



SIGMA
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PHILIPPINES
CONFERENCE 2020

Seeing things Clearly

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HDA uk

Current key issues and long terms trends in Healthcare Distribution

The backbone of NHS medicines supply

- 54 MHRA fully validated cold & ambient warehouse locations, with CD stores
- Delivering 90% of NHS medicines – 2.4billion packs per year
- Full range of products – 25,000
- 250,000 deliveries per week across the 4 countries of the UK
- All sites fully audited and compliant to GDP
- 24-hour emergency supply
- Dedicated account management
- Bespoke customer service teams
- On-line management & ordering functionalities
- Full e-commerce capabilities
- Single packet to full pallet capabilities
- Undertaking medicine recalls on behalf of MHRA
- 'End-to-end regulation'



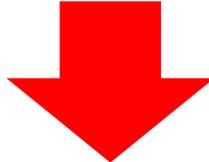
Who we are



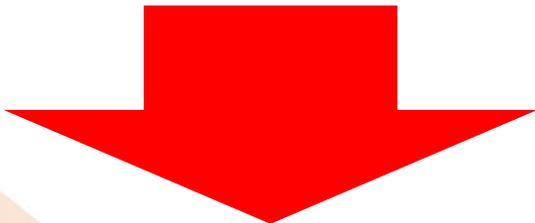
Seeing things Clearly



**1250
manufacturers**



9 HDA distributors



**14,200 pharmacies + 330 hospitals
+ 2,000 dispensing doctors' practices**



The Association

OUR MISSION

Building awareness, understanding and appreciation of the vital importance of the healthcare distribution sector.

OUR VISION

To enable a safe, secure and efficient medicines supply chain that ensures patients get the right medicine, in the right place, at the right time.

