The Falsified Medicines Directive

What pharmacy teams need to do…

Alastair Buxton FRPharmS
Director of NHS Services
@ABuxtonPSNC

Overview

- Explain the FMD requirements
- How the authenticity of products will be checked
- The implications of Brexit
- The responsibilities of pharmacies and how it will work in practice
- Funding issues
- What contractors need to do now

The Directive

"Safety features should allow verification of the authenticity and identification of individual packs, and provide evidence of tampering."

Directive 2011/62/EU, Para 11

The Delegated Regulations

"**Persons authorised or entitled to supply medicinal products** to the public shall verify the safety features and decommission the unique identifier of any medicinal product bearing the safety features they supply to the public **at the time of supplying it to the public**."

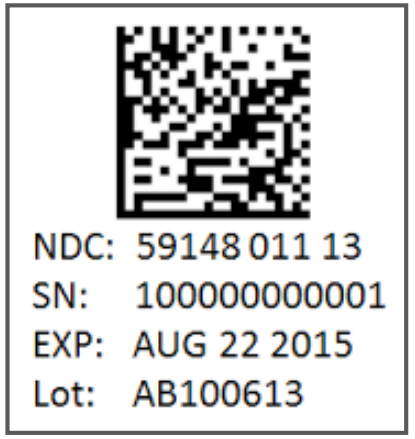
Delegated Regulation 2016/161, Article 25(1)

Implementation must be undertaken by

Saturday 9th February 2019

The two safety features

- All packs of almost all **prescription medicines*** will have to have two safety features:
  - Visual **anti-tampering device**
  - **Unique identifiers** (serial numbers) plus product ID, expiry date and batch number in a 2D barcode

