



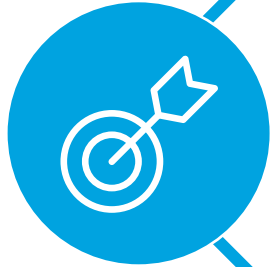
# International Benchmark of Hospital Drugs Management

*Project Deliverable*

Provided 29<sup>th</sup> January, 2021

*The search was carried out by IQVIA*

# Document Objectives



The aim of this document is to provide an overview of the different European models for delivery of hospital medicines direct-to-patient or near-to-patient

## Document scope

- Overview of France, Germany and Spain, with a deep-dive in the UK market
- Comparison of direct-to-patient and near-to-patient models for hospital drugs
- Relevant regulations and drivers of uptake for hospital home delivery across in-scope countries

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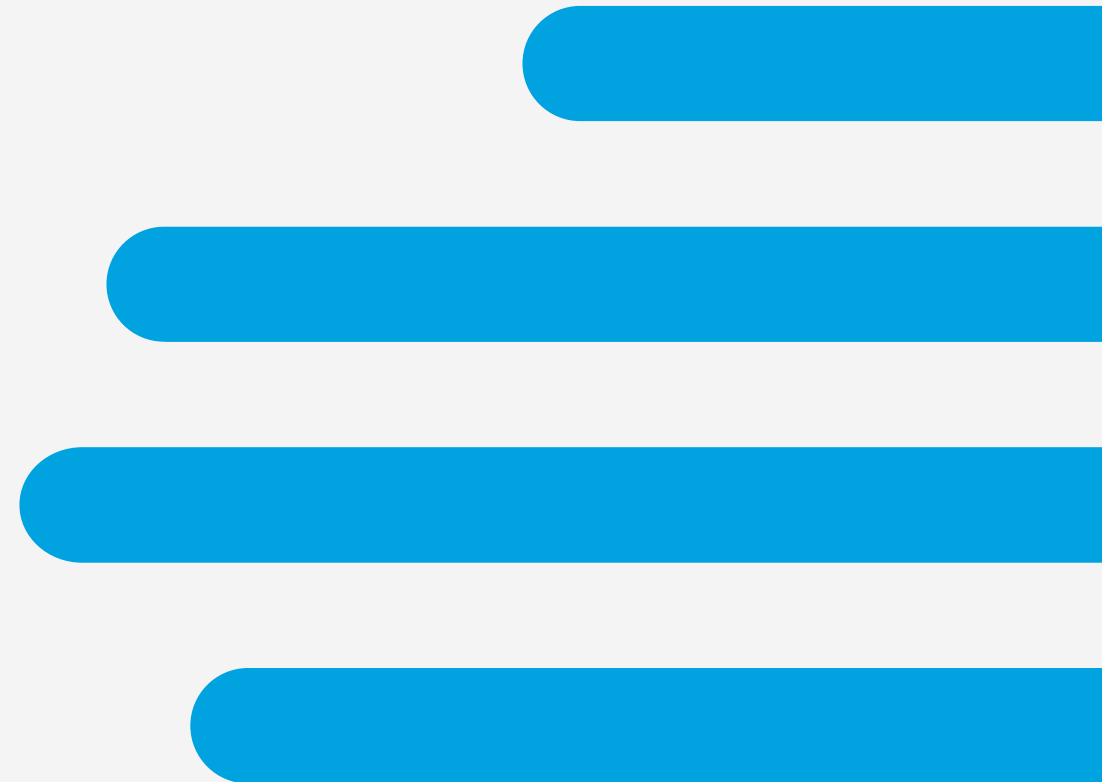
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# Contents of Report

1	Introduction	4
2	Spain	10
3	Germany	16
4	France	25
5	UK Deep-Dive	31
5.1	UK Rules and Regulations	35
5.2	Direct-to-patient delivery in UK Hospitals	39
5.3	Near-to-patient delivery in UK hospitals	46
6	Closing Remarks	51

# Introduction



# The focus of this report is to understand how hospital-dispensed products can be delivered at a convenient location for the patient

## DEFINITION OF A HOSPITAL PRODUCT

Under the IQVIA definition, products are allocated into the hospital or retail channel depending on the **classification or location of the dispensing pharmacy**

This report explores the dispensing of hospital pharmacy products by “**direct-to-patient**” or “**near-to-patient**” means

For a country-by-country breakdown on the hospital and retail channel definitions, please see the “MIDAS and National Audit Data Sources”, available from:

<https://www.customerportal.iqvia.com/sites/portal/product-support/midas-products-psa/iqvia-midas/psa/country-coverage>



## FACTORS LIMITING DRUGS TO HOSPITALS

There are several reasons in a given country that may cause a product to be limited to hospital pharmacies.

### ○ **Restricted Reimbursement**

In certain countries, a regulatory decision is taken to limit the reimbursement of products to the hospital channel, in order to allow for centralised purchasing and greater cost control measures – e.g. “Tariff exclusion” in the UK<sup>1</sup>

### ○ **Safety reasons**








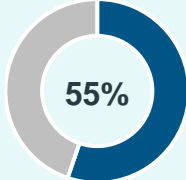
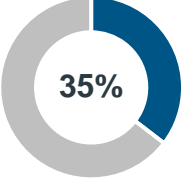
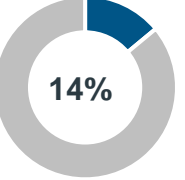
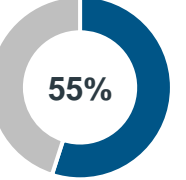
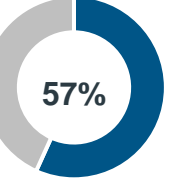












Certain drugs require specialist physicians or equipment which are not viable in a community setting – e.g. cell and gene therapies (Yescarta) or products administered via lumbar puncture (Spinraza)

### ○ **Logistic reasons**

Some products are impractical to distribute into the community due to exceptionally low numbers of patients and doses, high cost, or unusual storage requirements – e.g. Zolgesma (one-time injection with very high cost)

1) NHS England drugs list, Available from: <https://www.england.nhs.uk/publication/nhs-england-drugs-list/>


























# The magnitude of the hospital channel varies between countries, influenced by which products are dispensed through hospitals

All values for MAT Nov'20	 Italy	 France	 Germany	 Spain	 UK
 Size of hospital market (value)	<b>€14.7Bn</b>	<b>€11.3Bn</b>	<b>€6.8Bn</b>	<b>€12.5Bn</b>	<b>€14.0Bn</b>
 Hospital share of total prescription medicines market (value)	 55%	 35%	 14%	 55%	 57%
 Number of hospitals	<b>1,048</b>	<b>~2,000</b>	<b>~1,900</b>	<b>769</b>	<b>505</b>
 Hospital share of therapy area (value)	Oncology  95% Neuroscience  44%	Oncology  60% Neuroscience  33%	Oncology  25% Neuroscience  16%	Oncology  95% Neuroscience  31%	Oncology  95% Neuroscience  29%

Source: IQVIA MIDAS MTH, Nov'20; Oncology products defined as ATC2 Class L1,L2, V3C plus Revlimid, Xgeva, Proleukin, Pomalyst; Neuroscience products defined as ATC1 class N (Nervous System); Hospital/Retail split calculated according to the respective MIDAS panel, with Italy DPC products being included with Italy retail products  
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# The uptake of home delivery for hospital-dispensed medicines is impacted by regulatory, financial, and behavioural factors





*These have led to a much greater uptake of home delivery in the UK versus EU countries*

Home delivery of hospital medicines	 Germany	 France	 Spain	 UK
Relative uptake	<b>Lowest</b>	<b>Low</b>	<b>Low</b>	<b>High</b>
 Drivers of Uptake Relative Impact				
 Barriers to Uptake Relative Impact				
Key insights	<ul style="list-style-type: none"> <li> No demand since most products already available near-to-patient through retail channel</li> <li> Some precedent for home delivery during hospital discharge management</li> </ul>	<ul style="list-style-type: none"> <li> No financial framework to pay for delivery from hospital</li> <li> Logistically highly restricted due to concerns over cannibalisation of community pharmacy</li> <li> Home delivery permitted by French law</li> </ul>	<ul style="list-style-type: none"> <li> No financial framework to pay for delivery from hospital</li> <li> Home delivery technically prohibited under national law</li> <li> Efforts by local authorities to implement home delivery during COVID-19 pandemic through use of bylaws</li> </ul>	<ul style="list-style-type: none"> <li> Significant financial incentive (tax framework)</li> <li> Home delivery formally recommended practice by NHS</li> <li> High patient need, due to relatively low number of hospitals</li> </ul>

Note: Further details on the drivers and barriers of uptake can be found in the detailed country sections  
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# Hospital drugs are delivered to the patient through various solutions depending on the country

*The solutions can be categorised as either direct-to-patient or near-to-patient*

Channel	 Germany	 France	 Spain	 UK
<p><b>Direct-to-patient</b></p> <p><b>Delivery of hospital medicines to the patients home</b></p>	<p><b>Hospital discharge management</b> Hospital discharge patients can receive nurse care at home for 7 days if required</p> <p><b>infusion@home</b> Outpatient home administration for rare diseases operating through <i>retail channel</i></p>	<p><b>Retail courier service</b> Courier from retail pharmacy to patient home for a fixed fee.</p>	<p><b>Hospital courier service</b> Initiated by some regional authorities in response to COVID-19. Courier service from hospital pharmacy to patients home through Spanish Red Cross or third-party logistics company.</p>	<p><b>Clinical homecare</b> Delivery direct to patients home through 3<sup>rd</sup> party provider. Currently 2.8% of hospital drugs by value</p> <p><b>Homecare nurse service</b> Infusion at home provided by hospital nurses in rural areas</p>
<p><b>Near-to-patient</b></p> <p><b>Delivery of hospital medicines at a site nearer to the patients home</b></p>	<p><b>Outpatient clinics (Ambulanzen)</b> Very common practice in Germany. Operating through the <i>retail channel</i> with the capability to deliver parenteral therapies</p>	<p><b>Hospital-to-retail courier</b> Transfer of hospital products to retail pharmacy for convenience. Initiated by some towns in response to COVID-19.</p>	<p><b>Hospital-to-retail courier</b> Transfer of hospital products to retail pharmacy. Initiated in select hospitals in response to COVID-19.</p>	<p><b>Satellite clinics</b> Clinics run by specialist hospitals at sites closer to the patient, such as community hospitals.</p> <p><b>Mobile clinics</b> Vehicles with infusion capability staffed by nurses.</p>



# The UK provides a range of home / near to home delivery drivers and examples for a deep dive assessment

## Key factors impacting usage of UK clinical homecare

Large hospital channel by value of total drug market



**20%**  
VAT saving

Financial savings through VAT that are shared between the health care system and home care companies

High share of products by value go through homecare<sup>2</sup>

28%

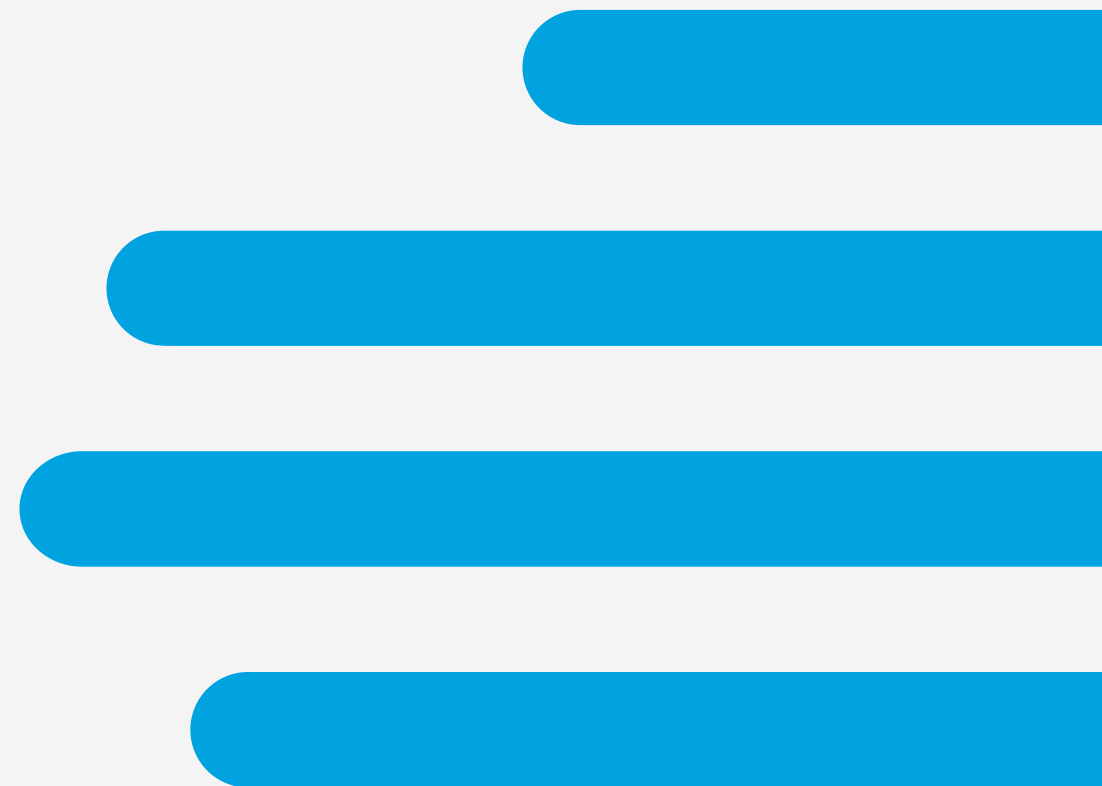
Relatively low number of hospitals



**505**  
hospitals<sup>3</sup>

- ✓ Large hospital pharmacy channel, similar to Italy in size and share of overall market
- ✓ Similar products dispensed through hospitals compared to Italy (e.g. high-value specialty)
- ✓ Highest uptake of clinical homecare in Europe, at 28% of hospital products by value
- ✓ Clear regulatory and financial drivers of uptake for home delivery of hospital drugs

