks were not correlated. But in practice, a multivariable risk model would be used, which would allow for correlation of risk factors. These correlations would also be required to be modelled to ensure consistency in the stochastic simulations.

Scenarios Tested

In reality, a company such as XYZ Pharma plc would be exposed to a large number of risks, each of which would need to be analysed and quantified as part of the company's risk reporting. However, for the purposes of this case study, we focused on 3 key risks to demonstrate the principles.

Scenario 1: Product pipeline risk

The initial scenario tested is product pipeline risk. This is the risk that the cost of developing a new drug in the pipeline and also the revenue from this new drug is not as estimated at the outset. In reality, the company may be developing many drugs simultaneously, of which the outcomes may or may not be independent of each other, but the general principle applied to modelling this single product development still holds. In practice, the stochastic model can be extended to take into account multiple developments and the levels of uncertainty associated with each of them, i.e. low to high risk.

It is worth noting that one outcome of developing many drugs in parallel is that it should help smooth out the random fluctuations in cost and revenue associated with a single development, i.e. due to diversification.

The model projects the estimated expenditure on the drug development and then applies a normal distribution to this estimate. This captures the uncertainty that the costs may come in under or over budget. Similarly, the sales revenue has been estimated and a different normal distribution has been used to capture the variation.

The normal distribution assumes an equal chance that the expenses/revenue will be above or below estimate. This may not be the case, for example if developments consistently end up over estimated budget. In this case the model can be updated to use a different distribution with different characteristics, e.g. log-normal or Poisson distributions. The choice of appropriate distributions requires some experience and judgement.

Scenario 2: Product liability risk+product pipeline risk

In this scenario, in addition to the product pipeline risk from scenario 1, the company also faces additional product liability risk. This is the risk of mass claims against the company due to an undetected harmful drug (an example being a thalidomide type event). We have assumed that the company has no indemnity insurance against these risks.

Some judgment is required in assessing how the combination of these two risks interact to affect the profits of the company, and the stochastic model can help show the variability in profits resulting from these risks. The future growth in profit is delivered by new products coming on line – this creates additional uncertainty in the level of future profitability. This, in combination with a large product liability claim, poses a significant risk, hence the choice of scenario.

Due to the binary nature of product liability risk (i.e. it either occurs or it doesn't), a Poisson distribution has been used to simulate this risk of a product liability event. The assumption used in the model is that this risk event will occur on average every 25 years.

Further to the occurrence of product liability risk, the impact upon occurrence has also been modelled. A Pareto distribution has been chosen to model this as this is considered a suitable distribution to model the severity of large losses for certain lines of business such as general liability insurance.

Scenario 3: FX risk+ Product liability risk + Product pipeline risk

Here, foreign currency exchange risk has been modelled in addition to the risks in scenario 2. This risk is present for all multinational companies which manufacture and sell products in many countries but report profits in their home currency.

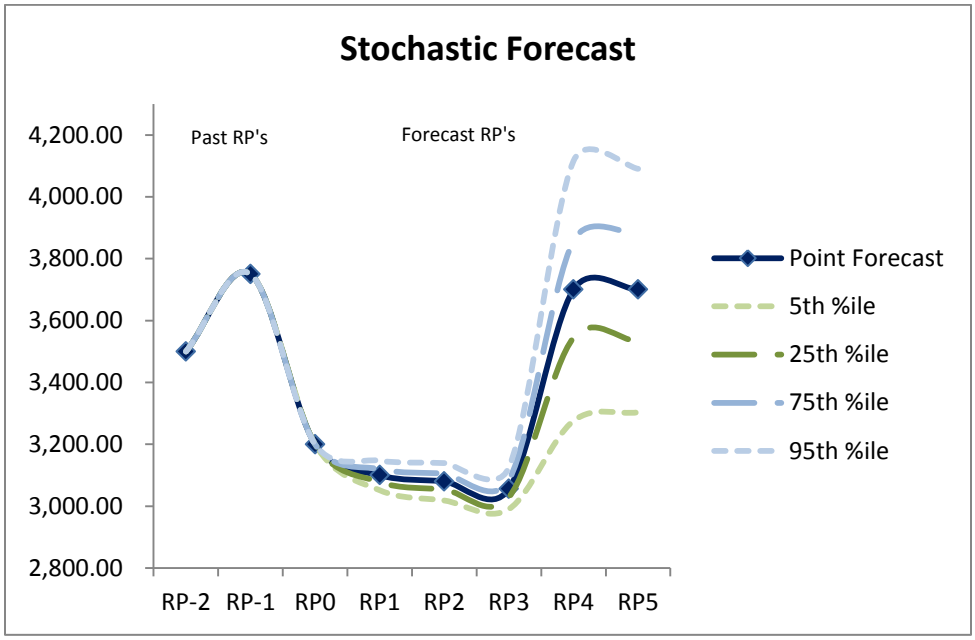
Within our model, we have simplified the FX risk by looking at the exchange rates of two currencies and using a normal distribution to simulate the variation over the next 5 years.