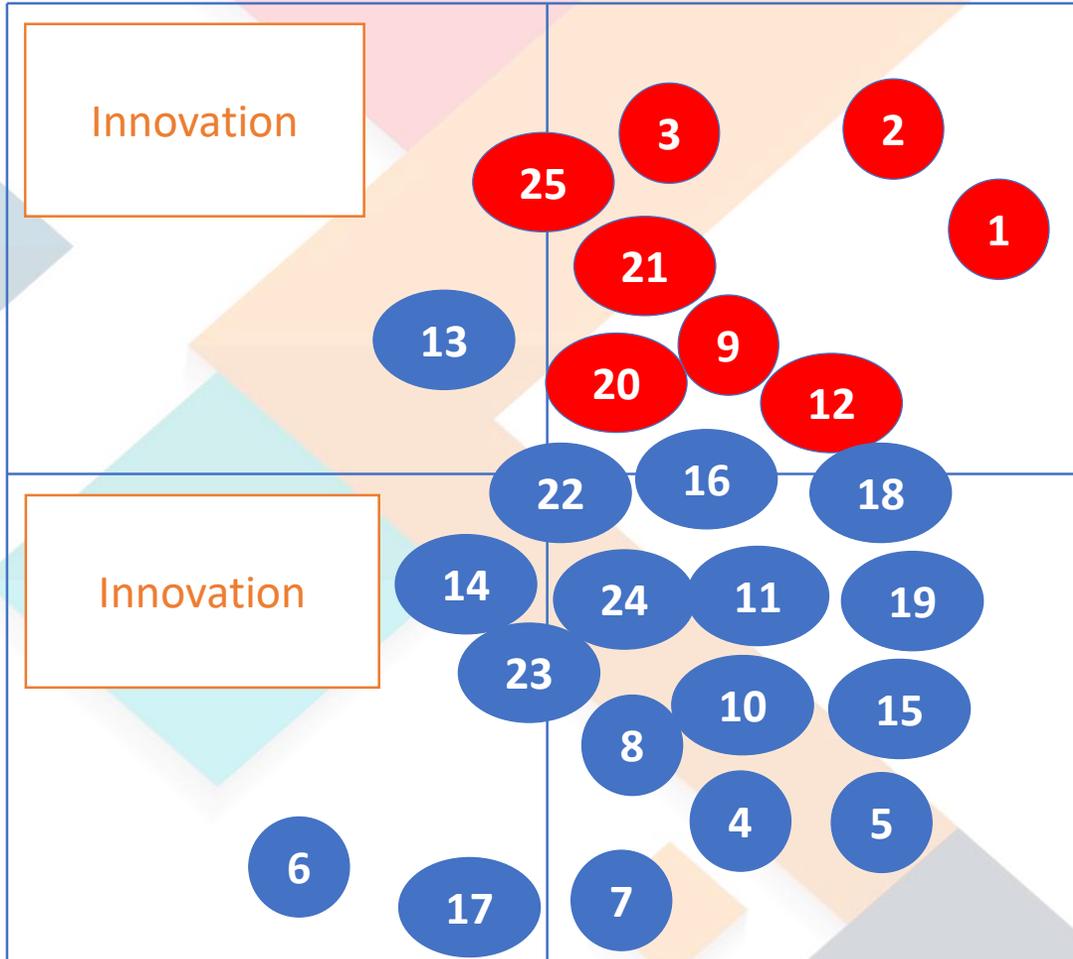
OUR ASSOCIATION

The voice of the industry

Leading the debate, discussion and strategy of the ever evolving healthcare distribution sector.

Our sector

ABILITY TO INFLUENCE



1. Regulation driving up costs
2. Government appreciation of the supply chain
3. Supply chain stakeholder understanding of the sector
4. Shifting NHS policy and funding
5. Squeeze on manufacturers on price
6. Availability of labour and wage rises
7. Changing product mix
8. Environmental issues – pollution, waste
9. Increasing transport costs and regulations
10. Higher priced products not going through wholesale
11. Manufacturers reducing pence per pack
12. Inconsistent application of regulation
13. Over servicing of the sector – twice a day by multiple wholesalers
14. NHS efficiency drive
15. Flat community pharmacy market
16. Growth in the hospitals' market
17. Splitting of market – high vs low value products
18. Online disruptors and unintended consequences
19. Downward pressures on margins
20. Upward pressures on costs
21. Information regulations leading to full transparency
22. No joined-up plan for the factory to patient medicine journey
23. Investment decisions vs network design
24. All growth is occurring outside of the wholesale sector
25. Lack of innovative; embracing new technologies – an old-fashioned image

The current landscape

- Economic pressures - wages, consumer spending/Brexit/uncertainty
- Decrease in high-street footfall
- Massive growth in online
- Retail pharmacy is in crisis- E&Y report
- New pharmacy contract is challenging
- Pharmacy + wholesaler margins under pressure
- Increased red tape and bureaucracy
- New models are evolving – eg: hub & spoke but.....



No clear road-map

Pharmacy - a change in relationship

Then

Focused on pharmacy
Pharmacy loan book

£ direct support
Personal relationships
Feedback loops

Highly flexible

Business + social engagement

Now

Focused on suppliers
no direct financial
support

£ professional chains
transactional interface
less listening - more
telling
less flexible

business engagement
only



from partnership to transactional

Our key current issues

A strategic approach to the 'shortages issue'

- Support for the pharmacy sector
- FMD/MDR?
- Hospitals - national KPIs
- Medicines & Medical Devices Bill – incl. hub & spoke, online pharmacy

- Temperature-controlled transportation
- Security & integrity of supply chain
- Increased scrutiny
- More collaboration

Shortages... 'frustrating... time consuming... unfair...'

Some Key Observations

- In the 12 months to January 2020 there were 178 recorded shortages versus 52 to Jan 2019
- 75% are caused by manufacturing issues
- There is a real lack of visibility by all constituents
- Generic shortages are market sensitive (trading)
- Trading, repeat ordering, skimming and stock-piling accentuate the problem
- Vertically-integrated chains - no preferential treatment
- It is a Europe-wide issue (more than 600 in Switzerland) - a major priority for GIRP
- The issue is incredibly patient and media sensitive



What are we doing?