**Spain**



# The majority of specialty medicines are dispensed via the Hospital channel in Spain



- The hospital channel is the predominant channel in the Spanish market, contributing over half of the market by value. **Specialist-initiated products**, including immunologics, HIV therapies, and oncologics, are **dispensed through the hospital pharmacy**
- Some therapy areas are almost entirely limited to the hospital, such as oncology where 95% of products by value are dispensed via the Hospital channel



## Retail Channel

Value, MAT Nov'20 € 10.2 Bn

Total number of pharmacies 22,070

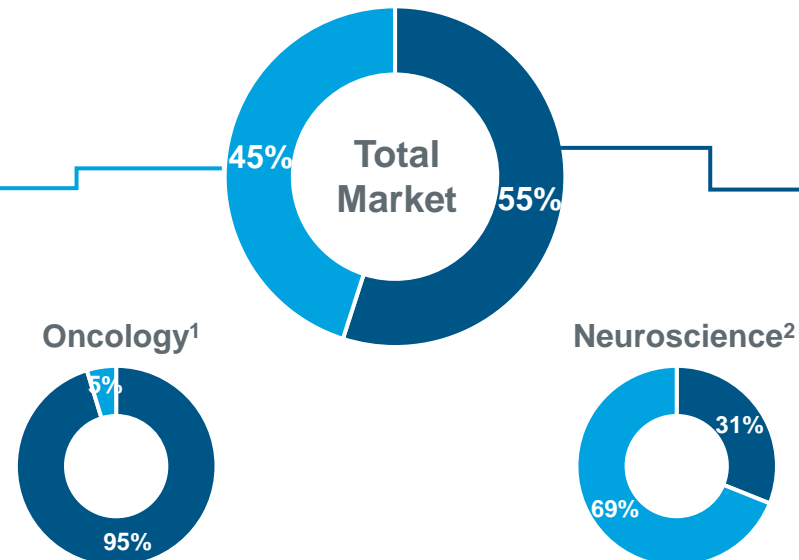
Leading retail products include self-administered diabetic and cardiovascular medications

Spain top-5 retail channel products,<sup>3</sup> MAT Nov'20

Rank	Product	Therapy Area	Value
1	Eliquis	Anticoagulants	€ 136.4M
2	Lantus	Antidiabetics	€ 134.8M
3	Xarelto	Anticoagulants	€ 106.1M
4	Symbicort	Respiratory	€ 84.7M
5	Trulicity	Antidiabetics	€ 74.0M

## Spain Hospital/Retail Channel Split, Value, MAT Nov'20

■ Hospital Channel ■ Retail Channel



## Hospital Channel

Value, MAT Nov'20 € 12.4 Bn

Total number of hospitals 769

Top products include monoclonal antibodies and IMiDs for cancer treatment that require dedicated hospital services for administration

Spain top-5 hospital channel products,<sup>3</sup> MAT Nov'20

Rank	Product	Therapy Area	Value
1	Keytruda	Oncologics	€ 367.0M
2	Revlimid	Oncologics	€ 326.0M
3	Imbruvica	Oncologics	€ 279.1M
4	Biktarvy	HIV Antivirals	€ 252.5M
5	Stelara	Immunosuppressants	€ 248.6M

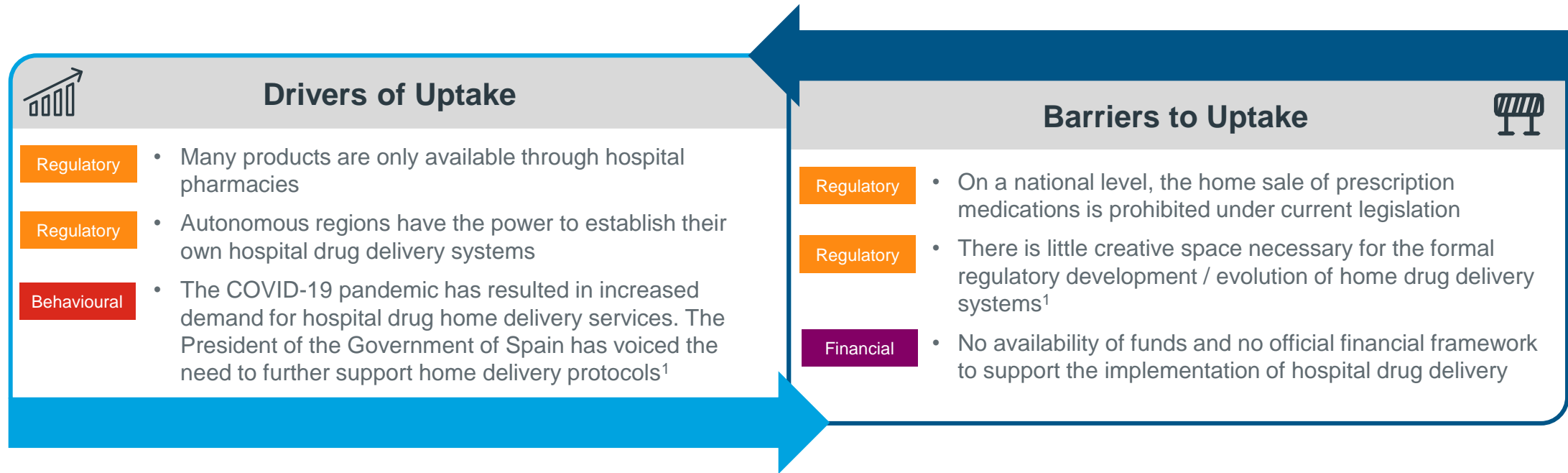
Source: IQVIA MIDAS MTH, Nov'20; 1) Oncology products defined as ATC2 Class L1,L2, V3C plus Revlimid, Xgeva, Proleukin, Pomalyst; 2) Neuroscience products defined as ATC1 class N (Nervous System); 3) Hospital products were defined as those with ≥95% of sales in the hospital channel during MAT Nov'20. Likewise, retail channel products were defined as those with ≥95% of sales in the retail channel

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# Home delivery of hospital medicines in Spain: what is possible?



Several autonomous communities have launched drug delivery systems encouraging uptake



## Key Regulations

Under current regulations, **the home sale of prescription medications is prohibited** under *Real Decreto Legislativo 1/2015*<sup>2</sup>.

Laws are similarly restrictive for hospital drug delivery, yet seldom address this directly. The existing legal “vacuum” has enabled several autonomous communities to implement their own regulations:

- In Cantabria, home delivery of medications by any pharmacy would not be considered a “sale”, and thus the practice would be fully endorsed by law<sup>3</sup>
- In Galicia, exceptional cases where patients live in rural areas or have a lack of functional autonomy are eligible for home delivery. Additionally, pharmacies are “free” to collaborate to establish the necessary conditions for such delivery<sup>4</sup>
- In Andalucía, pharmacies are permitted to establish protocols for home delivery and dispensing of hospital drugs, the regulations and exceptions of which are to be determined by the respective ministry of health<sup>5</sup>

Sources:1. <https://www.diariofarma.com/2020/03/25/medicamentos-a-domicilio-cuando-la-urgencia-por-parar-la-pandemia-desborda-el-marco-legal>. 2. <https://www.boe.es/buscar/doc.php?id=BOE-A-2015-8343>. 3. <https://www.boe.es/buscar/doc.php?id=BOE-A-2002-915>. 4. <https://www.boe.es/buscar/doc.php?id=BOE-A-2019-13517>. 5. <https://www.boe.es/buscar/pdf/2008/BOE-A-2008-3179-consolidado.pdf>.

# Home delivery of hospital medicines in Spain: what is changing?



*COVID-19 has driven Hospitals and communities to embrace home delivery of hospital drugs*

## RECENT TRENDS

Hospitals throughout Spain have begun to **reorganize hospital activity to respond to the needs of its patients**<sup>1</sup>. In hopes of refining a more streamlined and efficient model of care, Hospitals are focusing on:

- Promoting remote care and telephone consultations
- Optimizing care circuits to mitigate hospital saturation and delays
- Integrating care services
- Implementing technology-based discharge support

## IMPACT OF COVID-19 PANDEMIC



Granted by the Ministry of Health, the Spanish Society of Hospital Pharmacies (SEFAC) launched a **temporary action protocol** exclusively in response to the COVID-19 pandemic state of alarm to ensure patients received hospital-dispensed medicines, either via **home delivery, delivery to a local pharmacy, or to a local community center**.<sup>2</sup>

In response, hospital pharmacy services have begun **implementing a contingency plan and evolved their own internal organization and management procedures** by:

- Extending prescription durations to reduce frequency of visits
- Committing to ‘telepharmacy’ and home delivery
- Creating differentiated care circuits for patients with COVID-19

Mandated by the Ministry of Health, the **General Council of Pharmacists (CGF) and the Red Cross joined forces** to create a network of more than 22,000 pharmacies and 200,000 volunteers to **facilitate the home delivery of medicines to vulnerable patients**.<sup>3</sup>

Sources: 1. <https://2opfle1yeg2f3zqyqbpfbx76-wpengine.netdna-ssl.com/wp-content/uploads/2020/07/Plan-de-acci%C3%B3n-para-la-transformaci%C3%B3n-del-Sistema-Nacional-de-Salud-en-la-era-post-covid-19%E2%80%99-v5.pdf> .2. [https://www.sefac.org/system/files/2020-04/DOCUMENTO%20DISPENSACI%C3%93N%20DE%20MEDICAMENTOS%20Y%20PS%20CON%20ENTREGA%20A%20DOMICILIO%2016-4-2020\\_1.pdf](https://www.sefac.org/system/files/2020-04/DOCUMENTO%20DISPENSACI%C3%93N%20DE%20MEDICAMENTOS%20Y%20PS%20CON%20ENTREGA%20A%20DOMICILIO%2016-4-2020_1.pdf). 3. <https://www2.cruzroja.es/-/nueva-alianza-con-el-consejo-general-de-farmaceuticos>.

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# Spain Case Study 1: *Hospital Universitario de la Princesa*

In 2018, the *La Princesa* University Hospital in Madrid, Spain, launched a **hospital drug home delivery system coupled with a mobile phone application "MemoPast"**. Medicines were **dispensed through the hospital** and delivered through a courier service.

Coined *Princesa en Casa*, the delivery service aimed to **benefit over 7,000 patients** by:



- Minimising patient displacement and maximising patient comfort
- Facilitating patient monitoring and adherence
- Establishing a pharmaceutical ‘teleconsultation’ system
- Mitigating against hospital saturation
- Guaranteeing **same-day delivery of hospital drugs** to outpatients with chronic, oncological, or infectious diseases

The project was **funded by the Biomedical Research Foundation of the Hospital**, in collaboration with Amgen, Roche, Pfizer, Celgene, Boehringer Ingelheim, Novartis, BMS, Abbvie, and MSD laboratories.

The app is certified by the AEMPS and the European Commission.

Note: AEMPS – Agencia Española de Medicamentos y Productos Sanitarios

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## Channel

Direct-to-patient

Near-to-patient

## Relevant Products

Medications for chronic, oncological, and infectious diseases

## Drivers of Uptake

Financial

Costs were funded through research grant in collaboration with pharmaceutical companies

Behavioural

Use of technology solutions to integrate with other aspects of hospital care

## Relevant Regulation

### Statement by the Community of Madrid

Accion de la Comunidad de Madrid.

Enacted: 03.07.2018. Available from:

<https://www.comunidad.madrid/noticias/2018/07/03/7000-pacientes-beneficiaran-proyecto-humanizacion-princesa-casa>



# Spain Case Study 2: *Junta de Castilla y León*

On 23<sup>rd</sup> March 2020, the Regional Health Authority (GRS) of **Castilla y León** launched an **action protocol enabling the home delivery of hospital drugs dispensed from the pharmacy services of the National Health Service (SNS)** Sacyl hospitals during the COVID-19 pandemic.