Results of Scenario-Testing

This section shows the results of the model. The "Point Forecast" represents the anticipated result in each of the next 5 years ("Risk Periods" or "RPs") based on the best estimate scenario as set out in page 4 above. In this scenario, the company's profit grows from year 3 onwards as the income stream from the new product development begins to yield returns.

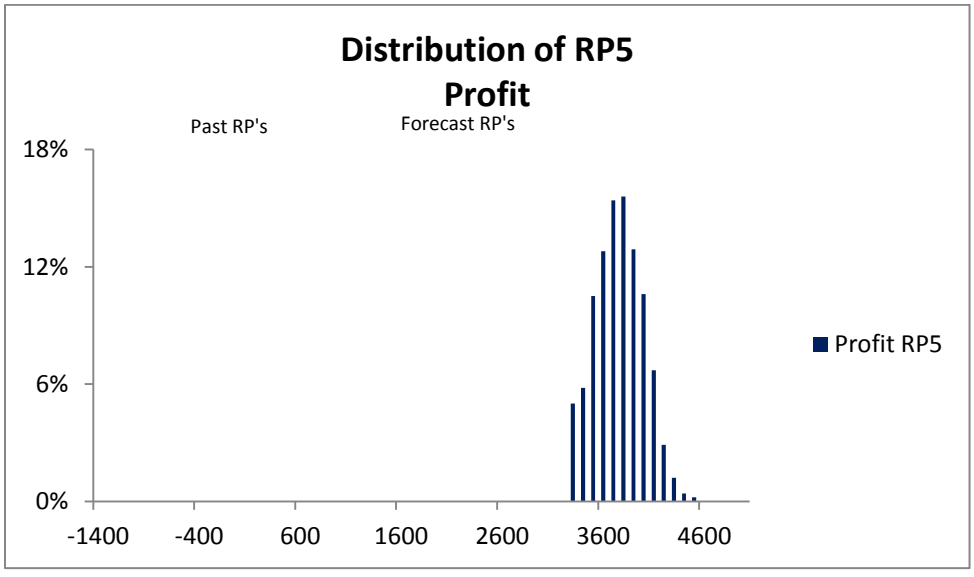
The other lines show the potential variability of those profits at different levels of likelihood of occurrence. For example, the 5^{th} percentile line shows the profit in each of the next 5 years if an adverse event with a 50^{th} worst outcome out of the 1000 modelled here.

Scenario 1: Product pipeline risk



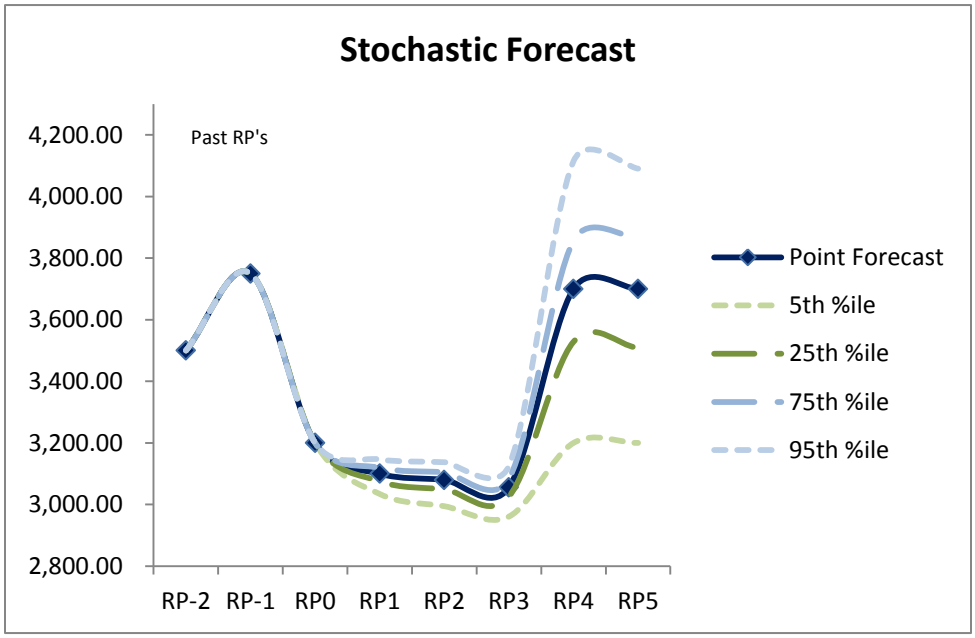
We can see that once the product pipeline risk is taken into account, the variability in future profits really emerges after year 3.The 5% percentile projects limited growth in profits, but the likelihood of this scenario occurring is relatively small. The 'risks' modelled can also generate an upside, i.e. sales better than expected, which is shown by the 95th percentile and maximum results. The benefit of the stochastic model is that the company's management can understand both the potential impact and the likelihood of the impact occurring.

