

An Introduction to Risk and Uncertainty

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Abstract

This paper lays out an economic framework to conceptualize the primary sources of risk and uncertainty that impede the accurate forecasting of demand for pharmaceutical products, with a focus on developing country markets. By adopting this common framework, stakeholders can ensure the use of a consistent vocabulary for key concepts; identify possible approaches to managing risk; and understand their implications.

While each market situation presents particular challenges, important commonalities exist and can be used to draw inferences about solving problems related to the supply of and demand for a given product. From the point of view of the costs and risks borne by the community, it is better first to reduce uncertainty wherever it is cost-effective to do so. Risk should next be diversified by pooling or hedging. Remaining risks should then be allocated to the stakeholder best able to minimize and bear them.

This paper informed the deliberations of the Center for Global Development's Global Health Forecasting Working Group and is summarized in Appendix C of their final report, *A Risky Business: Saving Money and Improving Global Health through Better Demand Forecasts*.

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September 2006

1. Purpose

This paper presents a simple conceptual framework for discussing risk and uncertainty in the supply and demand for pharmaceutical products. Some basic examples from the pharmaceutical sector are highlighted. While each market situation presents particular challenges, important commonalities exist and can be used to draw inferences about solving problems related to the supply of and demand for a given product.

The paper has two purposes. **First**, it offers a consistent vocabulary for key concepts such as risk, diversification, supply and demand. **Second**, adopting a common conceptual framework enables us to systematically identify and understand possible approaches to managing risk and to understand their implications.

2. The many types of “risk”

The pharmaceutical enterprise is generally considered to be a “risky” one, with the main sources of risk associated with distinct steps in the supply chain. From the suppliers’ perspective, risk is seen as part of the stages of R&D, manufacture, and selling products, including but not limited to:

- The transition from investments in the basic scientific discovery process to viable molecules that merit clinical studies.
- The “survival” of products being tested through the phases of clinical studies, so that they are candidates for licensure, through a regulatory pathway that may have unpredictable elements.
- The inclusion of a product on a list of recommended products and/or on a particular financier’s or institution’s formulary.
- The ability of manufacturers to secure adequate supplies of raw ingredients and/or to create biological products in a predictable fashion, at a marginal cost that permits the manufacturer to clear an expected level of returns, given a particular product price.
- The effective demand expressed by consumers or their agents, given a particular price, which manufacturers must predict with sufficient lead time to meet the demand.
- Post-marketing issues of adverse events, which may cause public relations and/or liability problems.
- The emergence of competing products, either those that directly compete (e.g., in same class) or those that reduce the incidence of the health condition for which the product is indicated. Among other effects, the presence of competing products may lead to the exclusion of products from recommended lists and/or formularies.

From the perspective of consumers and financiers, available supply and/or price may be unpredictable.

While those in the pharmaceutical business (and those who buy pharmaceutical products) face these risks to some degree in all product lines and markets, there are many ways in which products for developing country markets are seen as particularly risky. A few of the key reasons are listed below:

- R&D stage
 - Firms may know less about how to manage clinical trials in developing countries, and may face greater (yet unpredictable) logistical, political and other obstacles.
 - Because of historically low levels of investment in products for developing countries, much of the basic science may be in a less advanced stage.

- Licensure and regulatory stage
 - Manufacturers may be required to comply with national regulatory processes with which they are unfamiliar, and which may not conform to known FDA and/or EMEA approaches.
 - Manufacturers may not know either the criteria for or timing of the WHO recommendation and pre-qualification processes.

- Manufacturing stage
 - Basic historical consumption data that is routinely available in industrialized markets may be scarce.
 - Finance from donor agencies and/or other funders may be disconnected from predictable factors, like incidence of disease or even proportion of the affected population with access to health services. Because of the political content of donor decisions, price sensitivity may be difficult to predict based on historical trends.
 - Unexpected political / public relations pressures may be placed upon manufacturers to offer products at low margins.
 - Competing products may emerge rapidly, particularly if and when intellectual property regimes are challenged.

The picture is even more complex because there are some ways in which developing country markets may have lower levels of risk than industrialized country markets. For example, there may be fewer suppliers, and thus fewer competing products. Procurement agencies may be relatively well organized and few in number, which can make their behavior easier to predict (even if the monopsony situation leads to lower ability of manufacturers to raise prices). Liability concerns may be minimal.