In collaboration with the General Directorate of Civil Protection (DGPC) and the local delegations of the Junta de Castile and León, **the measure aims to benefit a total of 40,219 patients by:**

- Facilitating home confinement and minimizing contagion
- Establishing a pharmaceutical ‘teleconsultation’ system
- Ensuring pharmaceutical care, and provision of oncological, rheumatic, multiple sclerosis, HIV/AIDS, and anti-infective medications, amongst others, via a courier service
- Adding to the extended automatic renewal of all electronic prescriptions to two months

Similar projects have been launched in other autonomous communities, including Madrid,<sup>1</sup> Andalucía,<sup>2</sup> and Galicia.<sup>3</sup>



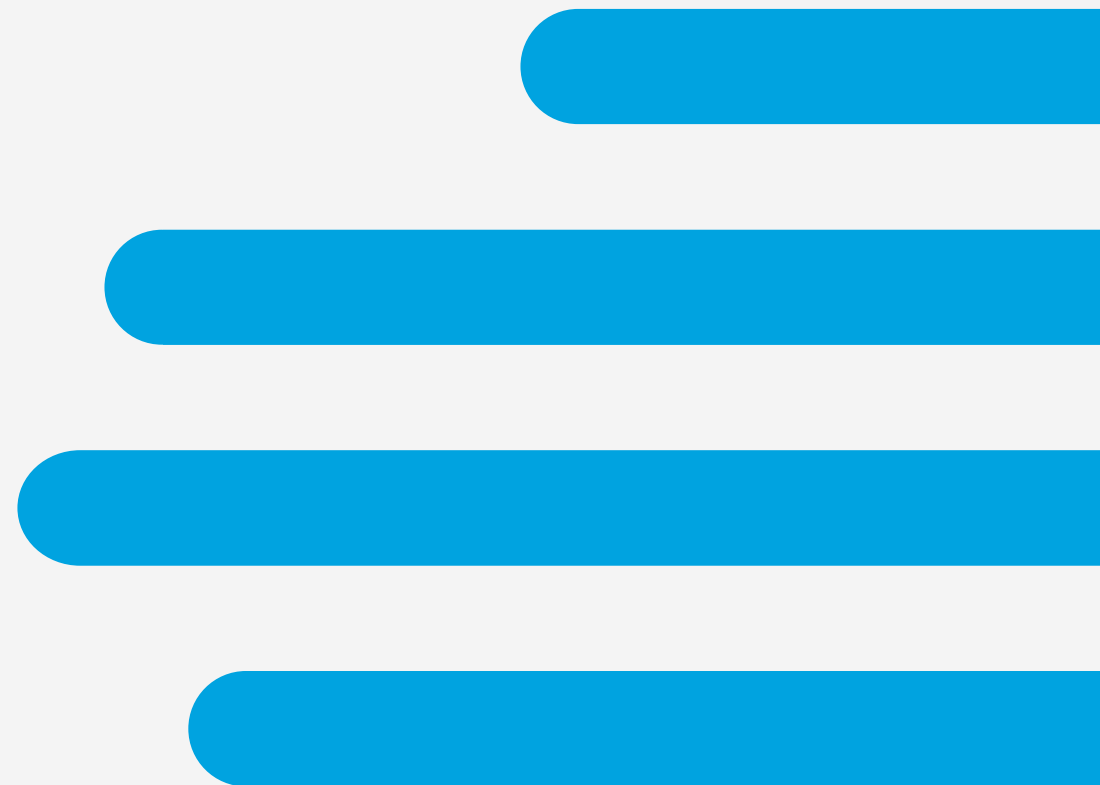
Note: GRS – Gerencia Regional de Salud; Sacyl – Sanidad de Castilla y León; SNS – Sistema Nacional de Salud; DGPC - Dirección General de Protección Civil

Sources: 1. <https://www.comunidad.madrid/comunicado/2020/04/12/comunidad-madrid-establece-protocolo-entrega-medicamentos-domicilio-oficinas-farmacia>. 2. <https://www.husc.es/noticias/la-farmacia-del-hospital-cimco-san-ccomil-reparte-a-domicilio-la-medicacion-de-sus-pacientes-para-evitarles-desplazamientos>. 3. <https://www.diariofarma.com/2020/03/23/covid-19-las-farmacias-de-pontevedra-recuerdan-que-pueden-hacer-entregas-a-domicilio-a-aislados-por-covid-19>.

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Channel	
Direct-to-patient	Near-to-patient
Relevant Products	
Oncology, rheumatic, neuroscience, HIV/AIDS, and anti-infective agents	
Drivers of Uptake	
Behavioural	Significant increase in need for home delivery due to COVID-19 pandemic
Financial	Cost covered by National Health Service
Regulatory	Local health authority of autonomous community endorsed home delivery of hospital drugs
Relevant Regulation	
<p><b>Statement by the Junta of Castile and León</b>          Comunicación de la Junta de Castilla y León.          Enacted: 23.03.2020. Available from:  <a href="https://comunicacion.jcyl.es/web/jcyl/Comunicacion/es/Plantilla100Detalle/1284939308625/Comunicado/1284941501964/Comunicacion">https://comunicacion.jcyl.es/web/jcyl/Comunicacion/es/Plantilla100Detalle/1284939308625/Comunicado/1284941501964/Comunicacion</a></p>	

# Germany





# Only a few highly specialised medicines are restricted to the hospital channel in Germany



- In Germany, a large **majority of medicines by value** are dispensed through the **retail channel**. There are a high number of outpatient clinics (ambulanzen) in the retail channel, allowing speciality drugs (including oncology) to be dispensed in a near-to-patient setting
- A very small number of medicines (e.g. Zolgesma & Kymriah) are impossible to order in retail pharmacies.<sup>1</sup> Other products (e.g. Spinraza) are technically available through the retail channel, however in reality are hospital-limited due to administration needs (lumbar puncture)



## Retail Channel

Value, MAT Nov'20 **€ 42.1 Bn**

Total number of pharmacies **19,600**

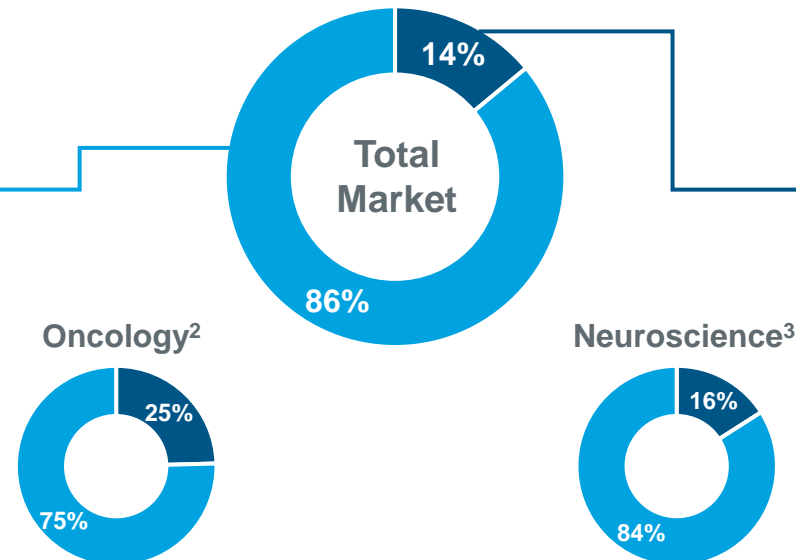
**Oncology** products like Revlimid, and **immunology** product like Humira are dispensed in the retail channel in Germany

Germany top-5 retail channel products,<sup>4</sup> MAT Nov'20

Rank	Product	Therapy Area	Value
1	Eliquis	Anticoagulants	€ 811.7M
2	Revlimid	Oncologics	€ 728.3M
3	Xarelto	Anticoagulants	€ 725.9M
4	Humira	Immunology	€ 473.0M
5	Zytiga	Oncologics	€ 404.7M

## Germany Hospital/Retail Channel Split, Value, MAT Nov'20

■ Hospital Channel ■ Retail Channel



## Hospital Channel

Value, MAT Nov'20 **€ 6.84 Bn**

Total number of hospitals **1,900**

Top products are **SMA infusions**, and **CAR-T** therapies that are unfeasible to administer out of the hospital

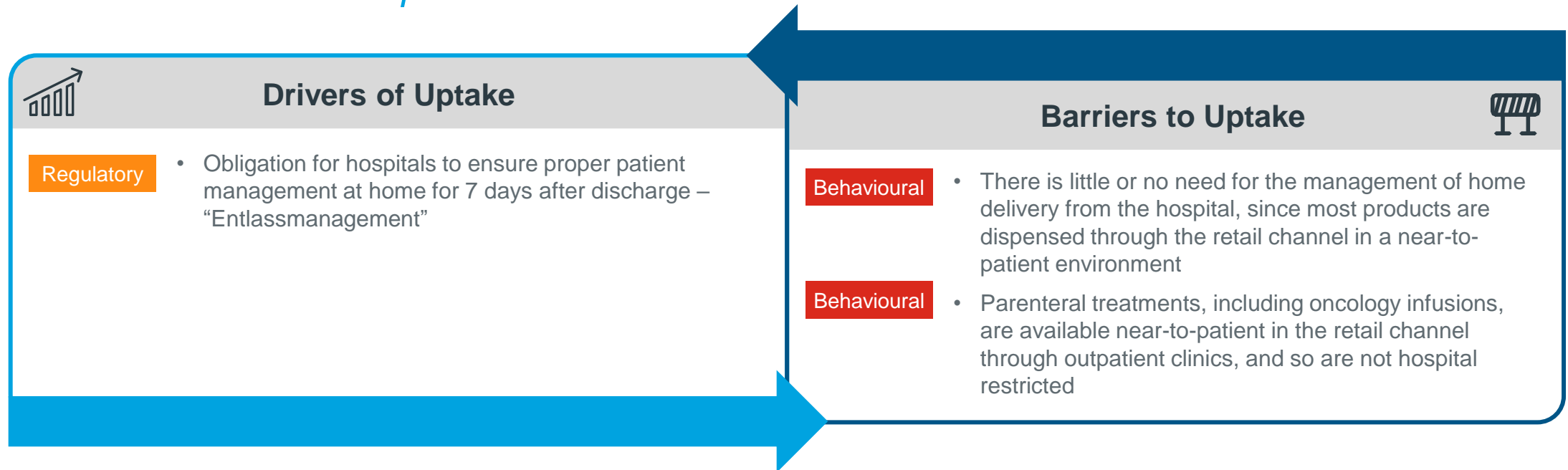
Germany top-5 hospital channel products,<sup>3</sup> MAT Nov'20

Rank	Product	Therapy Area	Value
1	Spinraza	SMA	€ 404.0M
2	Zolgensma	SMA	€ 175.1M
3	Haemocompletan	Blood Coagulation	€ 61.0M
4	Actilyse	Anticoagulants	€ 51.9M
5	Kymriah	Oncologics	€ 48.8M

# Home management of hospital drugs in Germany is limited to during discharge management



*The availability of products in the retail channel limits the need for direct-to-patient and near-to-patient solutions in the hospital*



## Key Regulations

### Patient discharge management framework.

“Rahmenvertrag Entlassmanagement nach Krankenhausbehandlung”

Initial publication: 06.06.2017. Latest update: 02.12.2020. Available from:

[https://www.kbv.de/media/sp/Rahmenvertrag\\_Entlassmanagement.pdf](https://www.kbv.de/media/sp/Rahmenvertrag_Entlassmanagement.pdf)

### Oncology outpatient management framework

Vereinbarung über die qualifizierte ambulante Versorgung krebskranker Patienten

“Onkologie-Vereinbarung“; Initial publication: 01.07.2009. Latest update:

25.11.2020. Available from: [https://www.kbv.de/media/sp/07\\_Onkologie.pdf](https://www.kbv.de/media/sp/07_Onkologie.pdf)

# Home delivery of hospital medicines in Germany: what is changing?



The introduction of ePrescriptions in 2022 is expected to accelerate the uptake of home delivery

## RECENT TRENDS

- The German patient data protection act<sup>1</sup>, passed into law on 18 September 2020, **mandates the use of ePrescriptions** from January 1, 2022.
- This is expected to enable the improved use of telemedicine services and home-delivery services in Germany



## IMPACT OF COVID-19 PANDEMIC



- To facilitate outpatient care during the coronavirus pandemic, special regulations for **prescribing home nursing** have been applied, **postal dispatch of prescriptions is now reimbursed**, and pharmacists have more **flexibility to change drugs** to provide relief to the strained supply chain<sup>2</sup>
- The Robert Koch Institute has issued **updated guidelines for hospital discharge management** in response to COVID-19, mandating PCR testing and ensuring safe management of potentially infectious patients<sup>3</sup>
- The number of **telemedicine consultations doubled** at the beginning of the pandemic, but only to around 2%, facilitated by the easing of restrictions and the introduction of incentives for telemedicine consultations by the Federal Association of SHI Physicians

Sources: 1. [https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3\\_Downloads/Gesetze\\_und\\_Verordnungen/GuV/P/Gesetzesentwurf\\_Patientendaten-Schutz-Gesetz\\_-\\_PDSG.pdf](https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/P/Gesetzesentwurf_Patientendaten-Schutz-Gesetz_-_PDSG.pdf); 2. <https://www.kbv.de/html/coronavirus.php#content45248>. 3. Information on COVID-19 Entlassmanagement guidelines available from: [https://www.rki.de/DE/Content/InfAZ/N/Neuartiges\\_Coronavirus/Entlassmanagement.html](https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Entlassmanagement.html). <https://www.deutschesapothekenportal.de/rezept-retax/dap-retax-arbeitshilfen/spezielle-rezepte/entlassmanagement-pandemie-sonderregelungen/>; 3. <https://www.kbv.de/html/coronavirus.php#content45248>