- Working with manufacturers on ordering algorithms
- Managing order quantities - regulating usage, account profiling
- Issuing out-of-stocks lists - although pmr coding is still a major issue
- Communicating with all regulatory stakeholders and adopting protocols on specific issues (g Epipen/methadone)
- Fulfilling orders as soon as stock becomes available
- Raising the issue persistently with all stakeholders and DHSC
- Working to improve education and communication



HDA Availability Infographic



This document aims to dispel some of the myths surrounding issues of availability of medicines and what causes them and highlight some of the initiatives HDA members take every day to mitigate supply problems.

All HDA members take any disruption to the supply of medicines to patients in the UK very seriously and are determined to tackle these availability issues.



There are many factors which can have an impact on the availability of drugs. These can occur at different points in the supply chain as follows: **ISSUES** **INITIATIVES** The HDA and its members work closely with supply chain partners to mitigate supply challenges and reduce the number of drug availability incidents:

INTRODUCTION

As part of the HDA's mission of building awareness, understanding and appreciation of the vital importance of the healthcare distribution sector, we commissioned a research study of the views of our supply chain stakeholders of medicines distribution.

The availability of medicines was identified as a key concern and as a result, the Association has pledged to lead the debate and discussion of the topic. This infographic is a key part of this strategy, as explaining the supply of medicines, and in particular the factors that can impact medicine availability, will hopefully provide reassurance that distributors are doing all they can to enable a safe, secure and efficient medicines supply chain that ensures patients get the right medicine, in the right place, at the right time.

FROM FACTORY TO MANUFACTURE	FROM FACTORY TO DISTRIBUTOR	AT THE DISPENSING POINT	OVERARCHING ISSUES	INITIATIVES
<p>Active Pharmaceutical Ingredient (API) shortages Medicines availability can be affected by sudden increases in demand or quality and raw material (API) problems prior to manufacturing.</p> <p>Unforecasted demand The UK (and non-UK) demand for a specific drug can increase beyond expectation or production capacity - for example if production of a medicine from one manufacturer fails and another has to suddenly pick up the unforeseen demand.</p> <p>Good Manufacturing Practice (GMP) licences Businesses must hold a licence to manufacture pharmaceutical drugs - this licence can be revoked or suspended by the regulator.</p> <p>Batch release failures If a batch of drugs fails to be released against their approved product specification, this can lead to an unexpected and sudden reduction in the supply of that product.</p>	<p>Competitor products out of stock If a product suddenly goes out of stock this can place additional pressure on the demand for substitutes.</p> <p>Manufacturer return on investment If the price achieved for a medicine falls too low, a manufacturer may decide to pull out of the UK market.</p> <p>Import / Export problems Strikes, or delays at entry points into the UK, can disrupt deliveries to the distributor.</p> <p>Exchange rate changes Medicines may be exported for sale abroad to take advantage of exchange rates, reducing UK available stock. Imported medicines can become more expensive, causing cost pressures which can affect availability.</p> <p>Global consolidation Medicines manufacture has consolidated into fewer global production sites. If one of these sites had a supply issue, it is difficult to switch supply.</p>	<p>Licensing changes If a drug is reclassified as a controlled drug, the increased regulations that accompany the reclassification could cause availability issues in the short term.</p> <p>Tendering Tenders for the supply of medicines can cause issues in some cases, as competitors are locked out of that particular market for the period of tender.</p> <p>Change in patient population A sudden change in patient demographic can cause an availability issue for particular medicines.</p> <p>Stock management Irregular ordering, last-minute surges in demand, or procuring, can lead to availability issues.</p>	<p>Stockpiling / speculation Medicines stockpiling or hoarding, at any point in the medicines supply chain, can contribute to availability pressures.</p> <p>Diverting stock to other countries Some supply chain players may consider diverting medicines to other markets which offer an increased margin compared to the UK.</p> <p>Disease pandemics If there is an unexpected pandemic, the demand for medications to treat this, and related symptoms, will increase exponentially.</p> <p>Weather Bad weather can impact the most efficient of supply chains, often on a localised basis.</p> <p>IT failures Everything is digitalised, IT failures can cause huge disruption in stock ordering, monitoring and controls at all points in the supply chain.</p>	<p>Working with regulators The HDA works with regulators to reduce the risk of availability issues arising from regulatory issues and by ensuring the most efficient and cost-effective supply chain system is in place.</p> <p>Collaboration with NHS/DHSC Often when a medicine is in shortage, HDA members work with CMO (NHS&A) and MST (DHSC) on jointly agreed mitigation protocols.</p> <p>Regulatory changes Alterations to supply chain regulations can temporarily reduce the availability of medicines.</p> <p>Acts of God Floods and fire can affect supply chain facilities, temporarily reducing the number of medicines available in the supply chain.</p>
<p>Active Pharmaceutical Ingredient (API) shortages</p> <p>Increased demand</p> <p>Batch release failure</p> <p>Good Manufacturing Practice (GMP) licences</p>	<p>Exchange rates</p> <p>Globalisation</p> <p>Export / Import logistics</p> <p>Manufacturer return on investment</p> <p>Disease pandemics</p> <p>Diverting stock</p> <p>Stockpiling / speculation</p> <p>Regulatory changes</p>	<p>Reclassification</p> <p>Tendering</p> <p>Competitor product out of stock</p> <p>Stock management</p> <p>Change in patient population</p> <p>I.T. failures</p> <p>Weather</p> <p>Acts of God</p>	<p>Stockpiling / speculation</p> <p>Diverting stock to other countries</p> <p>Disease pandemics</p> <p>Weather</p> <p>IT failures</p>	<p>2x day delivery</p> <p>24/7 service</p> <p>Emergencies</p> <p>Collaboration with NHS/DHSC</p> <p>Multi-sourcing</p> <p>Working with regulators</p> <p>Fast-tracking</p> <p>Forecasting & monitoring sales</p> <p>Generous returns regime</p> <p>Supply chain communications</p> <p>Building buffer stocks</p> <p>Investing in stock</p> <p>Managing stock</p> <p>Cascading</p> <p>Script validation</p> <p>Seasonal stock-build</p>

