The supplier perspective

How does the generics industry typically plan supplies and what is the impact of existing EU tender and purchase practice on secure supplies?

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How do we plan supplies?
Forecasts

- Forecasts – pivotal to manufacturing and are based on RUN RATE and future EXPECTED demand.
- Change with the best information
- Are not fixed but are a guide
- Create awareness of potential demand
- ARE LOCAL MARKET BASED

Sales Reporting

- Help shape understanding of underlying demand
- Useful Indicators of future demand.
- Must get appropriate level (ex-factory, wholesaler etc)
Demand Modelling

- Aggregates ALL RELEVANT information together including
  - Sales & Marketing Intelligence (e.g. competitor out of stock)
  - Forecasts
  - Batch Sizes
  - Lead time (manufacturing and delivery)

- Generates a proposed order for stock which links to procurement processes

Procurement

- Take demand order output and place orders both internally and externally for API, excipients, packaging materials (vials, capsule shells, foil, leaflets, cartons)
Manufacturing

- Check Demand orders against Manufacturing capacity and slots
- Set production schedules
- Receipt all materials required
- Manufacture products

QC release

- Critical part of the process – this provides the Certificate of Analysis to enable sale
- Can either be in house, external or even in a different country to production
- All product arriving from outside of the EU requires additional QC certification
Supply Chain Management

- Arranges product to be shipped to appropriate location – own warehouse, pre-wholesaler and/or wholesaler
- Maintains integrity of supply chain e.g. temperature
- Monitor shipments & liaise very closely with Demand Management

Key Challenges
Tender staging

- A challenge on alignment of tenders

- Many tenders start on 1 January and start congestion impacts on manufacturing/capacity/API availability/supply chain
  - Tension of sites where injectables are made (capacity, lead times)
  - Effect on shelf life
  - Availability of API & other materials

- In England, there is a proposal to align all hospital-only contracts away from rolling regional tender framework

Lead-times

- Tenders are often scheduled, pushing together the following
  - Submission date of tenders
  - Award date of tenders
  - Start date of contract
  - Time to first supply

- Little or no discussion from Contractor Authorities to Pharma Companies as to lead-time of production/supply

- ...And there are numerous tenders across Europe, some countries organise tenders every couple of weeks

- ...This creates huge workload, congested activity and demands product within timeframes which are not always credible or sustainable.

- IDEALLY 4-6 MONTHS LEAD TIME TO START OF SUPPLY WOULD BE APPRECIATED
Length of Contract

- Length of contract being awarded
- Too short, not attractive enough either financially or will not consume batches
- Too long may make products not sustainable as a company where we also supply price eroded markets (we can’t sell products below cost)
- Long contracts also limits out competition and bidding opportunities

No obligation to supply, but often penalties are disproportionate

- In some countries like the UK, a supplier wins the opportunity to supply whatever the demand is; it is not fixed
- But despite the lack of a fixed amount, many payors apply disproportionate damages if a supplier cannot supply, even if demand is more than predicted
- So poor estimates, and more dispensing creating weaker data is expensive!
- This risk imbalance affects decisions to tender
- An old example of Actavis weighing up whether to tender for a product in 2/6 English regions

<table>
<thead>
<tr>
<th>Contract Price</th>
<th>List Price of originator</th>
<th>Annual Revenue</th>
<th>Penalty for 1 month out of stock</th>
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</thead>
<tbody>
<tr>
<td>£20.00</td>
<td>£162.76</td>
<td>£672,000</td>
<td>£400,000</td>
</tr>
</tbody>
</table>
Global Manufacturing

- Global Manufacturing practices
  - Possibly one API manufacturer GLOBALLY
  - One site per company (or a number of companies) that can make a drug
  - Rationalisation of global manufacturing estates
  - Time to market

Ultimately, one size does not fit all

- Tendering for an aggregated demand works for many products
- But one size does not fit all
- Some products require more clarity around procurement, others common in primary care could prosper in a free market
- Some products may warrant longer contract lengths or lead times than others
- E.g. Should a low volume, difficult to manufacture product be procured like paracetamol?
- Categorisation, based on characteristics
Legal and Regulatory

- Litigation by originator companies is delaying tenders and forcing companies potentially to discard/write off products due to shelf life or packaging issues
  - Happening currently in the UK, many millions of Euros of drugs unable to be tendered
  - Requires additional resource to promote products

- Drug Registration process becoming more complex which aids ‘tender blocking’ tactics

- Payor does not recognise potential savings and we evolve into a system of less communication

One Plea = Talk to Us!

- If tender structure changes are happening, talk to the local Trade Association to seek feedback on impact

- If drug-level prescribing policy may change, alert the supplier and prevent out of stocks

- We’re experts in what we do and we can help better shape any changes
Thank you...any Questions?

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