# Specialist outpatient medical care is available throughout Germany for complex diseases

The ASV provide diagnostic, treatment, and aftercare services to patients with complex diseases

Channel

Direct-to-patient

Near-to-patient

## ASV Ordinance

Patients with complex diseases that require interdisciplinary care, including oncological, rheumatological, rare and severe diseases, may receive **specialist outpatient medical care** through “Ambulante Spezialfachärztliche Versorgung” (ASV) services<sup>1</sup>

## ASV Directive

For each ASV clinic or practice, the “Federal Joint Committee” (G-BA) regulates the ordinance by:

- Stipulating eligibility requirements (e.g. indications available and personnel)
- Specifying the scope of treatments available, including EBM services, diagnostics, and advanced machinery and treatment methods
- Safeguarding quality assurances and equipment requirements

In addition to medical treatment, people with statutory health insurance can, under certain conditions, request home care from suitable nursing staff<sup>2</sup>

Notes: ASV – Ambulante Spezialfachärztliche Versorgung; G-BA – Gemeinsamer Bundesausschuss; EBM – Evidence Based Medicine

Source: 1. <https://www.kbv.de/html/asv.php> 2. [https://www.kbv.de/html/haeusliche\\_krankenpflege.php](https://www.kbv.de/html/haeusliche_krankenpflege.php)

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**AMBULANTE SPEZIALFACHÄRZTLICHE VERSORGUNG**  
INTERDISZIPLINÄR IN PRAXEN UND KLINIKEN  
AKTUALISIERTE AUSGABE AUGUST 2018

PraxisWissen

**§ 116b Outpatient specialist medical care**

(1) Outpatient specialist care includes the diagnosis and treatment of complex diseases that are difficult to treat and which, depending on the disease, require special qualifications, interdisciplinary cooperation and special equipment. In accordance with paragraphs 4 and 5, this includes in particular the following diseases with particular disease courses, rare diseases and disease states with correspondingly low case numbers, as well as highly specialized services:

1. Diseases with particular disease courses such as
  - a) oncological diseases,
  - b) rheumatological diseases,
  - c) HIV/AIDS,
  - d) Heart failure (NYHA stage 3-4),
  - e) Multiple sclerosis,
  - f) cerebral seizure disorders (epilepsy)
  - g) complex diseases in the context of pediatric cardiology,
  - h) Consequential damage in premature babies or
  - i) Paraplegia with complications that require interdisciplinary care;In the case of illnesses under letters c to i, outpatient specialist medical care only includes severe forms of the respective illnesses with particular disease courses.
2. rare diseases and disease states with correspondingly low case numbers such as
  - a) Tuberculosis,
  - b) Cystic fibrosis,
  - c) Hemophilia,
  - d) Marfan syndrome, congenital skeletal system malformations and neuromuscular diseases,
  - e) serious immunological diseases,
  - f) biliary cirrhosis,
  - g) primary sclerosing cholangitis,
  - h) Wilson's disease,
  - i) Transsexualität,
  - j) Care for children with congenital metabolic disorders,
  - k) Marfan Syndrome,
  - l) pulmonary hypertension,
  - m) Short bowel syndrome or
  - n) Care of patients before or after organ transplantation and from living donors as well
3. highly specialized services such as
  - a) CT/MRI-based interventional pain therapy services or
  - b) Brachytherapy.

Examination and treatment methods can be the subject of the scope of services in outpatient specialist medical care, provided that the Federal Joint Committee has not made a negative decision within the framework of the resolutions pursuant to Section 137c for hospital treatment.

(2) Service providers participating in certified medical care and hospitals approved in accordance with Section 10b are entitled to provide outpatient specialist medical care services in accordance with Paragraph 1, the scope of treatment of which the Federal Joint Committee has determined in accordance with Paragraphs 4 and 5, insofar as they are relevant in each case fulfill the requirements and prerequisites according to Paragraphs 4 and 5 and notify the State Committee of

## Outpatient Specialist Medical Care

Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - § 116b Ambulante spezialfachärztliche Versorgung

Initial publication: 20.12.1988. Available from:

[https://www.gesetze-im-internet.de/sgb\\_5/\\_116b.html](https://www.gesetze-im-internet.de/sgb_5/_116b.html)



# Germany Case Study 1: Oncology Outpatient Clinic

Like many hospitals across Germany, the “Hospital of the Holy Spirit” in Frankfurt operates a **comprehensive outpatient service** for patients with oncological diseases, as well as benign and malignant hematological diseases.

The interdisciplinary oncological outpatient clinic offers a range of **diagnostic measures**, **tumour therapy**, and accompanying **aftercare** to effectively support treatment, including:

## Diagnostic measures

- Ultrasonic
- Computed tomography
- Bone marrow puncture
- Pleural puncture

## Tumor therapy

- Chemotherapy
- Antibody therapy
- Bisphosphonate therapy
- Immunotherapy

## Aftercare

- Regular check-ups
- Psycho-oncological care
- Connection to specialized outpatient palliative care
- Social services



HOSPITAL  
ZUM HEILIGEN GEIST



## Channel

Direct-to-patient

Near-to-patient

## Relevant Products

All oncology and haematology products for outpatients

## Drivers of Uptake

Financial

Cost covered by the German healthcare insurers

Behavioural

Care delivered to patient; Preference from many German patients to be treated in an outpatient clinic

## Relevant Regulation

### Oncology outpatient management framework

Vereinbarung über die qualifizierte ambulante Versorgung krebskranker Patienten “Onkologie-Vereinbarung”; Initial publication: 01.07.2009. Latest update: 25.11.2020. Available from:

[https://www.kbv.de/media/sp/07\\_Onkologie.pdf](https://www.kbv.de/media/sp/07_Onkologie.pdf)



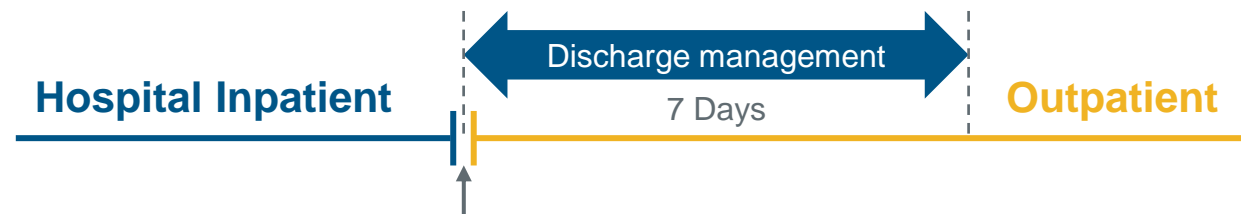


# Germany Case Study 2: *Entlassmanagement* (Discharge Management)

'EntlassManagement' (discharge management) dictates that when patients are discharged from hospital there is a **7 day period** where **the hospital has a responsibility to ensure treatment continues**.

- Usually provided by office-based specialists or general practitioners. Hospital physicians must inform the contracting physician (e.g. office-based specialist) about the patient's therapy at the time of discharge and about relevant changes in medication
- **Patients get their medication from the retail pharmacy**, not from the hospital pharmacy. However, patients must receive their medication for the **first few days at home**
- Nursing services can be arranged by the hospital if they are necessary. In the case of home care, the **nursing service procures medicines from the retail pharmacy**
- The 2015 statutory health insurance supply strengthening act dictated that there must be a published framework for patient discharge management from hospital

During COVID-19, the 'EntlassManagement' period was extended to 14 days to safeguard the successful transition to outpatient care.



Discharge

Channel	
Direct-to-patient	Near-to-patient
Relevant Products	
All hospital products received by recently discharged outpatients	
Drivers of Uptake	
Regulatory	7-days of “entlassmanagement” required by law for all discharged patients
Financial	Cost covered by the German healthcare insurers
Relevant Regulation	
<b>Statutory health insurance supply strengthening law</b> GKV-Versorgungsstärkungsgesetz; Enacted: 23.07.2015; Available from: <a href="https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&amp;jumpTo=bgbl115s1211.pdf">https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&amp;jumpTo=bgbl115s1211.pdf</a>	
<b>Patient discharge management framework.</b> “Rahmenvertrag Entlassmanagement nach Krankenhausbehandlung” Initial publication: 06.06.2017. Latest update: 02.12.2020. Available from: <a href="https://www.kbv.de/media/sp/Rahmenvertrag_Entlassmanagement.pdf">https://www.kbv.de/media/sp/Rahmenvertrag_Entlassmanagement.pdf</a>	

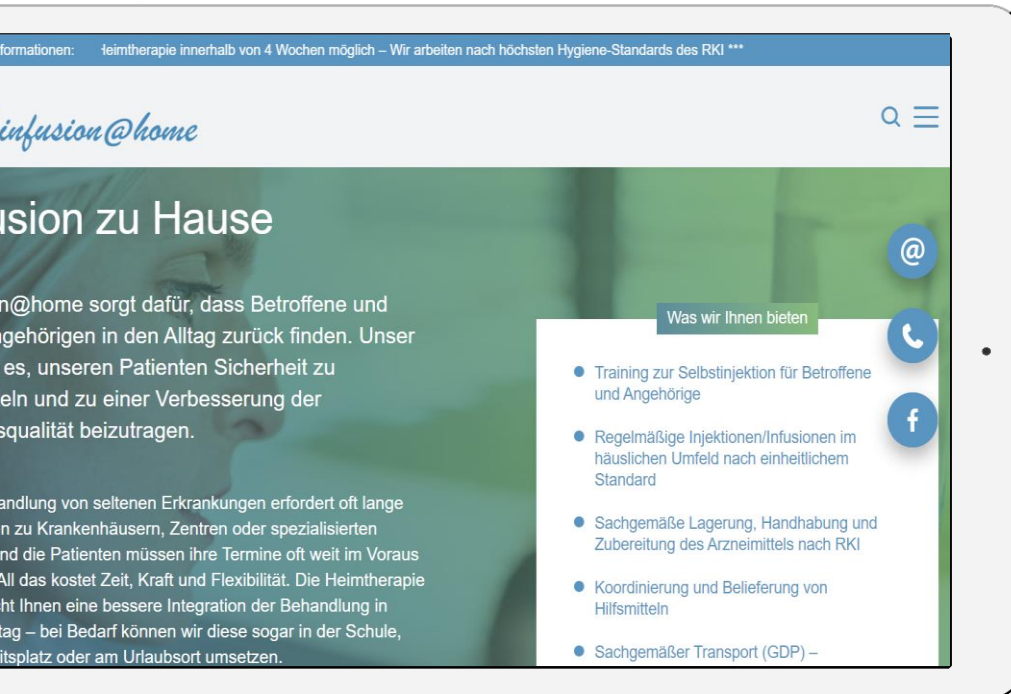


# Germany Case Study 3: *Infusion@Home*

In the case of rare and orphan diseases, the patient is unlikely to have access to a relevant outpatient clinic nearby, resulting in a greater need for homecare services for infusion medicines.

In these cases, private companies, such as “infusion@home”, offer a **nurse infusion service** at the patients house.

The products are provided through **retail parenteral formulation channels**, and is a private service that is typically paid for by the patient.



Available for diseases including:

- Fabry disease
- Gaucher's disease
- Pompe disease
- Hereditary angioedema (HAE)
- Atypical hemolytic uremic syndrome (aHUS)
- Amyotrophic lateral sclerosis (ALS)
- Haemophilia
- Generalized myasthenia gravis (gMG)

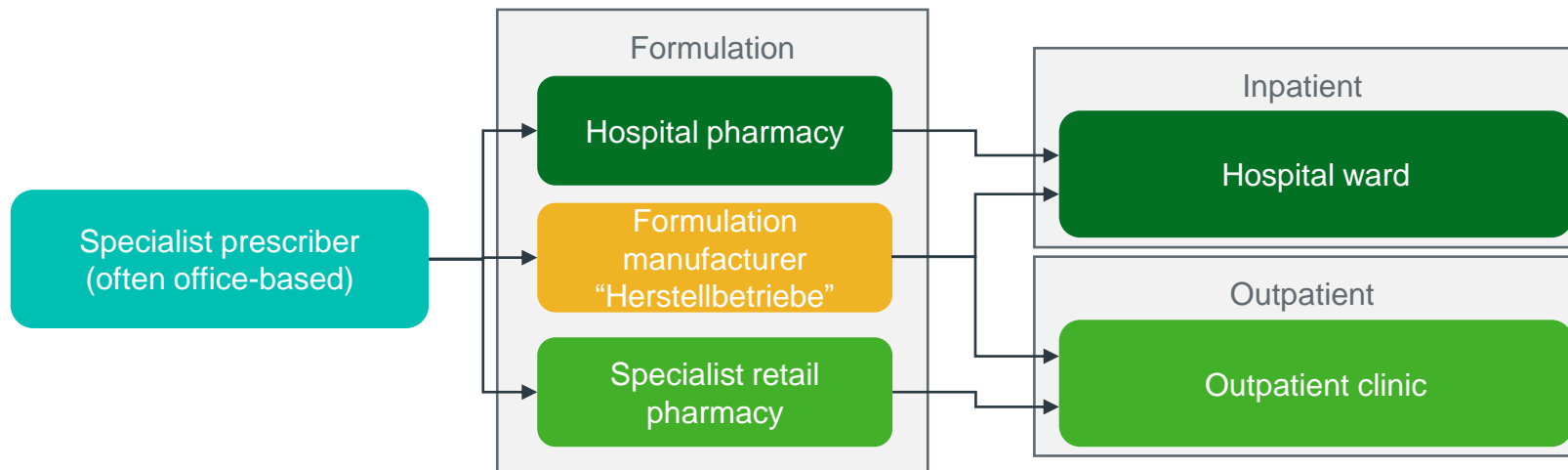
<b>Channel</b>	
<b>Direct-to-patient</b>	Near-to-patient
<b>Relevant Products</b>	
Infusion products for rare and orphan diseases	
<b>Drivers of Uptake</b>	
<b>Behavioural</b>	Orphan disease patients have less opportunity to be treated in an outpatient clinic, and so have a greater need for homecare
<b>Relevant Regulation</b>	
<p><b>Law for more safety in the supply of pharmaceuticals</b> Gesetzes für mehr Sicherheit in der Arzneimittelversorgung (GSAV); Enacted: 16.08.2019; Available from: <a href="https://www.bundesgesundheitsministerium.de/gsav.html">https://www.bundesgesundheitsministerium.de/gsav.html</a></p> <p><b>Annex 3 to the contract on pricing for substances and preparations made from substances</b> Anlage 3 zum Vertrag über die Preisbildung für Stoffe und Zubereitungen aus Stoffen; Published: 01.03.2020</p>	



# Germany Case Study 4: *Parenterale Zubereitungen*

Parenteral formulations (parenterale zubereitungen) in Germany can be procured through retail pharmacies, hospital pharmacies, or "Herstellbetriebe" (manufacturers) that produce these preparations in a clean laboratory.