ABOUT THE HEALTHCARE DISTRIBUTION ASSOCIATION

The Healthcare Distribution Association (HDA UK) represents those businesses who supply medicines, medical devices and healthcare services for patients, pharmacies, hospitals, doctors and the pharmaceutical industry. HDA UK members operate across the four nations of the United Kingdom enabling a safe, efficient and high-quality supply chain for the healthcare sector. They are responsible for distributing over 93% of NHS medicines and provide wholesaling services including working capital, stock management and IT systems to their supply chain partners. The HDA and its members are at the forefront of the constantly evolving healthcare supply chain, which is seeking innovative practices and technologies to make new services possible for manufacturers and to those who dispense medicines, reflecting the needs and choices of individual patients.



Regulatory burden is increasing

- 2012 Govt Red Tape Challenge - fizzled out (250 MHRA regulations were to be reviewed)
- Shipping to label specs – temperature-controlled vehicles
- FMD and MDR implementation
- Information requests - DHSC/NHSE statutory and ad hoc
- Export controls management
- Responsible Person - introduction of import roles



Costs to our sector

£35M

- **Last 3 years**
- FMD *approx.* £8.75m
- Warehouse air cooling *approx.* £6.5m
- Temp monitoring equipment *approx.* £1.1m
- Temperature-controlled vehicles *approx.* £18.1m
- CD controls (due to expansions) *approx.* £775,000

- **Next 3 years (budget estimates)**
- MDR (dependent on new UK/EU relationship) *approx.* £350,000
- FMD (dependent on new UK/EU relationship) *approx.* £610,000
- Temperature-controlled vehicles *approx.* £19.2m
- Increased administrative burden due to DHSC data requests
approx. £480,000



Brexit planning... a major consumer of time and effort



- Interaction with the DHSC planning committees
- Stock-build planning (6 weeks)
- Evidence to Parliamentary committees
- Additional transport and freight planning
- Regulatory consultation on emergency supply/dispensing
- Data-gathering and analysis
- Contingency planning for clinical trials
- Shortages committee input
- Implementing Serious Shortages Protocols (SSPs)

Stakeholder feedback





Research objectives

- Analyse current issues relevant to participants and HDA members
- Understand more fully perceptions of the healthcare distribution sector
- Identify how the sector can best meet the expectations of stakeholders
- Understand more on which issues we can, and should, collaborate



Most important current health-care issues

- Manufacturers are focussed on Brexit and managing uncertainty
- **Pharmacists are focussed on their future role and funding issues-profitability and survival**
- Payors/regulators are focussed on funding, medicines availability and stressors



Biggest issues facing medicines supply chain by audience

Manufacturers

Shortages/supply issues for pharmacists/patients

- Availability of medicines
- Complex system, no easy solution
- Grey market, shortages

FMD

- A headache at first but good in the long run as makes easier to track and trace

Future model

- How will we distribute medicines in the future?
- Going from analog to digital world
- How can the distribution model remain relevant?