Although all of the issues described above are often referred to as risks, some are what economists would refer to as “risks,” because the decision makers know the probabilities of distinct outcomes, and others are more precisely referred to as “uncertainties,” because they represent situations in which this randomness cannot be expressed in terms of mathematical probabilities. In an example given by Keynes, making a bet in a game of roulette is “risky” but not “uncertain”: we know the exact probability of each possible outcome; but betting on the price of copper in 20 years time is “uncertain” because there is no scientific basis on which to assign probabilities to different outcomes.

In real life – and certainly in the pharmaceutical sector – a spectrum of unknown situations are represented, ranging from those in which we know the likelihood of all the possible outcomes at one end (i.e., risk) to those in which we have no knowledge of the likelihood of possible outcomes at the other (i.e., uncertainty). The difference between risk and uncertainty is often *subjective*: it relates to the information that is available to an individual. From the perspective of astronomers, the possibility of earth being hit by an asteroid is a risk, they can calculate the likelihood of it happening; from my perspective it is an uncertainty because I know nothing at all about the probabilities.

Taken together, the set of risks and uncertainties in the pharmaceutical sector gives the appearance of a wildly unpredictable situation, in which it is impossible for manufacturers to know how much to produce for what price to maintain a viable business, and equally impossible for consumers (or those who finance their pharmaceutical purchases) to know how much dealing with particular health problems will cost. However, when the “risks” are disentangled a bit, regularities emerge – and the dynamics of the market help, over the long-run, to establish demand-supply equilibria. Moreover, specific actions can be taken to smooth out the unpredictable features that are manifested in the short-run, partially protecting both suppliers and consumers (and funders) from shortfalls in revenue and/or products.

3. Decisions made in risky situations are based on “expected returns”

In the pharmaceutical sector, as in all other business domains, decisions are taken with the full knowledge that outcomes are unknown; sometimes the bets will pay off with positive returns, and sometimes they will result in losses. When decisions are made in risky situations, the “expected returns” from each choice serve as a guide to action. The expected return is calculated by considering the return in each possible state of the world and then constructing a weighted average, where the weights are our estimate of the probability of each state. This can either be done formally or through some process whereby decision makers have internalized the probabilities and weights, and arrive at a decision based on something they might refer to as a hunch, intuition or experience.¹

Here’s a simple example of calculating expected returns: If we offer to toss a coin, and give you \$3 million if it comes up heads, but nothing if it is tails, then the expected return from this offer is \$1.5 million. (Note that in this case, the actual payoff will never equal the expected return: the payoff from each toss of the coin will either be zero or \$3 million.)

Expected values are measured in the same units as the variable itself: so expected revenues and expected profits are measured in dollars; expected temperatures are measured in degrees; expected lives saved are measured in numbers of people.

By contrast, risk is a way of characterizing the range of possible outcomes, and no single variable completely describes risk. Risk is sometimes summarized by the *variance* of the returns. Risk might also be characterized by the probability of making a net loss (“There’s a 40% chance of losing money”), or an estimate of the maximum possible loss (“We might lose up to \$2 million, in the worst case scenario”), or the variance and skewness of the return (“The returns on investment might range from –10% to +20%”).

In short, the unit of measurement of risk is not dollars. Expected returns and risk measure different types of things and there is no simple way to combine the two into a single indicator.

¹ Risks are sometimes described as if they were possible future costs, which have to be subtracted from expected returns. Technically, this is incorrect. The expected return is a weighted average of all the possible outcomes – positive and negative – and so the expected return already takes into account the possibility of losses, suitably weighted. So risks do not reduce expected returns: on average they are as likely to increase as to reduce expected returns.

4. Tradeoffs and risk aversion

Other things being equal, people always prefer higher expected returns to lower expected returns. But other things are rarely equal: in practice, we look at both expected returns and the amount of risk that they involve, and we choose a combination of risk and returns that suits us.