- There are **400 Retail pharmacies** who are licensed to formulate these parenteral preparations in-house
- The infusion is then **administered by the office based specialist or in outpatient clinics** (e.g. onkologischen Ambulanzen).
- The products are provided to the clinic directly by the pharmacy, since the price and cold chain requirements make it unfeasible for the patients to transport the medicines themselves.
- The latest regulations for parenteral preparations were set out in the Law for more safety in the supply of pharmaceuticals (GSAV) in 2019



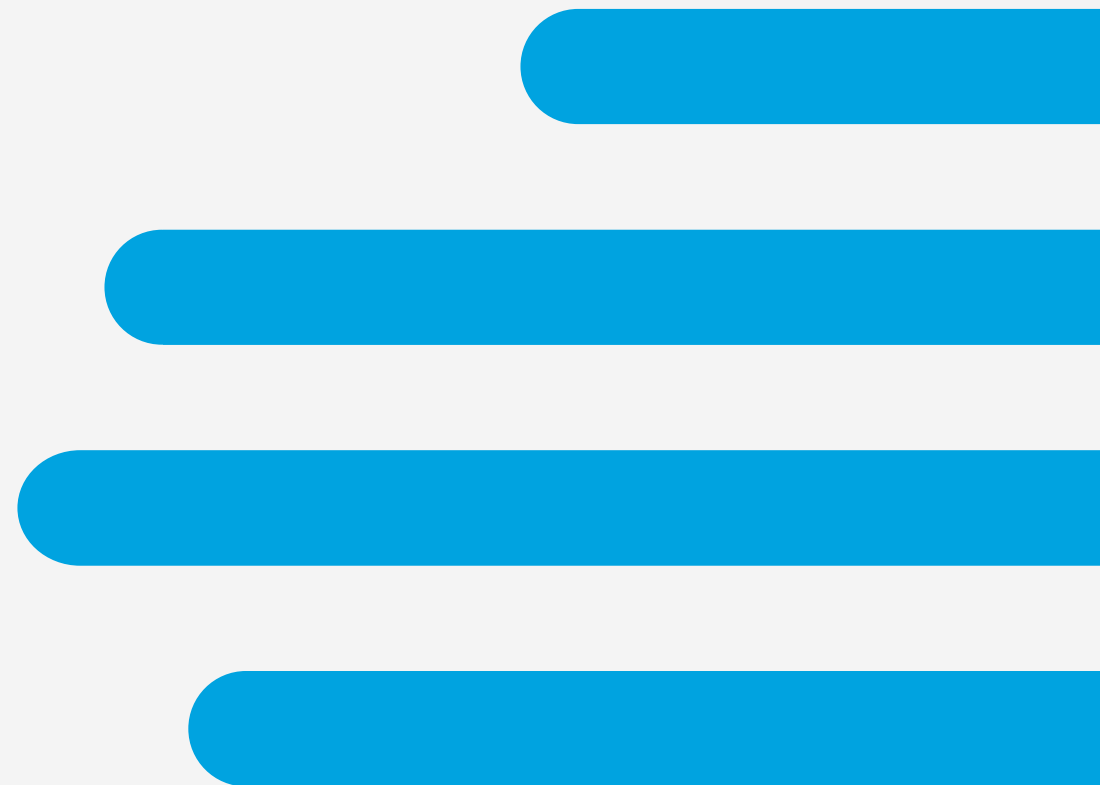
Channel	
Direct-to-patient	<b>Near-to-patient</b>
Relevant Products	
Parenteral products for infusion, including oncology	
Drivers of Uptake	
<b>Behavioural</b>	It is preference for German patients to receive specialist medicines in outpatient clinics
<b>Financial</b>	Nearly all parenteral products are reimbursed in the German retail setting
Relevant Regulation	
<b>Law for more safety in the supply of pharmaceuticals</b> Gesetzes für mehr Sicherheit in der Arzneimittelversorgung (GSAV); Enacted: 16.08.2019; Available from: <a href="https://www.bundesgesundheitsministerium.de/gsaav.html">https://www.bundesgesundheitsministerium.de/gsaav.html</a>	
<b>Annex 3 to the contract on pricing for substances and preparations made from substances</b> Anlage 3 zum Vertrag über die Preisbildung für Stoffe und Zubereitungen aus Stoffen; Published: 01.03.2020	

Sources: IQVIA Local Expertise; <https://www.deutsche-apotheker-zeitung.de/news/artikel/2020/02/25/zyto-apotheker-kritisieren-hilfstaxen-einigung>; <https://www.apotheker-adhoc.de/nachrichten/detail/apo-tipp/preisbildung-fuer-parenterale-zubereitungen-teil-1-apo-tipp/>

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**France**



# In France, ~1/3 of total market value is dispensed through the hospital channel although oncology is majority hospital



- In France, the **majority of drugs by value** are dispensed through the **retail channel** (65%), including some high-value specialty products such as immunology biologics (e.g. Humira) that are available as self-administered injectables
- Oncology products, including Keytruda and Revlimid, are generally restricted to the Hospital channel, where the oncology clinics are located



## Retail Channel

Value, MAT Nov'20 **€ 20.6 Bn**

Total number of pharmacies **21,703**

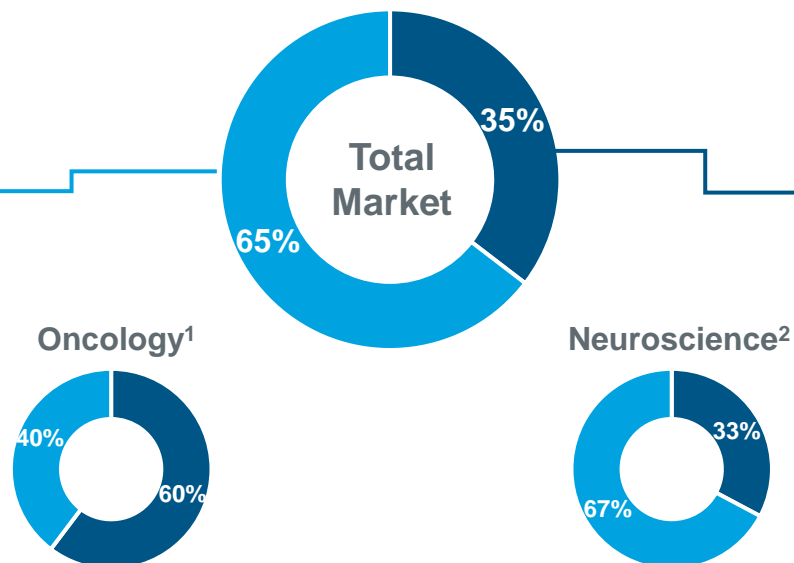
Leading retail products include a range of self-administered products, such as oral Eliquis and subcutaneous injection Humira

France top-5 retail channel products,<sup>3</sup> MAT Nov'20

Rank	Product	Therapy Area	Value
1	Eliquis	Anticoagulants	€ 454.4M
2	Lucentis	Antineovascularisation	€ 356.2M
3	Humira	Immunology	€ 350.1M
4	Xarelto	Anticoagulants	€ 312.7M
5	Eylea	Ophthalmic	€ 312.6M

## France Hospital/Retail Channel Split, Value, MAT Nov'20

■ Hospital Channel ■ Retail Channel



## Hospital Channel

Value, MAT Nov'20 **€ 12.4 Bn**

Total number of hospitals **2,000**

Top Hospital products include monoclonal and humanized antibodies administered via intravenous infusions

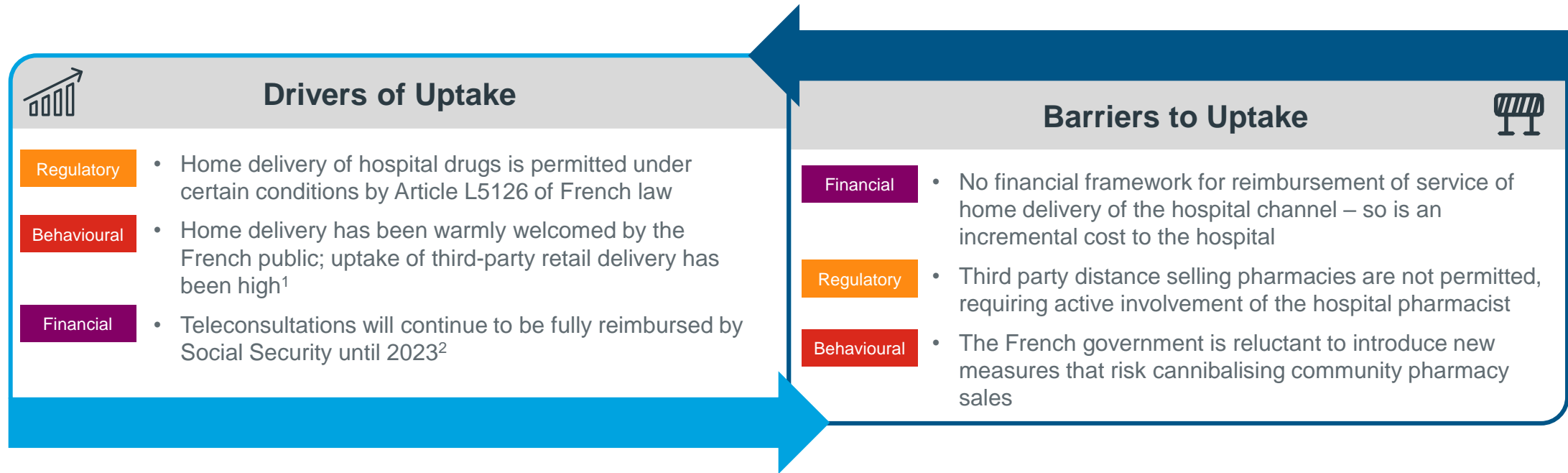
France top-5 hospital channel products,<sup>3</sup> MAT Nov'20

Rank	Product	Therapy Area	Value
1	Keytruda	Oncologics	€ 661.9M
2	Darzalex	Oncologics	€ 386.4M
3	Revlimid	Oncologics	€ 358.4M
4	Soliris	Immunosuppressants	€ 243.7M
5	Avastin	Oncologics	€ 196.0M

# Home delivery of hospital medicines in France: what is possible?



*Regulatory approvals mandated in 2017 endorse home delivery of hospital drugs*



## Key Regulations

Established in 2017, **Pharmacies, including hospital pharmacies, are authorized to sell drugs to the public** and dispense them for home delivery<sup>3</sup>, under certain conditions:

- Drugs must be delivered in a sealed, opaque package with full patient contact details
- Under direct supervision of the pharmacist to safeguard condition of medications and ensure adequate information is available to the patient

The Ministry for Solidarity and Health has published a list of drugs authorized for hospital home delivery.<sup>4</sup>

Other drugs that may be dispensed to the public by hospital pharmacies include drugs subject to a nominative temporary authorization, import authorizations, and hospital/magistral preparations.<sup>5</sup>

Sources: 1. [https://www.francetvinfo.fr/sante/medicament/la-livraison-a-domicile-de-medicaments-en-plein-essor\\_3995463.html](https://www.francetvinfo.fr/sante/medicament/la-livraison-a-domicile-de-medicaments-en-plein-essor_3995463.html). 2. <https://www.vie-publique.fr/loi/276423-loi-14-decembre-2020-financement-securite-sociale-2021-plfss-budget-secu>. 3. <https://www.legifrance.gouv.fr/codes/id/LEGIARTI000042685681/2021-07-01/>. 4. [https://solidarites-sante.gouv.fr/IMG/pdf/liste\\_des\\_medicaments\\_retrocedes\\_20200421.pdf](https://solidarites-sante.gouv.fr/IMG/pdf/liste_des_medicaments_retrocedes_20200421.pdf). 5. <https://solidarites-sante.gouv.fr/soins-et-maladies/medicaments/professionnels-de-sante/prescription-et-dispensation/article/medicaments-retrocedes-retrocession>.