New delivery needs for new drugs and special circumstances

- Need for new mechanisms (cold chain)
- Getting medicines to remote areas

Pharmacists

Shortages/availability

- Has gotten worse over time
- The major frustration
- Lose time and resource dealing with it

Concentration of supply

- Vertical integration seen to create conflict of interest, with big players favouring their own retailers
- Single distributor model, hub and spoke, and quotas compound supply issues

(Perceived) market manipulation

- Widespread belief that wholesalers game the system to increase their margin – at pharmacists'/system's expense

Quality of customer service by distributors/wholesalers

- Call centres not able to resolve issues
- Lack of flexibility

Payers / Regulators

Continuity/availability of supply

- Suppliers failing to supply, impacting patients
- Grey market leads to shortages
- Using increasing/significant resource to manage the issue

Concentration of supply

- Single distributor model – doesn't work for us (want to buy from my wholesaler)
- A big driver of shortages

How to enhance role of community pharmacist

- Working to find ways to do this
- See it as a way to relieve pressure on other parts of the system
- Pharmacist is under tremendous stress, though

Q: Thinking about the entire medicines supply chain – from manufacturers producing medicines to patients using them – what do you think are the most important issues facing the medicines supply chain? (Volunteered responses; multiple responses allowed) (n=30)

Key areas of underperformance

- Transparency
- Being focussed on partner's needs
- Innovation
- Customer-service orientation
- Working closely with partners to address emerging issues (collaboration)
- Products available when and where needed