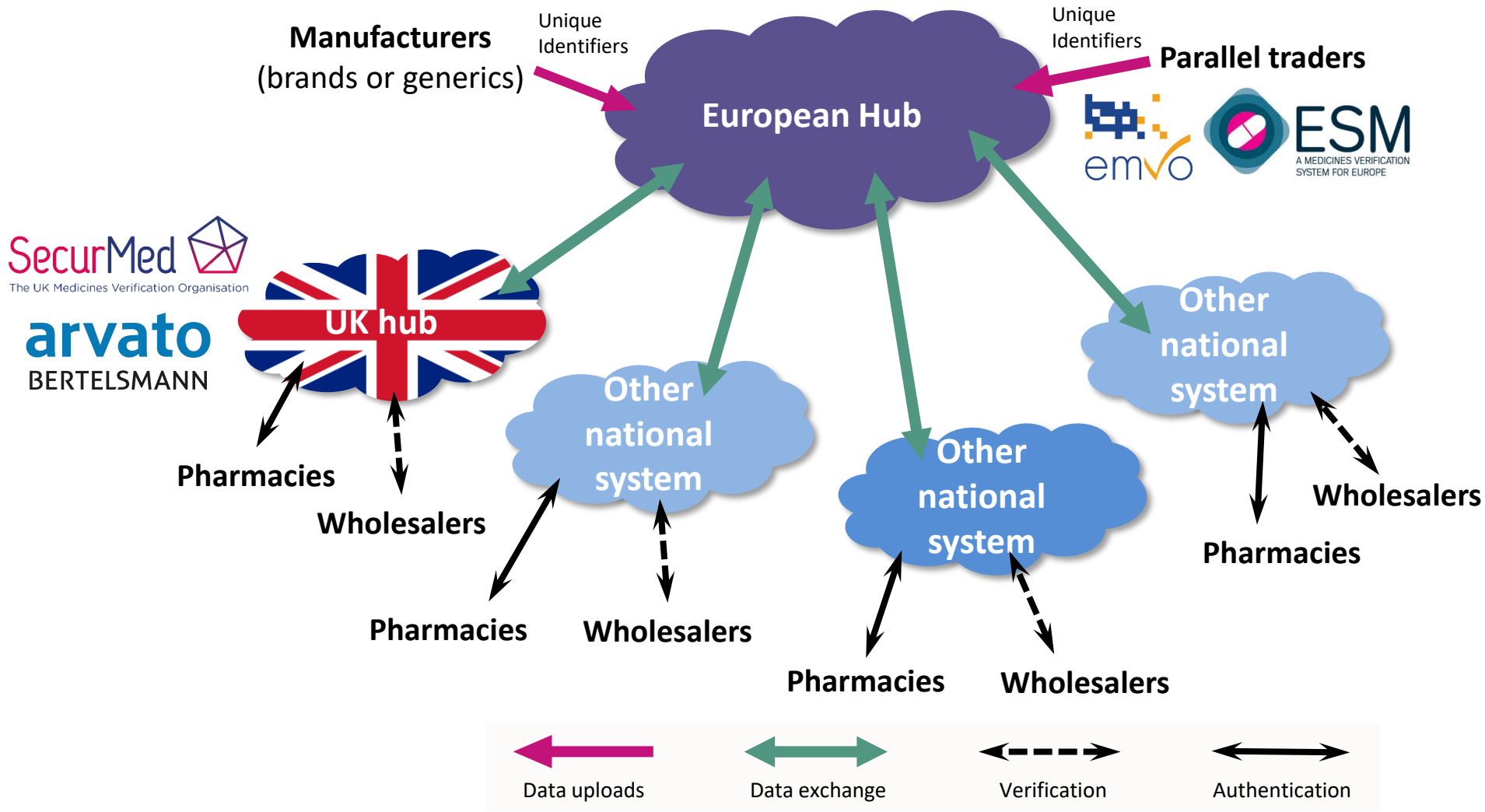


* homoeopathic products, radionuclides, gases, advanced cell therapies, intravenous products, specials are excluded. OTC omeprazole is included.

