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# Pharmaceutical Development Trends and Their Impact on Healthcare Policy Planning and Delivery

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A look into the impetus behind pharmaceutical development trends and how healthcare policymakers and payers should adapt to emerging new treatments and considerations for a managed approach to adoption.



## Key Points

- Policymakers and payers must plan for healthcare delivery and services within cash-constrained budgets while also accounting for beneficial medical innovations.
- The pharmaceutical industry tends to develop therapies in clinical areas of high unmet needs, specialised care, or ones requiring complex manufacture. Such innovations may come with a price premium that could add stress on cash-limited health budgets.
- To prepare for upcoming pharmaceutical trends and developments, healthcare policy planners should maintain a dialogue with pharma to maintain situational awareness.

Healthcare remains a costly enterprise. Healthcare either may be funded by governments (through taxation income), by health insurance providers underwritten by governments, or by a combination of these. Capitation-based fees for consultation and a capped contribution to drug costs may also be included. Additional 'private', 'out-of-pocket', or 'self-funded' funding models exist outside this structure and are rarely considered in the context of pharmaceutical development.

The stresses and strains burdening healthcare systems arise through many factors. These factors pressure healthcare budgets exacerbating funding issues and furthering the strain on healthcare.

These factors inter alia include:

- Longer life expectancy
- Higher incidence of chronic conditions like diabetes
- More medical screening across diverse disease areas
  - Screening obligates healthcare to treat patients who may not have presented for treatment and need ongoing

surveillance. Surveillance of disease progression for treatment has a cost. The strategy of 'wait-and-see' only avoids the drug cost.

- Advances in:
  - Imaging and diagnostics through sophisticated and costly technologies
  - Surgery through new equipment, like robotics for hip replacement
  - Therapeutics
- Diversification into 'digital' services
  - These include virtual consultations, virtual coaching in surgical techniques by skilled surgeons training remote surgeons, virtual access to a senior clinician for advice, management plans, and treatment proposals.
- Development of algorithms that drive management frameworks based on evidence and best practices
  - These may lead to AI developments and implementation.



These factors increase the challenge for healthcare professionals planning and delivering services within cash-constrained healthcare systems. In the past, healthcare systems were (mainly) inward-looking, planning and delivering services irrespective of pharmaceutical innovations and developments going on around them.

the pharmaceutical industry to push even harder to adopt new treatments through driving much bigger marketing spending and vocal promotion.

Suppose healthcare planners and providers develop a constant view of the landscape and the horizon of the pharma industry. In that case, they may gain a better situational aware-

## Healthcare policy planners require a fundamental shift away from internally focused dialogues and discussions

The life sciences and pharmaceutical industries comprised an external influence promoting the uptake of new therapeutics, devices, expensive imaging systems, and novel interventions. Healthcare budgets could quickly become overwhelmed if every clinician adopted every new asset launched into the market.

Thus, the need to consider healthcare evolved from a perspective of ‘setting priorities’, specifically termed to avoid using the ‘R word’ – Rationing. When is rationing not rationing? The answer for healthcare planners is when it’s ‘setting priorities’.

‘Setting priorities’ can be integrated into the early-stage planning before any asset receives regulatory approval. In the past, regulatory approval was used as a defensive wall, blocking the adoption of expensive new treatments. This strategy was intended to keep healthcare expenditures within cash-constrained budgets and negate the life science and pharmaceutical industry’s powerful promotional and marketing forces.

### How Can Healthcare Become Better at Planning and Delivering Healthcare or Optimise its Planning?

Healthcare policy planners require a fundamental shift away from internally focused dialogues and discussions.

My suggestion is for healthcare policy planners to take on a greater external focus – to be aware of and cognisant of the life science and pharmaceutical industry’s direction. This might be akin to forming healthcare providers/pharma partnerships to have earlier awareness of new developments before they surprise budget committees. And let’s face it, who likes surprises anyway?

And how do we react to surprises? We tend to be defensive, precautionary, and apply a set of brakes to slow down the adoption of new products and technologies, which causes

ness that helps in the healthcare planning and delivery for today and tomorrow. I liken this to a pilot using a radar mechanism to create awareness of potential issues along the way.

### What are the Pharmaceutical Development Trends?

To answer this, one needs to see where pharma ‘was’ and where it is ‘going’.

Where pharma ‘was’, put simply, the industry was focused on two main types of conditions:

1. Lucrative chronic disease areas like hypertension, asthma, diabetes, dyslipidaemia, etc.
2. Acute conditions like infections, dermatology, etc.

### Where is it Going?

The pharmaceutical industry changes the trajectory for its R&D as diseases and pathological processes are better understood. We now know of immunologically-driven conditions, conditions resulting from gene defects or gene absences, and other new pathologies. There’s a need to shift from empirical treatments to a more personalised healthcare agenda where a patient’s treatment is tailored based on genetic markers, as found in breast cancer, to determine the optimal treatments.

It is hoped that this greater understanding shifts us away from a metaphorical Arnold Schwarzenegger in the movie ‘The Terminator’, with his Austrian accent and ‘Uzi 9 millimetre’ spraying everything with therapeutic bullets in the hope that one or more hits the disease. The therapeutic approach in a personalised healthcare plan shifts toward that of a pharmaceutical sniper’s rifle: shooting one shot that hits the target.

One example might be a breast cancer patient treated with hormonal manipulation but whose tumour is not hormonally-dependent [oestrogen-receptor negative]. This may result in the tumour progressing and metastasising.

Adopting a gene-based treatment (the single shot, single



bullet from the medical sniper) in this personalised health-care plan would be the treatment of choice, rather the routine standard-of-care which calls for hormonal manipulation.