The next chart shows the distribution of profit in the 5th time period as modelled in the scenarios. It can be observed from the chart that the spread in profits ranges from 2,950m to 4,480 with no scenario resulting in a loss.

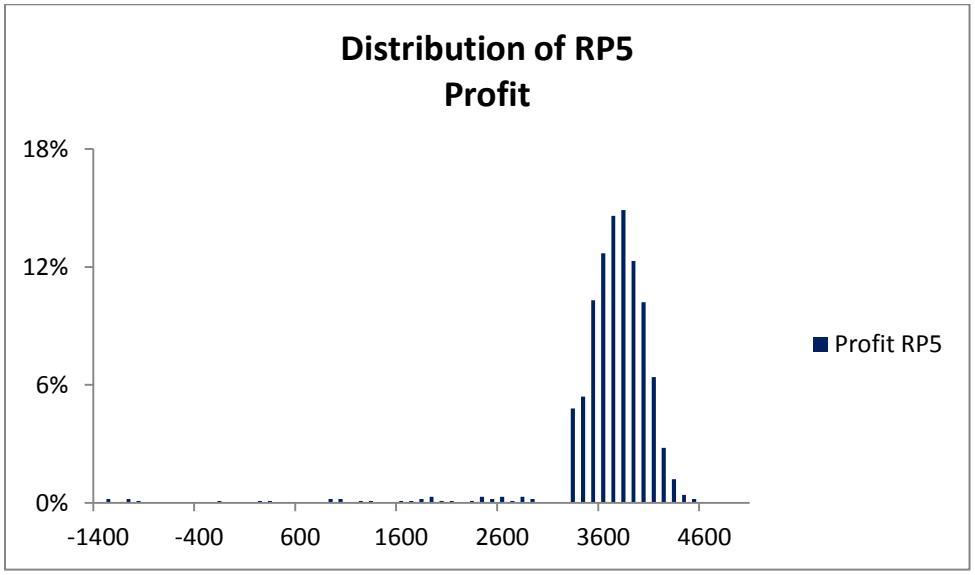


Scenario 2: Product liability risk+product pipeline risk

The graph below shows a similar shape to scenario 1 influenced by the product development expenditure and income, but now there is a greater variation in profitability between the percentiles as the additional impact of the extreme product liability risk is added.

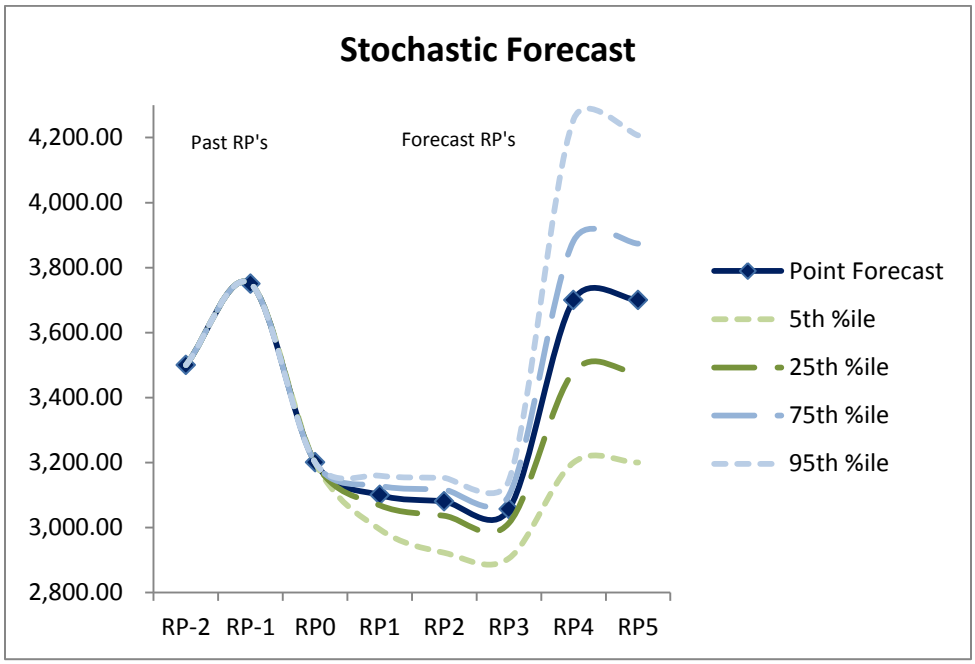


This can be observed more clearly in the time 5 distribution chart as some extreme scenarios result in a worst case loss of 1,900m. Note that the best case scenario is still the same as scenario 1 as the product liability risk does not generate any upside potential.

