MILLIMAN WHITE PAPER

Emerging risks in insurance: Antibiotic resistance

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Overview

The rapid development of bacterial resistance to antibiotics and resulting difficulties in treating and controlling infectious diseases is a significant cause for concern as it leads to longer hospital stays, higher medical costs, increased mortality rates and poorer animal health and welfare. In the long term, an increase in antibiotic resistance could result in more people becoming seriously ill or dying from routine illnesses and the ability to perform routine medical procedures could be compromised.

Though antibiotic resistance occurs naturally, misuse and overuse of antibiotics, poor infection prevention and control measures, as well as global trade and travel, are accelerating the process. According to a European Centre for Disease Prevention and Control study published on 5 November 2018:[1]

- In the European Union (EU) and European Economic Area, approximately 33,000 people die each year as a direct consequence of antibiotic-resistant bacteria
- The burden of these infections is comparable to that of influenza, tuberculosis and HIV/AIDS combined
- 39% of the burden is caused by infections with bacteria resistant to last-line antibiotics (i.e., the last treatment option available)

To date, drug innovation and development have not kept pace with antibiotic resistance. The need to conduct large trials involving acutely ill patients that are difficult to identify can make antibiotic development prohibitively costly and complex. Furthermore, antibiotics offer limited opportunities to generate returns, as they are relatively cheap and the newest and most powerful antibiotics are reserved for patients who do not respond to first-line treatment. As a result, there are only a handful of companies currently in the market and the development pipeline is very thin.

The five-year national action[2] plan of the National Health Service (NHS) acknowledges that, while the UK cannot solve the market failures alone, it can catalyse efforts to address problems at an international level and work to change incentives to improve the rewards for investment within the domestic market. This involves supporting research and development (R&D) initiatives and stimulating positive competition as well as exploring new approaches for funding. For example, de-linking price and volume or adopting a 'pay or play'[3] approach.

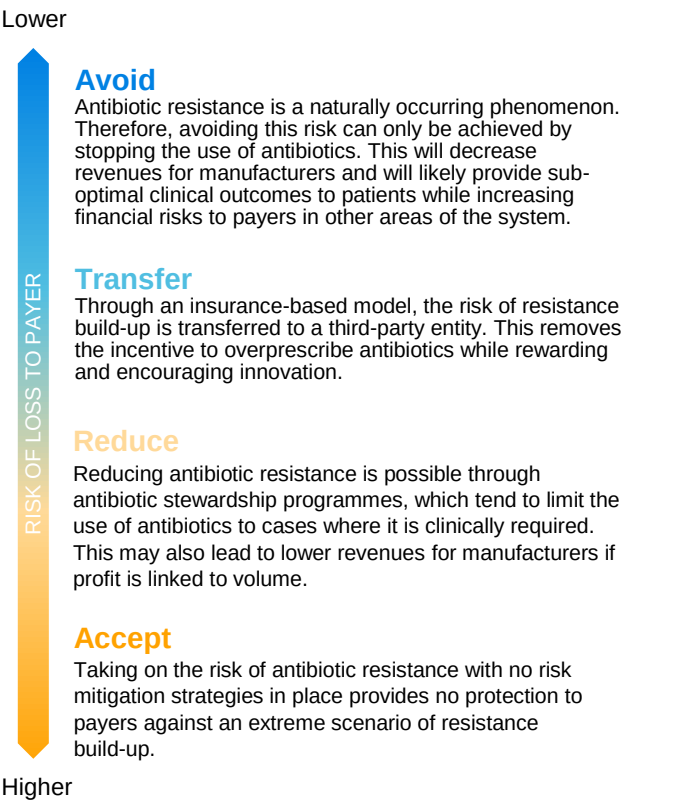
In this paper, we discuss how actuarial risk management and insurance principles can be applied when considering the de-linkage of price and volume.

Approaches to risk of loss

The O'Neil Review[4] discusses how insurance-type models are a potential approach for national-level purchasing arrangements that balance innovation and stewardship.[5]

A purchaser's approach to its risk of loss will reflect the potential financial impact and likelihood of loss (in this case, the prevalence of antibiotic resistance). Combining insurance-type payment models with effective stewardship programmes would be an example of combining transfer and reduction of risk strategies, as detailed in Figure 1.

FIGURE 1: APPROACHES TO RISK OF LOSS



1 Attributable deaths and disability-adjusted life-years caused by infections with antibiotic resistant bacteria in the EU and the European Economic Areas in 2015: A population-level modelling analysis.

2 The full text of the plan is available at https://www.gov.uk/government/publications/uk-5-year-action-plan-for-antimicrobial-resistance-2019-to-2024.

3 The 'pay or play' approach involves manufacturers choosing to either pay a charge or invest those funds in antimicrobial resistance R&D.

4 See https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf.

5 Stewardship programmes promote the appropriate use of antibiotics to limit the spread of resistance.

Risk management approaches to antibiotic resistance

In the context of limited innovation and incentives for manufacturers to develop novel antibiotics, we consider how insurance and risk-sharing principles can be applied to structure reimbursement models for novel antibiotics.

Although some principles of insurance do not translate directly in this context, it provides us with a framework to assess key considerations and risks to ensure that any agreed structure is fair to all stakeholders and appropriate risk mitigation strategies can be put in place.

THE INSURANCE MECHANISM

FIGURE 2: ILLUSTRATION OF INSURANCE MECHANISM

An insurer is an entity that underwrites risk, in exchange for receiving premiums from the policyholder. The insurer undertakes to pay compensation according to the insurance contract terms and the policyholder is insured against the financial risk(s) specified in the insurance contract.