# Home delivery of hospital medicines in France: what is changing?



*Home delivery systems have gained momentum in France in response to the COVID-19 pandemic*

## RECENT TRENDS

No significant trends have emerged since the amendments to the *Code de la Santé Publique* in 2017.

All recent trends have been prompted by COVID-19 and launched to mitigate displacement and contagion.

## IMPACT OF COVID-19 PANDEMIC



- In response to the COVID-19 pandemic, numerous **French cities have implemented social initiatives aimed at facilitating home delivery of medications** to especially vulnerable patients in hopes of minimizing contagion.
- The **Red Cross launched an action protocol in partnership with the FSPF** to serve all individuals incapable or unable to leave the confines of home during the COVID-19 pandemic, and ensure the provision of pharmaceutical care.<sup>1</sup>
- The **French Society for Oncology Pharmacy (SFPO) published a revised oncology pharmacy practice guideline** during the COVID-19 pandemic to secure the pharmaceutical care of patients with cancer.<sup>2</sup>



# France Case Study 1: Retail pharmacy home delivery

Since 2017, home delivery of prescription drugs has been made possible in the French **retail pharmacy channel** through delivery **infrastructure provided by La Poste**, at a cost to the patient.

- A number of **different 3<sup>rd</sup> party organizations** offer **technology platforms** for patients to book the delivery with the local pharmacy
- Medicines are **dispensed by the community pharmacy**, and deliveries are fulfilled by La Poste, who provide a **courier service** between **the local pharmacy and the patient**
- Certain retail products are excluded, including narcotics and drugs requiring cold storage

Channel	
Direct-to-patient	Near-to-patient
Relevant Products	
All retail dispensed pharmaceutical products	
Drivers of Uptake	
Behavioural	Increased need for home delivery due to COVID-19 has impacted uptake
Regulatory	Authorization of home delivery of prescription medicines since 2017
Relevant Regulation	
<p><b>Public Health Codes mandating home delivery under pharmacist supervision</b> Code de la Santé Publique L4211-1 <a href="https://www.legifrance.gouv.fr/codes/id/LEGIARTIO00028747979/2014-03-19/">https://www.legifrance.gouv.fr/codes/id/LEGIARTIO00028747979/2014-03-19/</a></p>	

## Examples



**Service:** Mes médicaments chez moi partnership with La Poste offering home drug delivery throughout France

**Requirements:** Original prescription, *carte vitale*, and *carte mutuelle*

**Price:** 2-hour express delivery available from 7,90€, normal delivery starting from 4,90€



**Service:** Aprium Pharmacie partnership with La Poste and its courier platform “Stuart”

**Requirements:** Original prescription, *carte vitale*, and *carte mutuelle*

**Price:** 2-hour express delivery available from 8,90€, normal delivery starting from 1€



# France Case Study 2: *Community partnerships, Evreux*

In the French city of Evreux, a **collaboration between local pharmacies and regional health authorities** was established to provide a prescription home delivery service free of charge in response to the COVID-19 pandemic.

- The service was provided through a collaboration between the CCAS, community health centres, and local pharmacies.<sup>1,2</sup>
- By calling a dedicated hotline, a **public health official or volunteer** will travel to the patients home to pick up an original prescription and *carte vitale*
- The envelope will then be transferred to a **local pharmacy**, where a pharmacist will confirm the order and return the prescription securely to the patient

The home service system is **free of charge**, and is limited to **once per week per household**.



**COVID-19**  
Évreux SOLIDARITÉ



Note: CCAS - Centre Communal d'Action Sociale

Sources: 1. <https://evreux.fr/covid-19/evreux-entraide/?cn-reloaded=1>, 2. <https://france3-regions.francetvinfo.fr/normandie/coronavirus-peut-on-se-faire-livrer-ses-medicaments-domicile-1805542.htm>

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## Channel

Direct-to-patient

Near-to-patient

## Relevant Products

All retail dispensed pharmaceutical products

## Drivers of Uptake

Financial

Cost of delivery covered by the local health authority

Behavioural

Need for home delivery services due to COVID-19

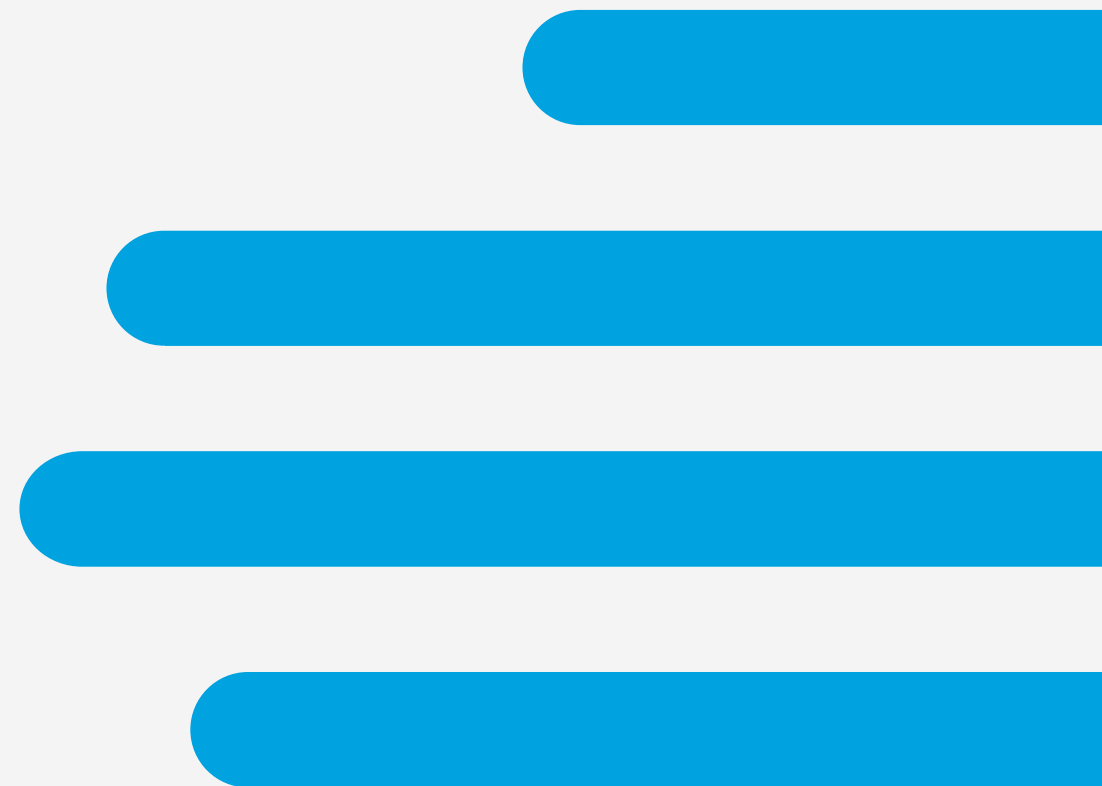
## Relevant Regulation

**Public Health Codes mandating home delivery under pharmacist supervision**

Code de la Santé Publique L4211-1

<https://www.legifrance.gouv.fr/codes/id/LEGIARTI00028747979/2014-03-19/>

# UK Deep-Dive



# Hospital is the dominant channel by value in the UK, accounting for more than half the market



- Most specialty medicines are restricted to the hospital channel, based on a financial decision to ensure centralised purchasing and greater cost control measures
- Some therapy areas are almost entirely limited to hospital, such as oncology where 95% of products by value are dispensed via the Hospital channel



## Retail Channel

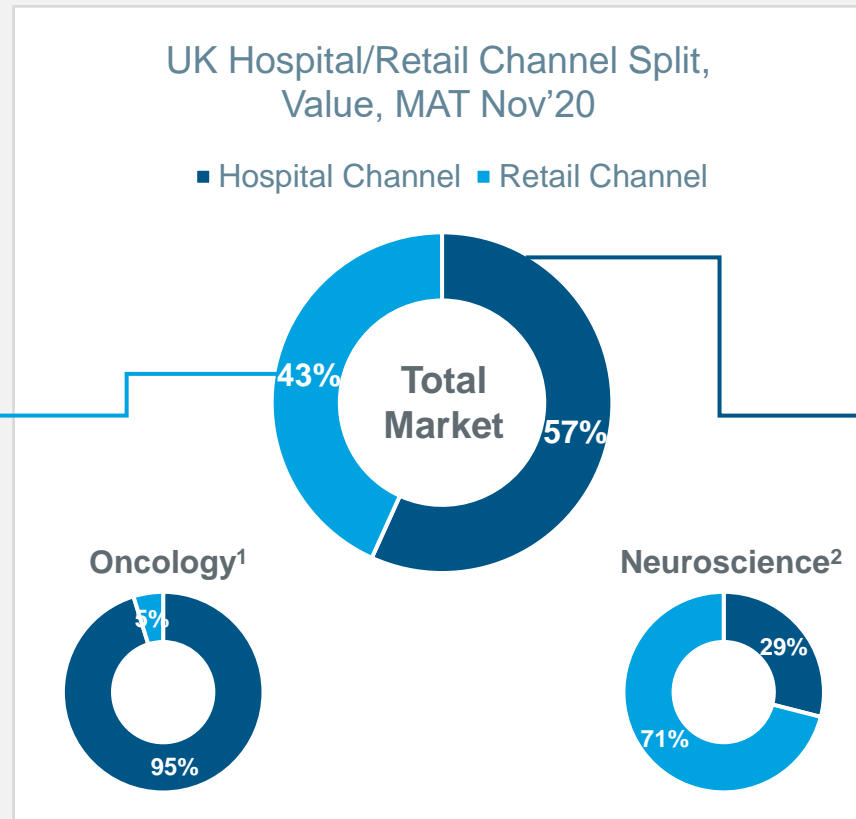
Value, MAT Nov'20 **€ 10.7 Bn**


Total number of pharmacies **14,252**

Leading retail products include those **prescribed through primary care**, including lipid regulators and anticonvulsants

UK top-5 retail channel products,<sup>3</sup> MAT Nov'20

Rank	Product	Therapy Area	Value
1	Lipitor	Lipid Regulators	€ 328.1M
2	Foster	Respiratory	€ 249.1M
3	Lyrica	Anticonvulsant	€ 198.3M
4	Lamictal	Anticonvulsant	€ 116.9M
5	Neurontin	Anticonvulsant	€ 115.7M





## Hospital Channel

Value, MAT Nov'20 **€ 14.0 Bn**

Total number of hospitals **505<sup>4</sup>**

Top hospital products include specialty biologics such as Eylea, adalimumab biosimilars, and various oncologicals

UK top-5 hospital channel products,<sup>3</sup> MAT Nov'20

Rank	Product	Therapy Area	Value
1	Eylea	Ophthalmic	€ 523.2M
2	Keytruda	Oncologicals	€ 380.2M
3	Kalydeco	Cystic Fibrosis	€ 350.9M
4	Revlimid	Oncologicals	€ 242.9M
5	Amgevita	Immunologics	€ 229.6M

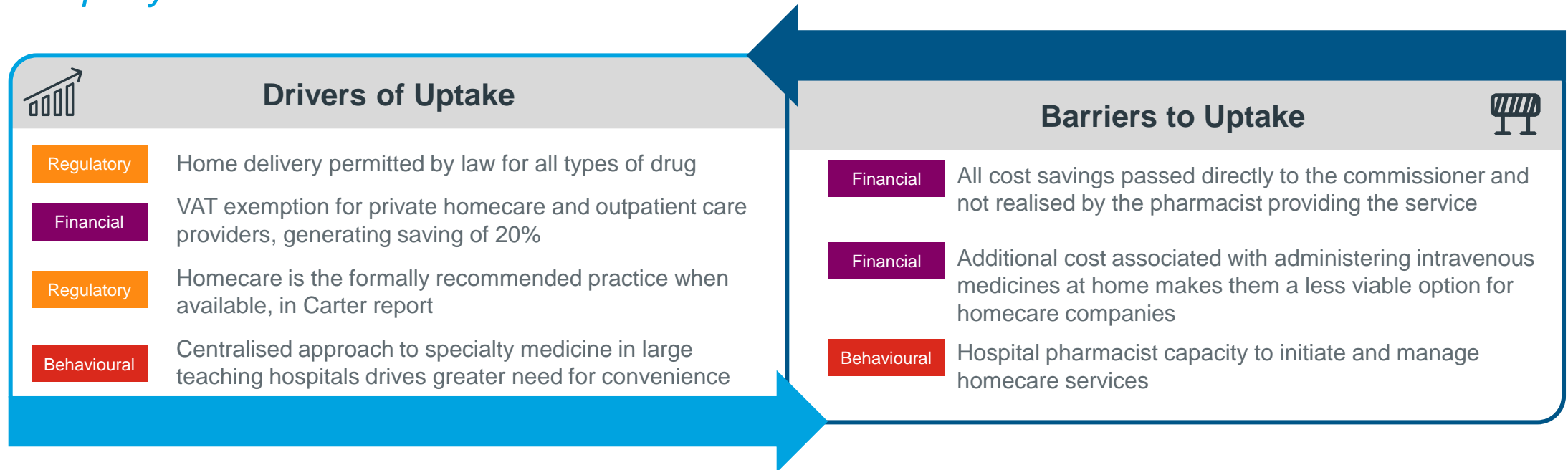
Source: IQVIA MIDAS MTH, Nov'20; 1) Oncology products defined as ATC2 Class L1,L2, V3C plus Revlimid, Xgeva, Proleukin, Pomalyst; 2) Neuroscience products defined as ATC1 class N (Nervous System); 3) Hospital products were defined as those with ≥95% of sales in the hospital channel during MAT Nov'20. Likewise, retail channel products were defined as those with ≥95% of sales in the retail channel 4) IQVIA OneKey Data 2021  
SMA = Spinal Muscular Atrophy