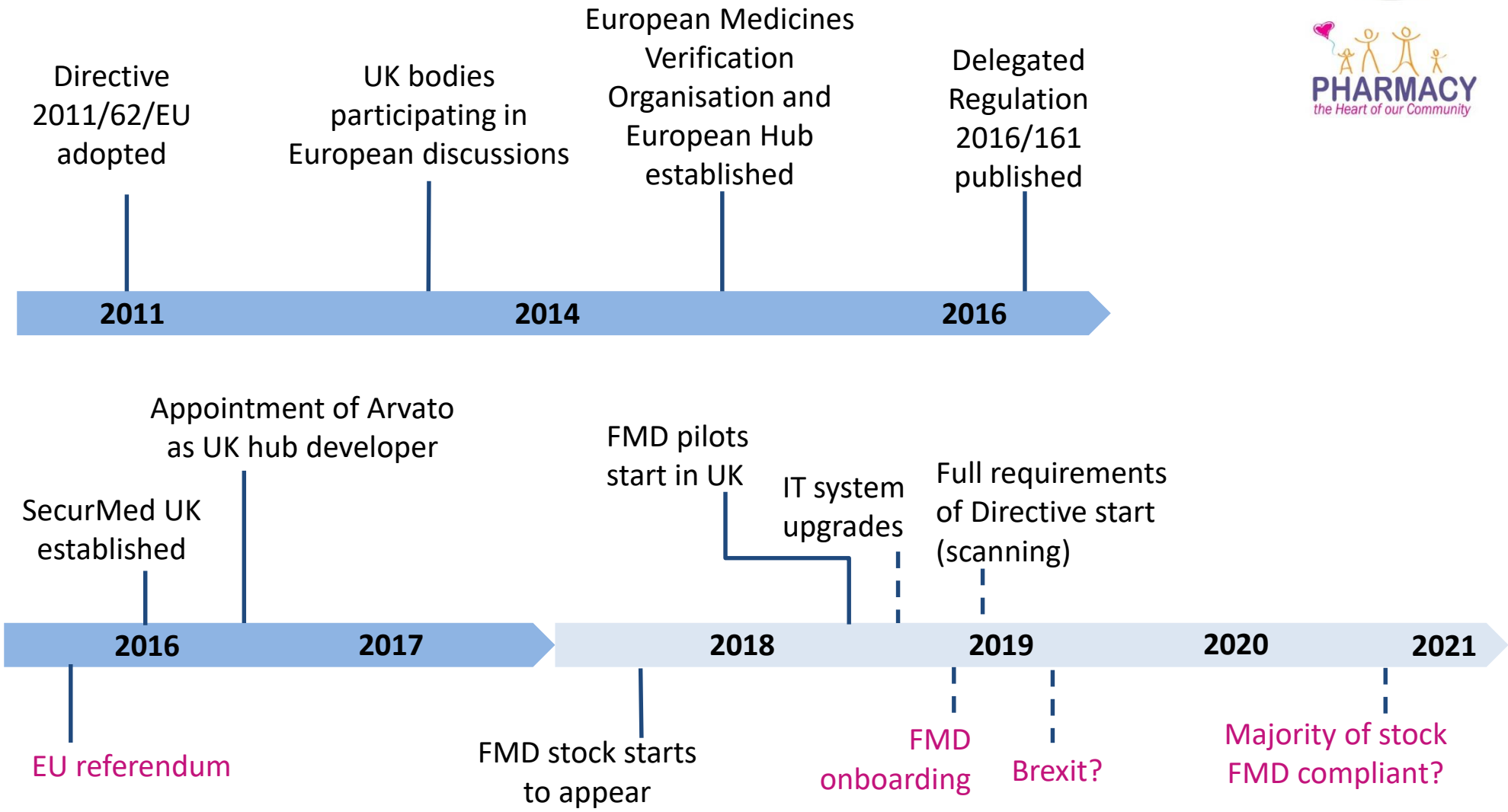
Checking authenticity…

- Authenticity is checked in two ways:
  - **Visual inspection** of the tamper-evident features
  - **Scanning and checking** unique identifiers against databases at EU and national levels
- Two actions to take when scanning a product…
  - **Verify** – check whether the product is listed in the hub (can be done multiple times as and when required)
  - **Decommission** – mark the product as supplied to a patient (or other end user)

Scanning and checking unique identifiers

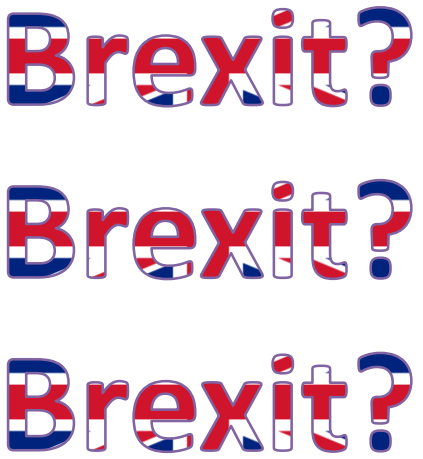


FMD timeline for the UK



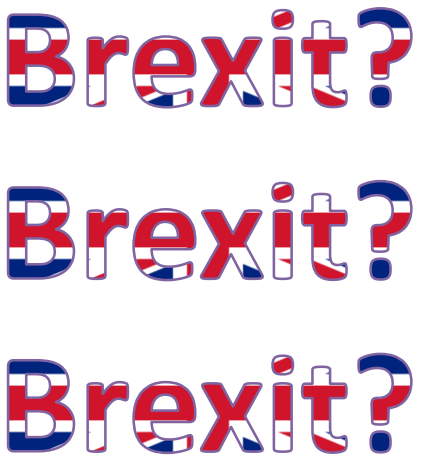
What about Brexit?

- Brexit adds an extra layer of confusion and complexity
- UK progress on implementation has been heavily delayed by discussions on Brexit and Government uncertainty on its implications
- The Delegated Regulation will be incorporated into UK legislation under the EU (Withdrawal) Bill
- Lack of clarity about what happens after Brexit and whether the UK will be “inside” FMD and connected to the European hub



What about Brexit?

- Clear patient safety risks if UK is outside FMD
- Expect a UK solution will be developed if we can't access the European system
- Contractors need to be conscious of the risks of the system needing to change post-Brexit when signing contracts for FMD systems
  - be cautious about signing contracts with long terms
  - ensure post-Brexit changes to FMD will be dealt with by the supplier



The FMD responsibilities of pharmacies

- **Verify the authenticity of products**
  - checking the anti-tampering device and unique identifiers and
  - then decommission the unique identifiers **at the time of supplying it to the public** (this is not an instant, but a period of time)

- Only be able to revert decommissioned products (recommission) **within 10 days of the original decommissioning** (the “10 day rule”)