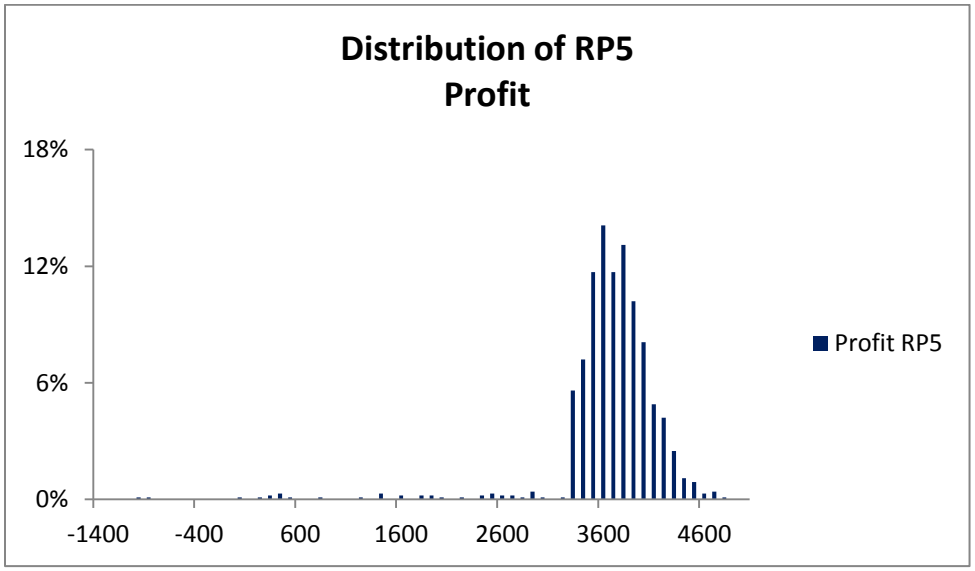


Scenario 3: FX risk+ Product liability risk + Product pipeline risk

Modelling this additional risk increases the volatility of results which causes a wider distribution of potential outcomes:



The underlying shape of the distribution is similar to scenario 2 but there is a greater spread in results due to the volatility in modelled FX rates.



Risk Mitigation Options

Understanding of the potential outcomes enables management to take actions in order to mitigate the impacts. In practice, these mitigation actions can be built into the models, resulting in a more realistic range of outcomes and provides management with additional information to support their decision-making process.

Product pipeline risk

As mentioned above, this risk can be reduced through having multiple product developments, something which happens in practice. However, this needs to be balanced against the cost of potentially spreading the focus too thinly.

Product liability risk

New drugs must meet stringent regulatory approval requirements before being made available to the public, so this helps reduce the probability of an occurrence. This introduces further subjectivity to the model as historical data may show a higher occurrence rate than is expected to be the case under present and future testing regimes.

Further to this, the company can take out indemnity cover against this risk. The modelling can help the company determine the level of cover required relative to the level of risk the company is comfortable with.

FX risk

It is common for multinational companies to smooth their foreign exchange volatility by entering into currency hedges where their key income streams arise from outside the home country. However, hedging costs money and potentially reduces the profit of the company, so the risk-return profile should be considered carefully.

The application of these mitigating actions can be added to the stochastic model, but in most cases, would result in a reduction in the volatility of the results. However, a good understanding of the range of potential outcomes gives management a powerful tool with which to help them in making decisions.

Conclusion

In this case study, we have identified some of the risks that a pharma company faces and we have developed a stochastic actuarial model to assess the financial impact of the business when one or all of those risks happen. The report has illustrated the combined impact of all scenarios on the financials of the company. It also discusses risk mitigation techniques to avoid or reduce the potential financial impact of certain risks. It may be worth noting that the model results are based on assumptions and the model can also be used to assess the sensitivity of the results with respect to the assumptions.

This report aims to increase the awareness of the strong expertise in risk management within the actuarial profession. We are aware of the increasing demand from FRC on risk management and believe that actuaries can be of assistance to industries other than our traditional areas of business.

The proposed framework provides a road map for future management decisions by considering the risk events in the pharma industry, their expected upside as well as downside thus assisting in optimal decision making process.

Reliances and Limitations

- This model only looks at 3 key risks to demonstrate how modelling techniques can be used in the risk management of the company. This can be extended to cover the multitude of risks faced by a multinational pharmaceutical company.

- The distributions of the risks were chosen for illustrative purposes here. In practice the company would observe historical data (both internal and industry data) and then apply expert judgment regarding future trends to fit distributions to the model.

- Although in this model no risk correlations were assumed in practice a multivariable risk model would contain correlated risks. These correlations would also be required to be modelled to ensure consistency in the stochastic simulations.