If we offered a choice between tossing a coin for \$3 million, or a guaranteed \$1 million, many individuals might choose the guaranteed \$1 million, even though the return from this (\$1 million) is less than the expected return from the gamble (which is \$1.5 million.) So in this example individuals are willing to accept a lower expected return because they are taking a smaller risk. This willingness to trade off lower returns for lower risk is a signal that the individual is *risk averse*. Most people (and correspondingly most firms) are risk averse to some degree, at some levels of risk and return. In other words, they have to be paid – in the form of higher expected returns – to take risks. However, in the business world, levels of risk aversion are neither uniform across types of firms, nor are they static.

5. Diversification of risk

Risks can be diversified so that individuals or firms can choose from a more advantageous set of risk-return combinations. A simple example helps to illustrate this point. Suppose that every member of the Global Health Forecasting Working Group were given the same choice: you can choose between either \$1 million guaranteed, or \$3 million on the toss of a coin. Most – possibly all – members of the Working Group would take the guaranteed payout, because they each want to avoid a 50% chance that they will get nothing at all. So if each member of the Working Group takes the guaranteed return, the expected return for each member of the Working Group would be \$1 million.

But a really smart Working Group might reach an agreement that they would all take the gamble, and then share the proceeds equally among them. If they do this, the expected return for each member would be \$1.5 million, rather than \$1 million if they all took the guaranteed payout. If there are 20 members of the group, the probability of the group ending up with no return at all is about 1:10,000. There is about a 1:500 chance of getting only one heads from 20 coin tosses – in which case each person would receive \$150,000. The probability of ending up with a payout of below \$1 million per person is less than 6%.

So by pooling their risks, members of the Working Group can make themselves better off on average than if they each bear their own risk. Although there has been no change in the actual risks – the odds of getting heads has not changed, nor has the payout for doing so – by spreading the risk among the group they are all able to take advantage of the higher expected payout from the riskier option while being reasonably confident that they will not go away empty-handed.

An exceptionally canny Working Group could further optimize their position by agreeing that some of them should take the gamble, and others should take the guaranteed return – again with an agreement to share the total returns. A hybrid option of with some certainty would entail a lower expected return for each member of the group than if they all took the gamble, but it would also ensure that they could not go away empty-handed. The number that should gamble, and the number that should take the guaranteed payout, would depend on how risk averse the members of the group are. The following table sets out some of the options available to the group:

Table 1: Payout per person with pooled risk

I	II	III	IV	V	VI	VII
Number of gamblers out of 20	Expected return (\$m) per person	Worst case per person (\$m)	Probability of worst case (\$m)	Best case per person (\$m)	Probability of less than \$1m per person	Risk
0	1.000	1.000	100.0000%	1.00	0%	Lowest
1	1.025	0.950	50.0000%	1.10	50%	Very low
2	1.050	0.900	25.0000%	1.20	25%	Low
5	1.125	0.750	3.1250%	1.50	19%	Low-moderate
10	1.250	0.500	0.0977%	2.00	17%	Moderate
15	1.375	0.250	0.0031%	2.50	6%	Higher
19	1.475	0.050	0.0002%	2.90	8%	Very high
20	1.500	0.000	0.0001%	3.00	6%	Highest

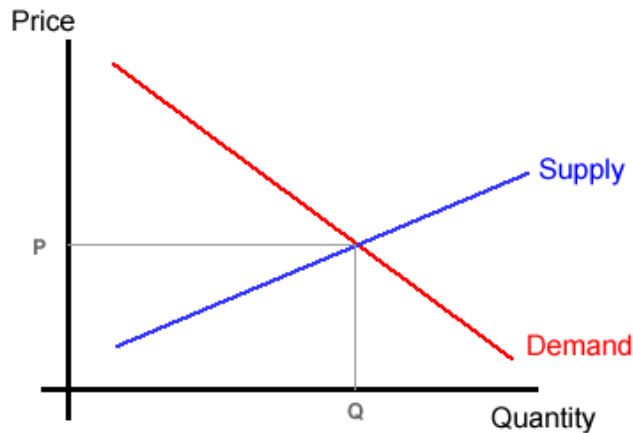
This table also illustrates the difficulty of completely describing risk. Columns III to VII are all ways of characterizing the risk which accompanies the expected return shown in column II. Risk is not a factor which reduces the expected return – in fact, in this case the riskier options have higher expected returns; instead, risk is a way to describe how certain we can be about those expected returns

It is also instructive to consider what would happen if the Working Group were larger than 20 people. If there were 100 or a 1,000 people in the group, then their optimal strategy would be to agree that everyone should take the gamble, and then share the rewards. A larger and more diverse group can bear greater risks.

