

Say What? A Look At the Issues of 2008 and What it Means for 2009

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Pangaea Consultants was recently asked to provide the members of CAHR with a retrospective on 2008. Rather than focus on a list of events, we decided to gather insight from those in the trenches on their issues from 2008 and their expected impact for 2009. We selected a senior manager from: government, brand and generic pharma, as their concerns are likely to be the most topical and displaying them in the same place could be enlightening. The selected representative from each of these groups holds a senior, strategic role and responded under the condition of anonymity. Here is what they said.

We decided to put our government policy-maker's responses first, given that in many ways, reimbursement starts and ends here.

1. Sustainability - The new drugs are changing the way we evaluate price: effectiveness.

Ultimately, this means we need to take a firm look at whether we should pay for every drug. There is already too much pressure on payers, prescribers and even consumers without looking at how therapy fits into a well-defined treatment plan. To reduce this pressure, we need to look systemically at drugs to better evaluate their role in the therapy of a given condition. At the same time, the industry needs to help us to do this as it is in their interest. A good example here is the growing list of oncology drugs. Cancer is gradually shifting from being a death sentence to being a chronic condition, yet the companies still want to charge 'acute care' prices for these drugs. As the number of patients goes up, partly due to improving survival rates thanks to earlier detection and better care (including from drugs), the industry needs to take new and innovative steps with costs to make sure that we can sustain treatment. Ultimately, pharma must adjust from being 'of the system' to being 'in the system' if they want to achieve their objectives going forward.

2. Citizens are shareholders, not stakeholders

Patients need to play a more proactive role in the treatment of their condition. It is not so much about adherence as it is about informed participation. For example, how often do you see education on diet and exercise, versus education on the latest oral anti-diabetics or cardiovascular therapeutic agent? It is critical that we get the patient involved and that all of us make commitments to improving patients, just as we make commitments to improving drug treatment.

3. Safety – the formularies have become the unofficial guardians of safety in Canada

There is no doubt that the brand drug industry continues to develop and design increasingly effective products, but their 'carpet-bombing' sales effort causes many drugs to become overused thus overstating the risks of what are otherwise highly beneficial drugs. Branded pharma needs to shift away from the 'home-run' mentality of

past years and do a better job of positioning drugs more realistically in therapy and protecting their role there. If not, we are likely to see more of the costly, high profile withdrawals that adversely affected their credibility. While the regulators are stiffening up and we now have emerging approaches to licensing such as the progressive licensing framework, which is essentially field evaluation that then puts resulting evidence back into the application, we need to work with pharma to shift their mindset about their current 'regulatory-sales model'. We don't want to lose effective new drugs; we want them to be used better.

4. The increased demand for real-time information sharing is growing

Whether we like it or not, the best source of information is undoubtedly the manufacturer. The drug companies have massive expertise in disease management but the concerns about biased information limits their ability to disseminate it. Going forward, we need to work together to build a robust health informatics capability (HIC). This HIC would incorporate the advances in technology we have experienced in the last decade along with leveraging the expertise of the best clinicians available so that patients and professionals alike would get the information they need with the click of a button. We need to support efforts from industry to move away from the face-time sales model to supporting the delivery of the industry's vast pharmaceutical knowledge base to the people that need it, when they need it. With the increasing sophistication of drugs, this is becoming more difficult to do, however, the impacts would be highly positive for industry, prescriber and patient alike. The walls of us versus them would be lowered, and meaningful information within context would allow everyone involved in healthcare to perform better.

5. Generics have had a free ride for too long, grown lazy and their sales practices now hold them hostage.

They have never viewed us (the payers) as their customer despite the fact that their only competitive feature is price. They are still married on to the 70% of brand pricing approach and are only now reluctantly moving to 50% in some places. The 'jig is up' and they have been caught because big pharmacy is now more potent than they are and their model is difficult to change given that everyone's back pocket is occupied. As payers we have had enough and while we are likely to see new legislation about price differences, it would likely be in the best interests of generics to improve their working relationships with us. Ultimately, a change in the retail pharmacy business is coming as the current business practices scheme is time-limited.

Seeing as brand drugs are the first to come to the market, we thought our brand pharma participant should take the next turn:

1. The current reimbursement system does not deliver timely access to new medications

We are experiencing a continuing high proportion of 'no' decisions with a few restrictive 'yes' decisions. With the recent House of Commons health committee report as a basis, stakeholders will continue to work towards evolving a less adversarial, more transparent business relationship with the review groups and payers. The goal will likely shift from reflexively driving for full unrestricted access, to identifying specific opportunities where our products deliver particular value and then ensuring access remains open within those constraints. Ultimately, we need to improve at creating

valuable opportunities for payers and support them in their management of the system. The faster we learn to work together, the better off both sides will be.

2. Data quality is not always adequate for payer needs, especially since the increasing focus on specialty pharmaceuticals is drawing smaller groups of patients to be studied from smaller disease groups

There are a lot of inherent challenges with this, given that the sands of data requirements are often shifting on what needs to be provided. Additionally, many trials of the new drugs, especially those for smaller populations, cannot be expected to deliver on the end points being demanded by evaluators. Ultimately, the dialogue around payers' needs for data and how we can meet those needs must increase going forward with the result that companies will want to involve payers at an earlier stage of drug development. In the end, it is hoped that earlier and better dialogue will help build an understanding around the common goal of ensuring that patients can benefit from new medications.