3 big themes emerge

INNOVATION

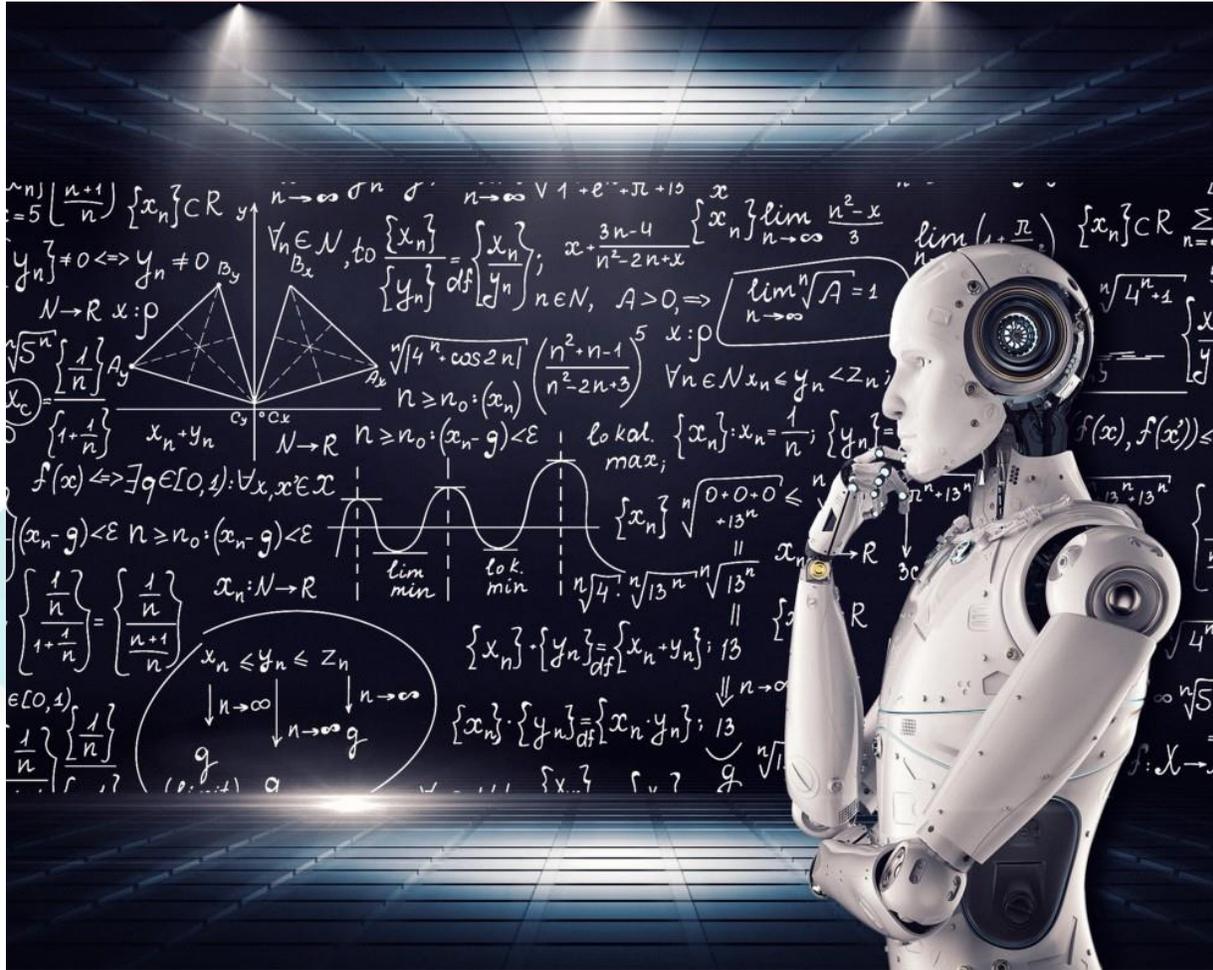
COLLABORATION

TRANSPARENCY

HDA re-connecting with independent pharmacy

- Working with the NPA on a service standard charter + customer service
- Pharmacy feedback forums (joint workshop tomorrow afternoon)
- Collaboration with pharmacy organizations on ideas to support independent pharmacy
- Continuation of shortages work - specifically communication and education
- Continued government joint lobbying on behalf of the industry
- Continued media interaction on current issues within healthcare sector
- Leading thinking on innovation and developing trends

Future trends



Multiple spheres of influence

Competition
+
Collaboration



Potential developments

- Integrated technologies
- JIT manufacturer-to-patient
- Fully-automated warehousing
- Online ordering and fulfilment
- Wholesaler apps
- Drone deliveries
- Integrated data suites
- Multi-wrapper solutions



The healthcare
distribution
space is ripe for
DISRUPTION

amazon.com

“Fears for the future of local pharmacies and warnings over patient safety have been raised after documents showed Amazon is eyeing Britain’s pharmacy market.

The online giant this month filed to register the name Amazon Pharmacy in several countries including the U.K

In documents submitted to Britain’s intellectual Property Office earlier this month the company applied to use the name Amazon Pharmacy for a number of products and services including pharmaceuticals, scientific research and medical devices”

HDA work on innovation

Collective promotion

Case study-led communication

Data

Analyse existing data for mutual beneficial conclusions

Facilitation

HDA to convene supply chain around the topic of innovation

Data

Standardised format for data reporting

Thought Leadership

Proactively adopt forward looking standpoints

International best practice

Identify and disseminate new innovations and best practice

HDA work on supply chain disruption

Specialties

Develop standards to integrate specialties into supply chain.

Disruptors

Anticipate change and ensure GDP is appropriately applied

Changing pharmacy model

Promote distribution model changes to match shift to services

Economic Impact

Quantify and explain potential increase in costs

Online services

Develop industry standards for digital services

Supply chain collaboration

Partner with manufacturers to develop future models

Summary

- An increasingly challenging environment
- The relationship has shifted but.....
- It is vital to re-connect and work together
- Current issues are very real....but

**We continue to actively work on them.
We have listened to our stakeholders and
know what the key themes should be.**

- **The world will change faster and faster**
- **Innovation and disruption will be future challenges**



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