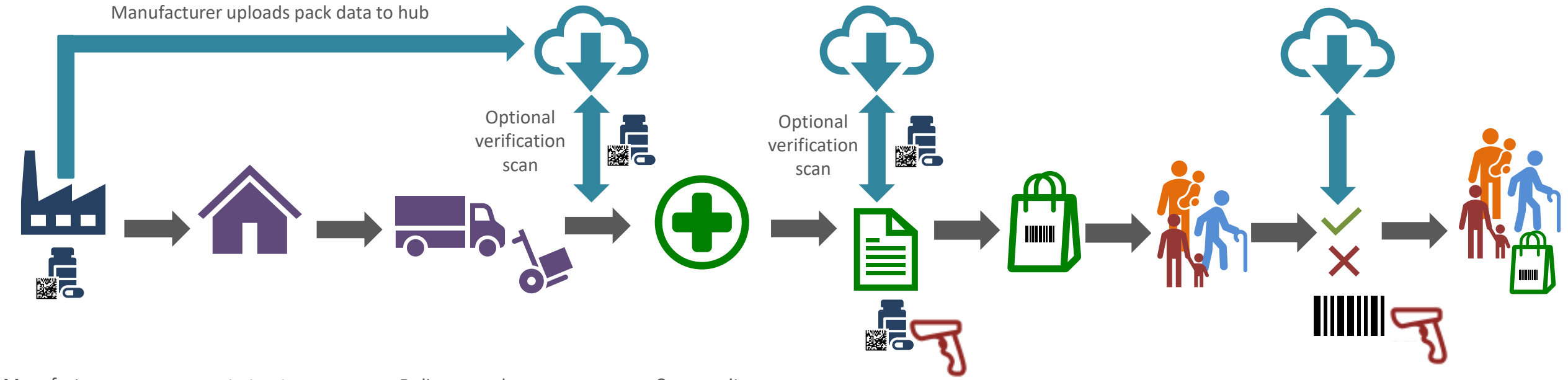
The FMD responsibilities of pharmacies

- Not to supply decommissioned products (other than those they decommission themselves as part of dispensing)
  - if a pack is decommissioned for a patient, but the item is not collected, the pack must be disposed of
  - split packs – decommission when the first part of pack is supplied to the patient

The FMD responsibilities of pharmacies

- If technical problems prevent authentication, to **record unique identifiers and then verify and decommission when possible**
- Decommission products that cannot be returned to wholesalers or manufacturers or which are taken as samples
- Notify authorities of any suspected incidents of tampering or falsification

How will it work in practice?