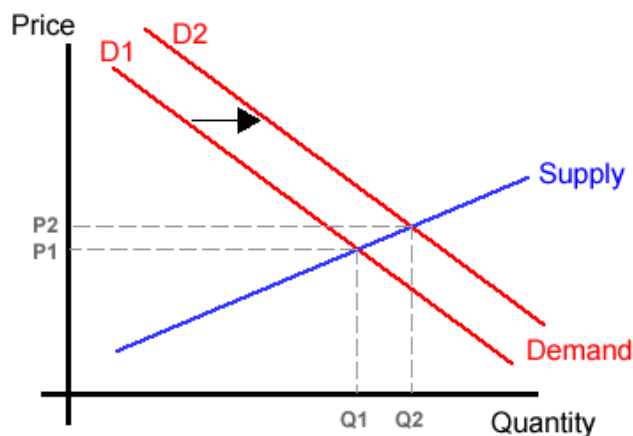
Diversification of risks does not change the total risk to the community as a whole – the actual probabilities are all unchanged. But as this example shows, diversifying risks enables the construction of a more advantageous set of risk-return choices.

6. What are supply and demand curves?

Mainstream microeconomic theory revolves around understanding how supply and demand relate to prices. These relationships are often shown graphically, with quantity along the horizontal axis, and price up the vertical axis. The downward slope of the demand curve indicates that a greater quantity will be demanded when the price is lower.



Conversely, the upward slope of the supply curve tells us that as the price goes up, producers are willing to produce more goods. The point where these curves intersect is the *equilibrium*. At a price P producers will be willing to supply Q units and at that price, buyers will demand the same quantity. In this example, there is one equilibrium price which equates supply with demand.



The demand curve therefore shows how willingness to buy varies according to price. When prices change, we move *along* the demand curve to find what quantity people will want to buy at that price. But demand is determined by other factors as well as price, such as the level of income, consumer preferences, the price of substitute goods and the price of complementary goods. If there is a change in any of these determinants of demand, then the demand curve will *shift* on the graph.

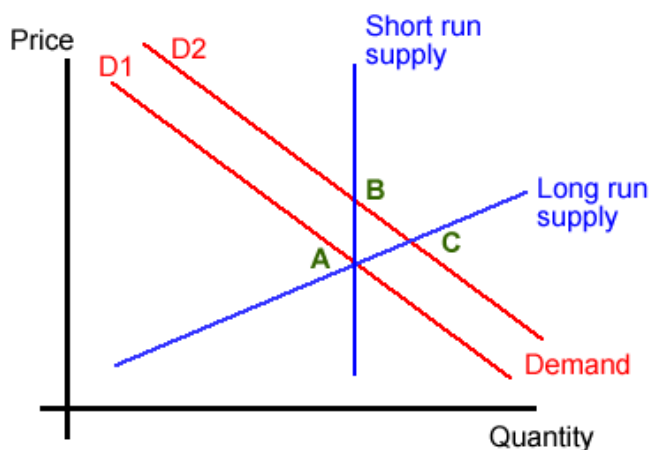
Suppose that $D1$ – the first red line on the graph – shows the demand for ice-creams. It is downward sloping, because as prices rise, quantities demanded fall. But when there is a heat-wave, the quantity demanded at each price rises, so the whole demand curve shifts to the right, to $D2$. So when there is a change in consumer preferences the demand curve shifts. If the supply curve does not change, then the equilibrium price rises (from $P1$ to $P2$), and the quantity produced increases (from $Q1$ to $Q2$).

The supply curve shows the quantity that producers are willing to sell at each price. Supply curves are traditionally represented as upward-sloping because of the law of diminishing marginal returns, which says that the cost of each additional item rises as volumes increase. This means that as quantities rise, so firms need to be paid higher prices to make them. (In reality, this can occur in a stepwise and discontinuous fashion – for example, if above a certain volume the manufacturer has to make new capital investments.)

