

# NorthEast Pharma

Solving critical supply: November 2020



## The need for UK API manufacture

- COVID 19 has identified weaknesses in the UK medicine supply chain
- Nearly 200 medicines were in short supply at the COVID peak
- 80% of these medicines are generic and sourced predominantly in Asia
- Many of these products, now generic, were once manufactured in the UK – e.g. Paracetamol
- The drive for low cost medicine prompted a shift to Far East supply options
- 15 years ago API manufacture in the UK was considered unsustainable
- Significant capacity was decommissioned – Dartford, Holmes Chapel, Huddersfield, Loughborough, Sandwich, Ulverston, Cambois (Penicillin), Avlon, Dudley (Paracetamol), Nottingham (Ibuprofen). Kent (Atricurium family and Foranes)
- Regulatory, Safety, Environmental and Quality issues have plagued Asian manufacture resulting in low confidence and a shift back to the West
- Limited Western manufacture now largely supports innovator space with high margin potential
- Western manufactures are in high demand by innovator space

How do we encourage  
western manufacturers  
to manufacture generic  
products?



## A new model for UK generic API manufacture

With limited capacity, why would current UK supply base consider low margin API generic business?

- **A new model to support supply chain integrity is needed**
  - Need to use and leverage
    - established skill base
    - safety and environmental system
    - established quality systems
    - existing utility infrastructure
    - collective skills and capabilities across North East companies
- **The proposal**
  - Build manufacturing capability on an existing site(s) dedicated to DS / DP manufacture for the NHS – 18 months £100M - £150M
  - Pricing model to be cost plus with long-term supply agreement
  - Establish and validate up to 25 API's (3 years)
  - Build appropriate strategic stocks
  - Employ novel manufacturing technology to drive productivity and reduce cost

## New NHS plant on an existing sites supported by multi company collaborative capabilities



## API (Drug substance)Development and Manufacture

North East Companies	Development	CPP	Analytical Development	Registration	Manufacture
High Force Research	✓	✓	✓		
Onyx	✓	✓	✓		
Arcinova	✓	✓	✓	✓	✓ (Niche)
Sterling Pharma	✓	✓	✓	✓	✓
Piramal	✓	✓	✓	✓	✓
Recipharm	✓	✓	✓	✓	✓

## Drug Product - Development and Manufacture

North East Companies	Formulation Development	CPP	Analytical Development	Registration	Manufacture	Packaging
Accord	✓	✓	✓	✓	✓	✓
Piramal	✓	✓	✓	✓	✓	✓
Arcinova	✓	✓	✓			
MSD	✓	✓	✓	✓	✓	✓
Wasdell Manufacturing Ltd.	TBC	TBC	TBC	TBC	TBC	✓

## Possible way forward

- Develop a portfolio of “in demand” products suitable for reshoring into NEPharma company consortium
  - Fully aligned with NHS, NuTH trust identified shortages
  - Based on critical need and supply chain fragility
  - Could be a mix of DS, DP and packaging
  - Likely to be small to medium volume
  - Likely to be medium to high cost
  - Fits with combined capability and technologies within NEPharma
  - Could leverage new technologies being developed within the NE – Cpi / Universities
- Once portfolio identified
  - Determine process, technology and supply chain requirements and complete feasibility on how this could be satisfied within NEPharma consortium



## Summary

- Proposal builds dedicated capacity to manufacture key generic products required by the NHS
- Provides a reliable and compliant solution with flexibility
- Cost plus approach providing cost protection to NHS
- Build on strong North East Pharma heritage
- Links to the well established innovation centres in the North East – CPI and Universities
- Creates high value employment in the UK
- Improves UK resilience
- Proposal is aligned to UK Life Sciences and North East England growth strategies
- NEPharma and NEPIC are being funded by grants from NELEP to further develop the proposal, recruit the consortium companies, prepare a feasibility study and develop a business case for submission
- The North East is well positioned to play a major role in stabilising medicine supply chains for the NHS

Thank you