In our example, the payer could make predetermined regular premium payments (or a lump sum payment) to the insurer. Claims would be equivalent to the antibiotics released into the market. Premium payments could be based on the expected utilisation of the novel antibiotics and the cost of resistance within the healthcare system as well as loadings for uncertainty and administration expenses. The manufacturer would partially or fully absorb the risk of higher than expected utilisation while being protected against low utilisation through the predetermined premium.

This arrangement enables innovation in the antibiotic space and de-links profit from volume. It is advantageous for the manufacturer if resistance is curbed and the volume of antibiotics is low, because there will be more profits to be gained from the insurance arrangement. It would be necessary to implement appropriate guidelines to prevent manufacturers from withholding antibiotics inappropriately.

THE PERIL

In insurance terms, the peril refers to the cause of loss. In this context, a key trigger for loss would be an increase in multidrug resistance.

Traditional insurance risk should be unpredictable but in this case, an increase in multidrug resistance can be triggered by events that are controllable.

Risk triggers should be accompanied by risk mitigation techniques to protect the insurer.

The payer is protected against the cost burden of multidrug resistance through the predetermined premium but there are broader implications within the arrangement, which:

1. Ensure manufacturers receive a minimum level of revenue for the drug regardless of utilisation.
2. Limit the perverse incentive for overutilisation which could lead to increased resistance over time.
3. Enable the payer to pay a predetermined premium amount to reduce the risk and cost of resistance by incentivising the development of new antibiotics while having some control over the volumes flowing through the system. The use of typical insurance mechanisms like excesses, deductibles and limits could be applied to antibiotic volumes and used to structure the transfer of risk between stakeholders.

TERM OF INSURANCE CONTRACT

Health insurance and property and casualty insurance usually have one-year terms while life insurance policies usually continue over multiple years, with some ability to revisit the premium on an annual basis.

In the context of an antibiotic-insurance arrangement, a one-year contract would be possible, but is unlikely to be optimal because there may be insufficient time for risks to materialise and for the manufacturer to be compensated for development and manufacturing costs through the premium payment(s). Further, some payers with short-term contracts may be less interested in this type of product, given they could struggle to realise the long-term benefits. For products where prices are annually adjusted, concerns around the impact of an uptick in costs would be mitigated.

The time period of such a contract would need to be long enough to address the above factors but short enough that the contract could be terminated or revisited in light of changing experience—notably, a change in resistance.

POOLING OF RISK

Pooling of risk is a fundamental principle of insurance. It provides protection against uncertainty of the insured perils materialising. Large risk pools contain risks with similar characteristics which enable the insurer to better quantify and protect against the risks that each pool poses.

Because the antibiotic-insurance model would involve a single policyholder (the payer), there would be no pooling of risk. There is a potential to aggregate similar risks by grouping similar drugs, provided similar drugs exist. The manufacturer's risk could be defrayed through capital or reinsurance markets, where it could be aggregated with other, uncorrelated risks.

DOUBLE INSURANCE

In typical insurance contracts, the policyholder cannot be insured for more than 100% of the loss incurred. If insurance is provided by multiple insurers, each insurer will pay a proportion of the loss incurred with the sum of the claims not exceeding 100% of the loss incurred.

If a new drug enters the market (follow-on or generic[6]), the payer could potentially enter into additional contracts with each insurer entitled to a portion of the premium. However, this could compromise the feasibility of the arrangement.

The fact that there is only one policyholder means that the usual competitive elements observed in insurance markets are not at play. A possible structure would be to include a single contract for a period of time, analogous to a patent period, with additional competing contracts added at later stages.

WHAT IF RESISTANCE DEVELOPS AGAINST THE NOVEL ANTIBIOTIC?

The incentive for stewardship would help mitigate this risk but decisions and guidelines regarding prescription and reimbursement would have to take place at a national, rather than local, level. Effective policies on antimicrobial resistance will consider:

1. The impact of new antibiotics on conservation goals.
2. The importance of aligning incentives among various stakeholders.
3. De-linkage of profit from volume.

6 A generic drug has an identical chemical structure to a novel or original drug that was previously protected by patents. A follow-on drug, also known as a 'me-too' drug, has a similar chemical structure to a drug that is already on the market.

Conclusion

With the prevalence of antibiotic resistance on the rise and limited innovation in the novel antibiotic space, alternative reimbursement methods can be considered as potential approaches to stimulating innovation and complementing antibiotic stewardship programmes. In the context of antibiotic resistance, de-linkage of profit and volume through the use of an insurance model has been proposed as a potential strategy to stimulate innovation and curb antibiotic resistance through the availability of novel antibiotics. The insurance principles described in this paper demonstrate a transfer of risk which, if implemented, would be complemented by risk reduction strategies. Although the principles of insurance do not translate completely, the framework can help when considering key design elements of alternative reimbursement models.

Milliman consultants have considerable experience helping firms to develop their risk management frameworks. We are well-placed to benchmark firms' approaches against the rest of the industry, and provide insight and advice that is tailored to your individual circumstances and needs.

We have helped numerous clients to introduce robust processes for identifying and assessing emerging risks, ranging from building up a narrative through to the use of new analytical techniques and artificial intelligence.

If you have any questions or comments on this paper, on the subject of antibiotic resistance or emerging risk or on any other aspect of your risk management framework, please contact any of the consultants below or your usual Milliman consultant.

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