Just as a shift in the demand curve moves the equilibrium along the supply curve, so a shift in the supply curve moves the equilibrium along the demand curve. A rise in the cost of labor would move the supply curve upwards, and so the equilibrium would move to the left along the demand curve. The equilibrium price would rise and the quantity bought would fall.

7. Short run and long run supply curves

In practice, supply may not be able to change rapidly in response to a shift in market conditions. For example, it may take time to build new manufacturing facilities, train workers, or to assemble the products. These periods of discontinuity – when demand expands more quickly than supply – are often highly disruptive. Again, for a variety of reasons, this may be more likely in developing country markets than in more established industrial market environments.



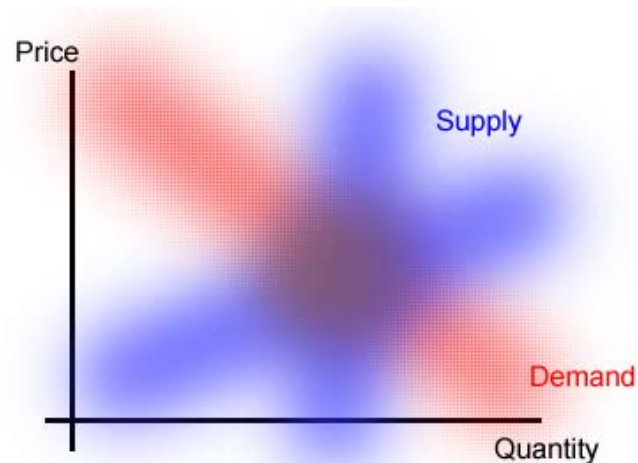
In this situation, the supply curve may be steep – possibly vertical – in the short run. The quantity of goods that can be produced and sold is effectively fixed in the short run. When demand increases, the price may rise but there is no immediate change in the quantity that is produced and sold.

In these circumstances, an increase in demand (from D1 to D2 on the diagram) leads to a movement up the short run supply curve at first, from A to B. If the increase in demand is expected to be sustained, then in the long run suppliers can adapt to higher demand, and the equilibrium shifts from B to C. Prices rise at first, and then fall back as supply increases.

Note that the long run supply response depends largely on *expectations* of what will happen in the future. If ice-cream vendors perceive a hot summer as part of a trend towards global warming, or a sustained trend in consumer tastes, they may invest in new vans or larger freezers. But if they think it is just a temporary phenomenon and that demand will fall back down next year, they may just move up the short run supply curve, pushing up prices temporarily, but there will be no movement along the long run supply curve. Uncertainty about future demand therefore makes a significant difference to the probable supply response.

8. Supply and demand with uncertainty

Many of the determinants of the supply and demand functions are not known with certainty. On the demand side, there is uncertainty about incomes or budgets of purchasers, tastes, and the prices of complementary and substitute goods. On the supply side, there is uncertainty about costs of inputs such as labor, and uncertainty about the technology that will be available to translate those inputs into the required output. We will look at those causes of uncertainty later.



Uncertainty and risk about the position of the demand curve lead to uncertainty about where equilibrium will lie on the supply curve. Conversely, uncertainty and risk about the determinants of supply leads to uncertainty about where the equilibrium will lie on the demand curve. Together, these uncertainties can lead to a potentially large set of possible outcomes.

This means that both prices (on the vertical axis) and quantities demanded and supplied (on the horizontal axis) are highly uncertain, and could vary considerably depending on the actual position of the supply and demand curves.

9. The costs of uncertainty and risk in supply and demand

If all economic agents were risk-neutral, or could fully diversify their risks, then they would only take account of the expected returns from each option and they would not care about the risk. But if firms or customers are risk-averse, then they will be willing to forego some expected returns to secure lower levels of risk. In other words, the existence of undiversified risk imposes a cost on risk-averse economic agents.

In concept, firms should be less risk averse than the individuals that own or run them. Shareholders invest in a diversified portfolio of stocks, so that they do not depend on the performance of any particular company. If they have sufficiently diversified holding, investors should be risk neutral about the returns from any particular company. (This is analogous to members of the Working Group who share the payoff: if they gamble and share the proceeds between them then they do not expect to be successful on every single toss of the coin, provided that they are successful on average.)