The pharmaceutical industry is now divided into two basic camps:

1. Innovator R&D-based companies, who spend and take risks to discover, develop, and commercialise new treatments and breakthroughs
2. Generic drug companies, who do not spend and take those risks; 96% of R&D fails to deliver a new product due to failure across one of the development stages

survival time and reduce mortality.

Often drugs that fulfil the first aim may have no result on survival – thus leading to an unmet need – a need to increase survival. There are many areas of medicine with unmet needs. These are just two examples. Clearly, for a pharma company to succeed, fulfilling unmet needs is high on the selection register for which assets to invest and which to cease development. Pharmaceutical companies can charge a premium when they fulfil an unmet need as the candidate offers clinical benefits over-and-above current treatment. Ideally, these change the direction of disease and outcomes rather than

## As users of innovation, it pays to be engaged with these pharma partners (to understand) where best practice and evidence are shifting. Forewarned is forearmed

This second group of generic drug companies are sustained by copying the originator R&D and undercutting the innovator. They can wait for patent expiry and copy the products cheaply (thus avoiding development costs and risks). Or they can challenge innovators' patents to make generic copies early. In doing so, they risk litigation from the innovators for copyright and patent breach. One result of this litigation is that they are paid off to delay the launch of the generic.

Healthcare planners should look at the innovation landscape of the first (R&D) group of pharma companies.

The focus for Big Pharma R&D will revolve around the following:

1. Clinical areas of high unmet needs
  2. Products with a complexity factor in their manufacture
- Let me explore these further.

### High Unmet Need

Simply put, clinical areas of high unmet needs are where no medical treatment exists.

For example, orphan diseases and rare disease areas are where R&D does not prioritise new development because of such low global patient numbers. Return-on-Investment and development risks make these commercially non-viable for some companies.

But there can also be unmet needs in areas with many treatments, like oncology.

Many cancer treatments may fulfil one aim of treatment. This could be cancer tumour size reduction, reversal, or arresting growth.

But as people with cancers inevitably die from the disease or complications, another treatment aim could be to increase

survival time and reduce mortality. Hence, Big Pharma R&D has a focus on unmet needs.

### Move into Specialised Care

The pharmaceutical industry sees the healthcare audience as Primary Care and Specialist 'Secondary' Care. The first point of contact for a patient is primary care. In the UK, primary care consists of the NHS's General Practitioners (GPs), of which there are approximately 52,000 in the UK in 2020 (Statista 2021). That figure has increased from 39,000 in the year 2000 to 52,000 in two decades. As a frontline service, the GP acts as prescriber and gatekeeper for services and products in the NHS. For marketing purposes, that is a large group to target.

GP prescriptions tend to be categorised as 'high volume/high margin'. So, each GP might only raise twelve prescriptions a month for a new antihypertensive treatment. However, the value of prescription sales becomes big when enough GPs are convinced to make these prescriptions by a large number of representatives in the salesforce.

This model's downside is that, as medicine becomes more specialised and personalised, the GP relies on experts in the hospital to direct and guide him on best treatments. The UK has around 124,000 hospital doctors spread across all specialities. But splice that figure by speciality, and there are around 1,500 consultant-grade clinical and medical oncologists employed by 62 cancer centres in the UK in 2019 (The Royal College of Radiologists 2019).

Oncology is an area where (1) treatment is determined by a specialist in the secondary care setting, and (2) the cost of drugs is high. We can call the model 'low volume/high margin'. If a treatment cycle costs \$3,000 per patient, the number of



patients on an antihypertensive treatment at \$10/month to generate \$3,000 is considerable. Furthermore, many of the primary care products have lost patents. For an R&D company, they see a fraction of the new opportunities in primary care – the bulk going to cheap copycat generics.

Unsurprisingly, pharma is moving into the less crowded specialist care setting with high priced products and biologics reflecting the R&D investment that has gone into them. Healthcare planners and providers must be cognisant of this as a potential source of pressure on their budgets. But earlier surveillance and dialogue with the industry can enable them to plan for the managed uptake of new drugs in the personalised and specialised care agenda.

### Move into Complexity of Manufacture

In a bid to exploit the patent life to the fullest and beyond its expiry date, planners and healthcare professionals need to be aware that pressure on their budgets may not decrease as much at the patent expiry of expensive specialist care products. This may be due to the complexity of the manufacture and formulation technique in some of these products.

Examples may include a specialised dedicated aseptic plant to manufacture just one line of product to prevent cross-contamination. Or it could be a formulation such as a sustained-release system that is not easy to copy.

Many high-end cancer treatments are biologics and not easy

to copy by generic companies that make the copycat product – termed a ‘biosimilar’, not a ‘generic’. The choice of biosimilars tends to be small, and the prices may still be high but less than the innovator drug.

### Conclusion

The message for healthcare planners and delivery is to engage early with pharma to understand their trajectory. And then to consider how one might manage to adopt these in a controlled manner rather than with knee-jerk defensive stances and being caught by surprise.

There are areas within medicine where for a planner for healthcare services, it is quite possible to ‘rob Peter to pay Paul’ within the current budget where there are clear outcomes and impacts across a large group of patients. As users of innovation, it pays to be engaged with these pharma partners and know where best practices and evidence are shifting. Forewarned is forearmed.

### Conflict of Interest

None. The author is not a director or board member of any life science company and has not received any sponsorship from any private or government body to write and publish this article. This article is the author’s own independent work sharing his experience and personal thoughts and opinions. Other viewpoints also exist to the themes covered. ■

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