3. The current yes/no framework for role in therapy decisions can unnecessarily limit patients' access to therapy

Ultimately, this issue will likely be the next to be addressed depending on the outcomes of our efforts around our first issue. The industry will have to develop more robust approaches for defining role in therapy and work closely with CDR, JODR, and payers to confirm where drugs are appropriate or inappropriate in therapy and then commit to staying within the restrictions of the reimbursement conditions. The goal would be to shift away from the outright 'No' recommendation to conditional reimbursement for specific situations where a product is appropriate. In its essence, companies should look to move the dialogue from a yes/no discussion to one that is focused on defining the place in therapy where the drug is cost-effectively used supported by educational efforts from the company.

4. We need to better understand the late life-cycle opportunities for our legacy products

This is a much more complicated issue than it sounds. It may be beneficial in the near-term to compete with generics on multisource medications for large scale contracts such as we have seen in Ontario. However, the industry needs to work with payers to ensure these savings can at least in part be dedicated to funding new medications which will always be the life-blood of the industry.

5. Our commitment as an industry to engage governments on partnerships to preserve Canada as a favorable destination for research and development must be increased

Despite the recent downturn in the economy and the transitional state of the industry with many of our products coming off patent, it is critical that we work to ensure that Canada remains a competitive destination in the fight for R&D investment at a global level. With other jurisdictions becoming lower cost destinations for R&D investment and with many global companies looking to achieve more effective R&D spending, Canadian industry leaders must continue to engage governments on new joint pharmaceutical policy initiatives to ensure Canada is well positioned versus other nations.

Finally, generic pharma gets their turn to close things out here is the perspective and prospects of our generic pharmaceuticals participant:

1. Global tendering trend transferring to Canada

Under tendering models price compression would be pushed to a level that could compromise the surety of supply for the majority of medicines Canadian patients depend on. Currently the majority of medications prescribed in Canada are manufactured by Canadian-based companies. But for the sake of insignificant savings in the context of overall health spending, governments and other payers are putting this secure supply at risk. Further, these government policies will result in the devastation of a strong high tech research and development segment of our economy, the loss of retail pharmacy services which are subsidized by generic manufacturers, and ultimately the transfer of costs back to the payer. Potentially, we could lose pharmacists the same way we lost doctors not so long ago. If the system is to change, all parties must work together to develop a Canadian solution that ensures value while balancing impacts.

2. The value that generic drug manufacturers provide is not well understood

Generic manufacturers provide considerable value to the Canadian health system. By challenging patents we bring generic products to market sooner than would have otherwise occurred, saving public and private health plans hundreds of millions of dollars. Further, through professional allowances generic manufacturers subsidize critical frontline pharmacist healthcare services; services which are not fully compensated under existing drug plan programs.

3. Aggressive and persistent Rx&D lobbying of federal officials to extend patent life

Inappropriate legislative changes are being made to patent and NoC rules, and further are being lobbied for by big pharma, that will extend brand monopolies in Canada well beyond appropriate time frames. The effect of this monopoly extension offsets any potential savings created through generic drug pricing changes, creating massive incremental costs to the system with no added benefits.

4. The generic industry has not staked a claim with payers that we are a solutions provider

Unfortunately, and I think incorrectly, the generic industry is seen as a part of the problem of health care sustainability and not as part of the solution. Going forward we have to change our dialogue with government (and private payers) from 'We (government) have a problem with you (generic manufacturers)' to 'We have a problem, how can you help.' It is imperative that we shift our position in the mindset of policy makers to that of a key solutions partner in the sustainable provision of healthcare.

Looking at what they said, what struck us were the common themes of each perspective. These may well lead to the possible insights that we are all looking for as we move into 2009. There is clearly a common understanding that all efforts must be directed towards maintaining a sustainable system in the face of mounting costs, despite disagreement on how this can be achieved. All parties demonstrated an objective, in one way or another, to improve dialogue on the use of knowledge, adapting product role in therapy and the willingness to partner in a more open and transparent environment.

In the coming year will we see both brand and generic drug makers address their stated issues of improving dialogue with payers? Will the payers be able to work openly towards partnering frameworks of reimbursement that address the needs of both manufacturing groups in terms of allowing the right drugs to be delivered at the right time in therapy to the right patients, without compromising either the supply of product or safety. Will we see the beginnings of an end to the absolute 'No' to so many new products?

While some things are unlikely to change, such as the perennial battle over the 'right' patent life, we may be coming to a point where all parties, recognizing that they can work together, start opening up constructive dialogue beyond the submissions/reimbursement process and start looking at how they can work cooperatively to improve the system we all live with. Based on these discussions, 2009 looks to be a watershed year, not only in terms of the unprecedented willingness to collaborate on the very high stakes game we play in, but also the potential fallout over research, manufacturing and retailing in our industry. Maybe next year our panelists will agree to be interviewed at the same time in the same room, perhaps as some sort of coalition, then again, maybe not...

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