Shareholders should provide incentives to managers and employees to reflect the risk appetite of the owners of the company. If the shareholders are risk-neutral about each investment, then they should encourage the managers to maximize expected returns and be indifferent to risk. In reality, however, shareholders, managers and staff in most firms do display a degree of risk aversion.

Being risk averse does not mean that firms entirely avoid all risky behavior. It simply means that, other things being equal, most firms will accept a somewhat lower expected payoff in return for lower risk. (Risk-neutral firms would always choose the highest expected return, irrespective of the amount of risk.) For these firms – and their shareholders, employees and customers – there are real financial costs to undiversified risk.

10. Supply side risks

In a sort of real-world shorthand, many firms argue that uncertainty in product price is one of the principal risks they face. But in the framework of supply and demand, uncertainty about price is the result of uncertainty about the position of the demand and supply curves. Price uncertainty is a consequence, not a cause, of risks. The underlying causes of risk are those which affect the position of the supply and demand curves.

There are three broad classes of risk that might affect the location of the supply curve:

1. **Input Market Risks**

The position of the supply curve may be affected by market price movements, such as the cost of inputs, exchange rates, interest rates or spreads, and commodity prices. Supply will also be affected by uncertainty in the supply chain.

2. **Credit Risk**

The possibility that a borrower, supplier or customer might fail to honor its contractual obligations. In the pharmaceutical market, this may be quite pronounced if the contractual obligations are weakly enforced – again, a feature of developing country markets.

3. **Operational Risk**

Uncertainty about the effectiveness of internal processes and systems to manage and produce the products, and to external events that might interrupt supply.

In markets for **pharmaceutical products and diagnostics** for global public health, the main supply-side relate are technical and regulatory:

- **Batch failures**

A short-term supply risk is that a firm produces batches of products that fail tests for effectiveness, uniformity or safety. This may occur because of failures in a process, component, system, or because of personnel error.

- **Supply chain failures**

Health products may depend on intermediate products from other suppliers – for example, adjuvants for vaccines. If agricultural commodities are required as inputs to pharmaceutical products, the supply of those commodities – and the weather and other factors that affect the amount of commodities supplied at different prices – confers important risks. Uncertainty in the supply of these other products will affect the supply of the final product.

- **Regulatory risk**

For many suppliers, a key risk is that the regulatory regime will change, or that it will be applied in unexpected and possibly capricious ways. This includes the WHO recommendation and prequalification process, and national regulatory procedures for licensure and/or registration.

11. Demand side risks

Four broad classes of risks might affect the location of the demand curve:

1. **Budget Risk**

Uncertainty about the future incomes or budgets of purchasers.

2. **Competition Risk**

Uncertainty about the amount of market share that competitors might capture, including the possibility of technological improvements by competitors that improve quality or reduce prices of competing products.

3. **Changes in preferences & obsolescence**

The demand curve will shift if the purchasers want more (or less) of a product at a given price because their tastes have changed. This includes the risk of obsolescence – demand for some products can be replaced by demand for alternative ways of meeting the same needs.

4. **Bargaining and expectations risks**

In uncompetitive markets with small numbers of buyers or sellers, buyers may adjust the price they are willing to pay for strategic reasons. Buyers may also adjust demand in response to their expectations of future market conditions.

In markets for **pharmaceutical products and diagnostics** for global public health, the main demand-side relate to funding, public sector demand and the bargaining power of public sector purchasers:

- **Budget and purchasing power risks**

Volatility in donor budgets for global public health lead to volatile and unpredictable demand. Furthermore, if developing countries pay for some or all of the costs, volatility of domestically financed health budgets may also impact the position of the demand curve. Volatility may be the result of changes in revenues, or the volatility of competing pressures.

- **Bargaining risk**

Public sector purchasers have strategic bargaining strength. They are often the main or only purchaser of medicines or diagnostics for their jurisdiction (a monopsony situation), and they may collaborate across countries to secure lower prices through greater bargaining strength. If suppliers have to invest in production without a binding pre-commitment from purchasers, then the buyers have an incentive subsequently to negotiate down the prices once the investment is sunk.