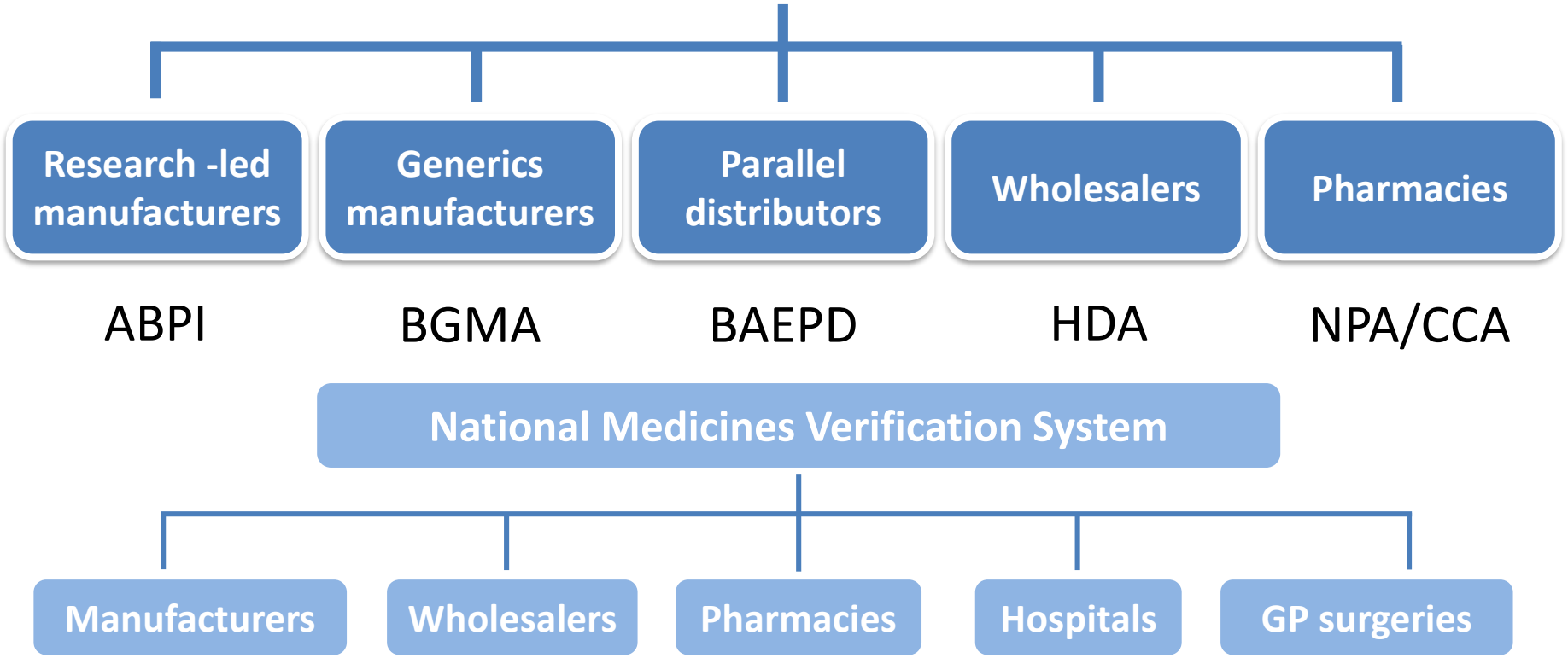


How will it work in practice?

- Standalone systems are an option
  - may be less complicated to implement in the early days (when less FMD compliant stock in pharmacies)
  - possibly cheaper than integrated systems
- Care homes / MDS – decommission at the point of deblistering
- Deliveries – decommission when the driver/courier leaves the pharmacy
- Be aware – some products are already serialised, but will not be in the FMD hub

Who pays for FMD?

SecurMed
The UK Medicines Verification Organisation



Funding for pharmacy contractors

- “Each sector is responsible for its own costs for connecting to the system”
- Each of the four national community pharmacy negotiators (PSNC, CPS, CPW and CPNI) is working to ensure that contractors’ FMD-related costs are recognised in future NHS funding settlements
- Costs for contractors relate to:
  - equipment, e.g. 2D scanners
  - software purchase and maintenance
  - additional workload related to FMD checks

What do contractors need to do now?

1) Read the guidance available at **fmdsource.co.uk**
2) Explore the system options – list of suppliers on FMD Source
   - Integrated with PMR
   - Standalone
3) Decide how you want to implement FMD and whether you will take a staged approach?
4) Select your supplier, contract with them and decide what hardware you need (additional terminals, power supplies, wireless scanners…)

What do contractors need to do now?

5) Register with SecurMed (“on-boarding”)
   - pharmacies will have to individually register with SecurMed
   - SecurMed will need to verify the identity of the pharmacy
6) Finalise the optimal way you will implement FMD in your pharmacy and then revise your SOPs
7) Develop your implementation plan and start to train your staff on FMD and the new processes which will be introduced

Enforcement and sanctions…

- GPhC will enforce the requirements in community pharmacies
- Sanctions
  - DHSC and MHRA proposed in their recent consultation that a mixture of both criminal and civil sanctions be used to tackle non-compliance
  - civil sanctions might include written warnings, stop notices and civil fines, before the application of criminal sanctions which would only be used for the most serious (intentionally fraudulent) breaches
  - criminal sanctions – with a person liable on summary conviction to an unlimited fine or liable on conviction on indictment to a fine, or to imprisonment for a term not exceeding two years, or to both

Potential benefits of FMD

- [Identification of falsified medicines]
- Improved accuracy and date checking of items being dispensed – an end of look alike, sound alike (LASA) dispensing errors?
- An impact on indemnity costs?
- Easier management of stock recalls, potentially at patient level if Unique Identifier is stored in the PMR

Potential benefits of FMD

- An opportunity to review the efficiency of the dispensing process?
- Pharmacy stock benefits
  - Accurate pack-level data for all products
  - Automatic expiry date checking

Conclusion

- There is a lot to do in a very short amount of time…
- Many contractors may initially choose to adopt a “simple” approach to compliance
- The additional benefits of FMD are likely to come from use of integrated systems once the majority of stock is FMD compliant
- But that also requires contractors and their teams to think carefully about how they redesign dispensary workflows

Questions

UKFMD
Working Group for Community Pharmacy

fmdsource.co.uk