# The UK has many driving factors behind the uptake of home delivery of hospital products



As a result, clinical homecare services now consist of >25% of the hospital budget, equivalent to £3-4Bn per year



## Key Regulations

### The Human Medicines Regulations

Enacted 14.12.2012, Available from:

<https://www.legislation.gov.uk/ukxi/2012/1916/introduction>

### Homecare Medicines Services Framework

Published 01.09.17; Available from:

<https://www.commercialsolutions-sec.nhs.uk/frameworks/homecare-medicines-services>

### Carter review on productivity in NHS hospitals

Published 11.06.2015, Available from:

<https://www.gov.uk/government/publications/productivity-in-nhs-hospitals>

# Several recent measures resulting from COVID-19 have accelerated the uptake of home delivery further



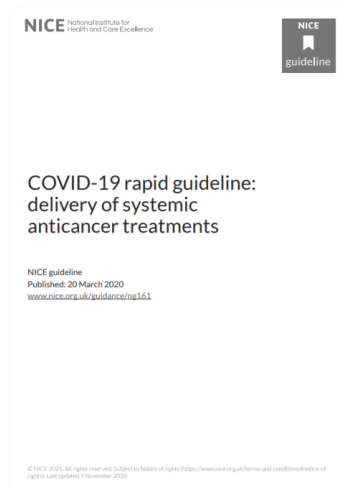
*Updated guidelines and funding measures have had a greater emphasis on clinical homecare*

## RECENT LEGISLATION - NICE GUIDELINES 161

In response to the COVID-19 pandemic, NICE published guidelines 161 [NG161] to **maximise the safety of patients with cancer**, minimise displacement and contagion, and streamline NHS resources.<sup>1</sup>

The NG161 set forth a list of recommendations to modify usual care of medicines and procedures to minimise the need for hospital admissions, including:

- Supporting home delivery of oral and subcutaneous cancer medicines
- Prioritising products with improved side effect profiles (e.g. Keytruda)\*
- Switching to modes of administration favourable for home settings\*
- Using shorter treatment regimens
- Providing repeat prescriptions



## IMPACT OF COVID-19 PANDEMIC

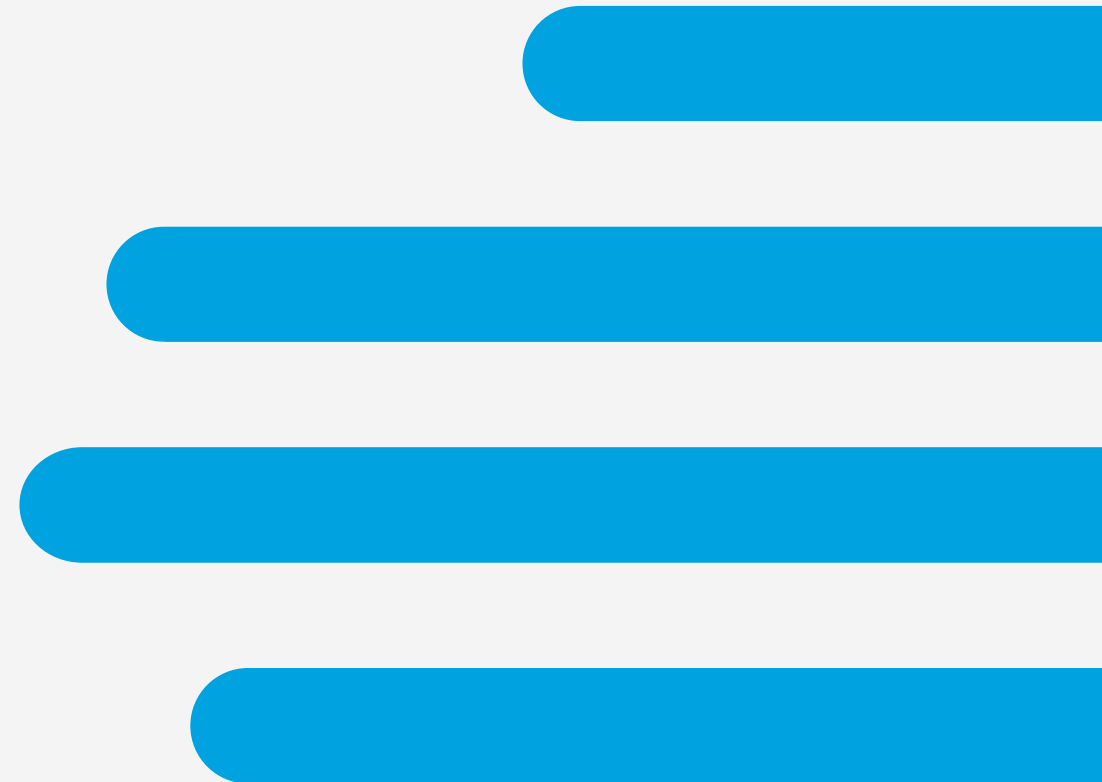


- In light of COVID-19, the NHS moved to a principle of **'digital first'** in primary care and with outpatients, **encouraging remote measures**, including teleconsultations, remote management and electronic prescription transfer to distance pharmacies, and home delivery.<sup>2</sup>
- The NHS commissioned **community pharmacy and dispensing doctor home delivery services** for shielded patients in outbreak areas<sup>3</sup>, and injected £300M of advanced funding into community pharmacies<sup>4</sup>
- A temporary, centrally-coordinated **volunteer scheme for home deliveries** was organised between the NHS, the Royal Voluntary Service, and the GoodSAM app<sup>5</sup>

Note: \* Full list of interim treatment options available at: <https://www.nice.org.uk/guidance/ng161/resources/interim-treatment-change-options-during-the-covid19-pandemic-endorsed-by-nhs-england-pdf-8715724381>

Sources: 1. <https://www.nice.org.uk/guidance/ng161/chapter/7-Modifications-to-usual-service/> 2. <https://www.bma.org.uk/advice-and-support/covid-19/adapting-to-covid/covid-19-video-consultations-and-homeworking>. 3. <https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-community-pharmacy/>. 4. <https://psnc.org.uk/our-news/covid-19-funding-update-ministers-agree-300-million-cash-injection/>. 5. <https://nhsvolunteerresponders.org.uk/>.

# UK Rules and Regulations



# Home delivery of medicines in the UK is permitted, with very few restrictions

The UK law relating to the dispensing of pharmaceuticals is dictated by The Human Medicines Regulations (2012)

- According to **Regulation 220**, prescription medicines must **only be sold or supplied through a registered pharmacy**<sup>1</sup>
  - This includes any homecare provider or distance selling pharmacist, meaning every homecare company must have a pharmacy license
- **Regulation 248** permits the **delivery of medicines**, providing they are not delivered to a public place<sup>2</sup>
  - Currently, no medicines are excluded from home delivery under this regulation, including controlled drugs

Several official practice guidelines covering the home delivery of medicine are also available:

- Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet (General Pharmaceutical Council, 2019)<sup>3</sup>
- Medicines, Ethics and Practice Guide, Chapter 3.7.4 (Royal Pharmaceutical Society, 2019)<sup>4</sup>



Guidelines for delivery and posting of medicines to patients: Chapter 3.7.4 Medicines, Ethics and Practice guide

1) The Human Medicines Regulations (2012) Reg. 220, Available from: <https://www.legislation.gov.uk/uk/si/2012/1916/regulation/220>; 2) The Human Medicines Regulations (2012) Reg. 248, Available from: <https://www.legislation.gov.uk/uk/si/2012/1916/regulation/248>; 3) Available from: [https://www.pharmacyregulation.org/sites/default/files/document/guidance\\_for\\_registered\\_pharmacies\\_providing\\_pharmacy\\_services\\_at\\_a\\_distance\\_including\\_on\\_the\\_internet\\_april\\_2019.pdf](https://www.pharmacyregulation.org/sites/default/files/document/guidance_for_registered_pharmacies_providing_pharmacy_services_at_a_distance_including_on_the_internet_april_2019.pdf) 4) Available from: <https://www.rpharms.com/publications/the-mep>

# For hospital restricted medicines, VAT-exemption provides a strong incentive for outpatient management and homecare

## UK HOSPITAL-RESTRICTED DRUGS

Drugs in the UK which have been “tariff-excluded” are restricted to the hospital channel

- These can't be reimbursed through retail pharmacies due to complexities of Patient Access Schemes and contract pricing
- As a result, tariff-excluded drugs are purchased centrally by the NHS provider, and reimbursed by the commissioner
- Includes all intravenous medicines and chemotherapies, and most high-price specialty drugs

Purpose: To have greater negotiating power and control over drug pricing, reducing overall cost

- Tariff-excluded drugs in England are available through the NHS website<sup>1</sup>

## VAT-EXEMPTION RULES



In the UK, NHS-run **hospital pharmacies must pay VAT on medicines**, whereas **third-party pharmacies are exempt**

- This traces back to decisions made at the founding of the NHS due to how medicines were managed at the time

As a result, hospitals can make a VAT saving of 20% by dispensing a medicine through a third-party, such as a homecare provider

This financial incentive is the **key driver** in the **success of clinical homecare** in the UK<sup>2</sup>

1) NHS England drugs list, Available from: <https://www.england.nhs.uk/publication/nhs-england-drugs-list/> ; 2) The Pharmaceutical Journal, 7 Jan 2020, "Half of NHS trusts outsource outpatient pharmacy services to avoid VAT", Available from: <https://www.pharmaceutical-journal.com/news-and-analysis/news/half-of-nhs-trusts-outsource-outpatient-pharmacy-services-to-avoid-vat/20207538.article>

# Carter Report: Driving efficiency and removing variation

*This report laid out the current strategic direction for greater uptake of homecare and outpatient services*

Review on productivity in NHS hospitals, led by Lord Carter, and published in February 2016

- Goal was to identify areas in hospital care where cost savings could be made through improvement in productivity and reduction in variation
- Combined recommendations from the report were expected to save the NHS £5Bn a year by 2021



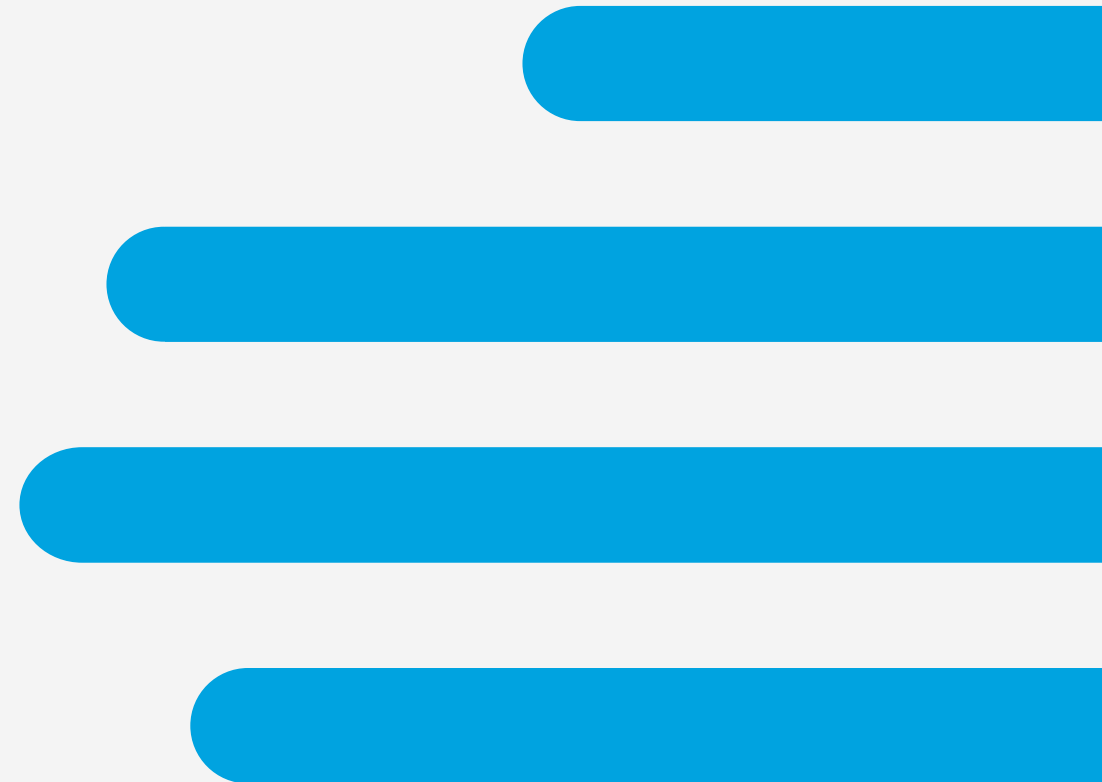
## Key recommendation from the report was to increase the use of homecare providers and community pharmacies to dispense hospital medicines