- **Competition risks**

Some products benefit from a temporary period of exclusivity through intellectual property protection and others face little competition because of the complexity of production or regulatory barriers. But where there are alternative products that can produce health benefits, the price and availability of these products can made a significant difference to demand for a company's product.

- **Obsolescence risks**

A long-term demand risk for some products is that they are made obsolete – for example, because a better alternative is developed, or because another approach is adopted for the condition.

- **Policy and preference risks**

Adoption of medical technologies is frequently dependent on a range of uncertain determinants, such as availability of data about the burden of disease, public attitudes to the disease, understanding of the range of interventions, and stigma and understanding about the particular product (e.g. fears about vaccination). In developing countries, the track record is relatively

short and poorly described, so these risks are more pronounced than in developed country markets.

- **Complementary input risks**

No medicine or diagnostic is introduced in a vacuum. Complementary inputs are required, including skilled personnel to diagnose conditions and to administer treatments, physical infrastructure such as clinics and roads, supply chain and logistics capacity, controls on corruption and theft, and the capacity to plan, budget and manage the introduction and use of new medical interventions. Under severe resource constraints in a health system, as an increasing number of products are introduced, the potential to deliver each of them may be compromised.

12. Managing risks

Genuine risks and uncertainty characterize the past, present and future, and must be taken into account in any decisions that affect supply and demand.

In principle, three types of approaches can reduce the cost of uncertainty:

1. **Reducing uncertainty and risks**

Some uncertainty and risk can be reduced by collecting more and better information and making it available inexpensively to decision makers, or by introducing ways to ensure that commitments to supply and/or purchase are binding and enforceable. This can be a net gain to everyone because total uncertainty is reduced. Where it is economic to do so, this is the best way to reduce the cost of uncertainty.

2. **Diversify risk to reduce its costs or hedge in financial markets**

To deal with the uncertainty that cannot be cost-effectively reduced, downside effects can be reduced by enabling market participants to diversify their exposure. For example, while there may be variation in health sector budgets in individual countries that affect demand, these can be diversified by making arrangements for pooled procurements. Risk can be diversified by pooling arrangements, or by laying off the risk in financial markets (e.g. insuring against failures of demand, or hedging against exchange rate movements). Using financial risk diversification can be cost-effective if the providers of hedging products are able to bear the risk by diversifying their own exposure.

3. **Allocate remaining risks to the stakeholder that can bear them at least cost**

Risks that cannot be reduced, diversified or laid off should be allocated to the stakeholder able to bear them at lowest cost. In general, this means ensuring that risks are borne by the agent for which (a) the amount of uncertainty and information costs are lowest; and (b) the costs of bearing risk are lowest.

From the point of view of the costs and risks borne by the community, it is better first to reduce uncertainty wherever it is cost-effective to do so. Remaining risk should be diversified by pooling or hedging. Remaining risks should then be allocated to the stakeholder best able to minimize and bear them.

13. Managing risks in global health

The analysis above provides an intellectual framework for considering the main risks to supply and demand for global health products, and how those risks can best be reduced, diversified and allocated.

Many layers of complexity underlie uncertainty in demand and supply for health products, and specific policy proposals would need to reflect those details. Table 2 below sets out on a very broad canvas the main risks, and the most promising avenues for reducing them or managing their impact.

Table 2: Broad outlines of risks and possible strategies

	Reduce uncertainty	Diversify risk	Allocate remaining risk to:
Supply risks			
Batch	Improved production systems	Self-insurance by producers	Producers
Supply chain	Contractual arrangements	Producers seek alternative suppliers	Producers
Regulatory	Stable & predictable regulation Supranational regulators		Regulators
Demand risks			
Budget	Predictable aid Medium term budgeting Improved sharing of information for demand forecasting	Demand pooling	Donors Developing country governments
Bargaining	Long term contracts Purchase commitments	Reduce monopsony	International organizations
Competition	(Benefits of competitive pressure outweigh costs)	Investors or producers may diversify portfolio Industry risk pooling	Producers
Obsolescence	Open publishing of scientific data (?)	Producers may diversify product portfolio	Producers
Policy & preference	Sustained investment in advocacy and education Improved mobilization and sharing of information for demand forecasting	Take-or-pay contracts	Developing country governments