- Purpose was to decrease burden on hospital pharmacists to improve efficiency, and to take advantage of 20% VAT saving

Available from:  
<https://www.gov.uk/government/publications/productivity-in-nhs-hospitals>

““” *Trusts that have not currently outsourced their outpatient dispensing services should ensure their HPTP plans include a review of these services and have a plan in place for improving productivity and efficiency, including consideration of alternative supply routes, such as **homecare providers** or **community pharmacies**.* ““”

# Direct-to-patient delivery in UK Hospitals



# Direct-to-patient delivery in UK hospitals is provided through clinical homecare

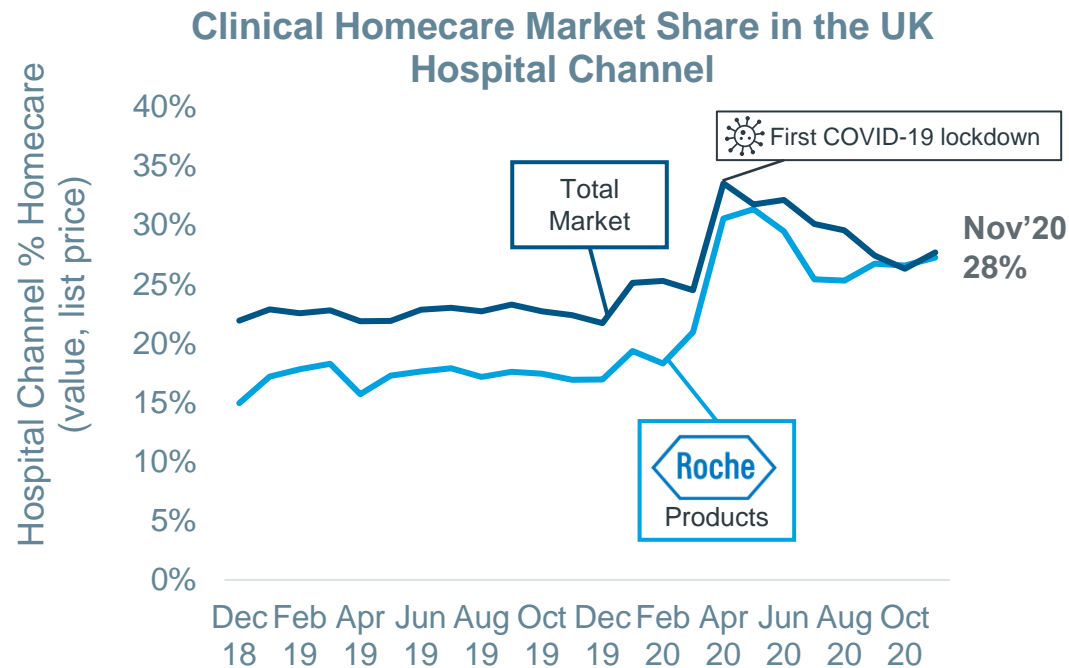
Channel

Direct-to-patient

Near-to-patient

Thanks to strong drivers of uptake, clinical homecare in the UK has seen much greater use than other European countries

Currently, over a quarter of the UK hospital pharmacy budget is delivered through clinical homecare, equating to £3-4Bn per year in cost-value for the National Healthcare Service



## Drivers of Uptake

Financial

Private homecare providers are VAT-exempt, providing a 20% saving on cost versus the hospital pharmacy

Regulatory

Formally recommended practice by NHS governing bodies, e.g. Carter Report

Behavioural

Improved control over patient adherence and proper product handling through homecare nursing service

Behavioural

Frees up resources in the hospital site, with less need to hold stock and improvements in cash flow

## Relevant regulations

**Homecare Medicines Services Framework**  
Published 01.09.17; Available from:  
<https://www.commercialsolutions-sec.nhs.uk/frameworks/homecare-medicines-services>

**Carter review on productivity in NHS hospitals**  
Published 11.06.2015, Available from:  
<https://www.gov.uk/government/publications/productivity-in-nhs-hospitals>



# Clinical homecare is normally provided in partnership with private, third-party providers

*The key benefit to this arrangement is to make use of VAT exemption rules*

There are several different models that exist, depending on the needs of the particular product

## Standard postal delivery with nurse-supported self-administration

- Suitable for products without cold chain requirements, such as HIV and HepC antivirals
- Deliveries can be fulfilled by Royal Mail, with national coverage<sup>1</sup>

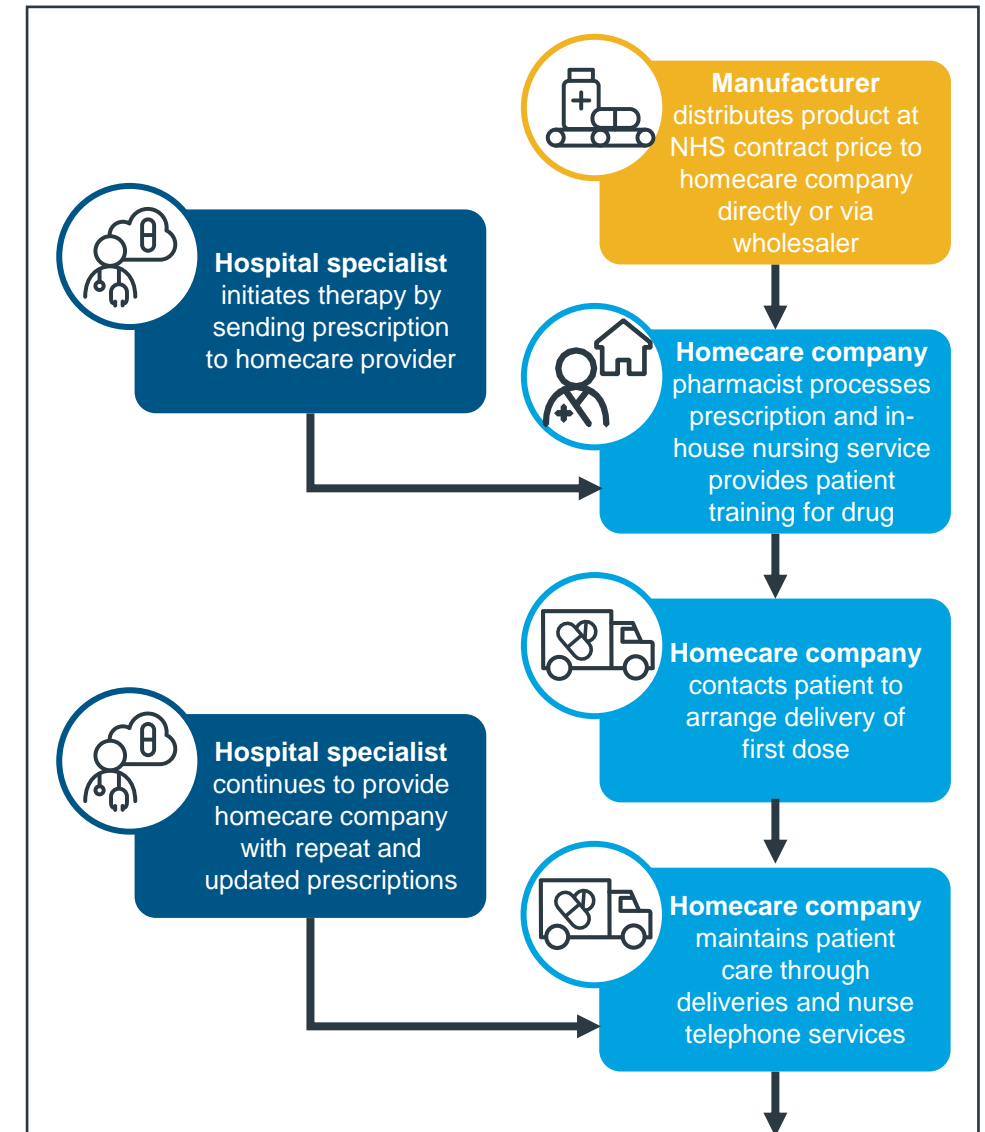
## Cold-chain courier delivery with nurse-supported self-administration

- Suitable for self-administered specialty biologics including Humira (adalimumab) and biosimilars
- Deliveries fulfilled by the homecare company using in-house logistics with the required refrigeration capabilities

## Nurse administration at home of parenteral treatments (in rare cases)

- Used in cases where it is important to keep patients away from the hospital, e.g. Outpatient Antimicrobial Therapy (OPAT) for cystic fibrosis, bone infection, and severe fungal nail patients

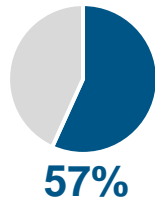
The NHS homecare guidance is overseen by the National Homecare Hospital Committee



# In its current state, the UK system has become dependent on homecare companies for continued provision of patient care

## Key factors impacting usage of UK clinical homecare

Large hospital channel by value of total drug market



€14Bn  
per year<sup>1</sup>



20%  
VAT saving

Financial savings through VAT that are shared between the health care system and home care companies



High share of products by value go through homecare<sup>2</sup>



Relatively low number of hospitals

505  
hospitals<sup>3</sup>

Dependency on private homecare companies for continued supply of medicine, with the NHS unable to shoulder the burden without 3<sup>rd</sup> party help

- **Cost burden** of homecare channel **too high** for NHS without change to VAT rules
- **Capacity** of hospital pharmacist to provide **physical throughput of medicines too low**

Therefore, the current system has become reliant on the continued existence of homecare companies



healthcare  
at home

LloydsPharmacy

Clinical  
Homecare



Alcure™  
Dedicated to patient care



Calea  
the heart of homecare



FRESENIUS  
MEDICAL CARE

# Homecare Medicine Services Framework (2017)

*This 2017 legislation is designed to streamline the use of homecare across hospital trusts in England and Wales*

The framework is issued by NHS Commercial Solutions and provides:

## A) A set of guidelines to ensure compliant implementation of homecare services within each hospital trust

- Categorisation of homecare into four pillars: Low-tech (e.g. oral), medium-tech (e.g. subcutaneous), high-tech (e.g. infusion), and high-tech antibiotics
- Pre-prepared templates and procedures compliant with NHS terms and conditions
- Guidelines for benchmarking and shortlisting providers

## B. A centralised contract between the NHS and homecare services which can be carried over to each trust

- National agreement with 14 private suppliers of clinical homecare, enabling their use at a hospital trust level without the need for further contracting arrangements
- **Fixed cost structure** providing transparency and allowing access to medicines for homecare providers, **under contract prices agreed through existing NHS access schemes**
- Flat cost structure and lack of supplier preference allows each trust to select preferred providers through direct award

**Contract Start**  
01/09/17

**Contract End**  
30/10/21

**Available From**

<https://www.commercialsolutions-sec.nhs.uk/frameworks/homecare-medicines-services>

14 private homecare providers included in the framework contract:

- Alcura UK Ltd
- Baxter Healthcare Ltd
- B Braun Medical Ltd
- Calea UK Ltd
- Fairview Health Ltd
- Fresenius Medical Care
- Healthcare at Home Ltd
- HealthNet Homecare
- Lloyds Pharmacy Clinical Homecare
- One Stop Pharmacy
- Pharmaxo Pharmacy Services
- Provide Health Ltd
- Smarta Healthcare
- UPS Polar Speed

Some providers offer general clinical homecare (e.g. Healthcare at Home) whereas others offer specialist services (e.g. dialysis from Fresenius)



# UK Case Study 1: *York hospital homecare services*

Like most NHS hospital trusts in the UK, York Hospital operates a comprehensive homecare offering

The Hospital Homecare Team are a dedicated team of NHS pharmacy staff at York Hospital who **manage and coordinate the home delivery of hospital prescribed medicines**

The delivery of medications is performed by **private, third-party homecare providers**, which are not part of the NHS or the hospital. Each homecare provider will employ **in-house pharmacists** who are required to dispense the medicines for home delivery

- Homecare providers include: *Alcura, Baxter, Biodose, Lloyds Pharmacy Clinical Homecare, Calea, Evolution, Fresenius, and Healthcare at Home*, and are bound by the same confidentiality rules as the NHS (The Data Protection Act 1998)

All deliveries require a signature as “proof of delivery”, and are arranged by:

- Van delivery to home
- Van delivery to an alternative address chosen by the patient

The **homecare provider will arrange a visit or telephone consultation from a nurse** to either administer the medication or instruct on its proper use



Channel	
Direct-to-patient	Near-to-patient
Relevant Products	
A wide range of hospital prescribed medicines	
Drivers of Uptake	
Financial	VAT-exempt, providing a 20% saving on cost
Regulatory	Mandated by Carter Report; Hospital-drug home delivery encouraged
Behavioural	Care delivered to the patient; Increasing need for home delivery services due to COVID-19
Relevant Regulation	
<b>Homecare Medicines Services Framework</b> Published 01.09.17; Available from: <a href="https://www.commercialsolutions-sec.nhs.uk/frameworks/homecare-medicines-services">https://www.commercialsolutions-sec.nhs.uk/frameworks/homecare-medicines-services</a>	
<b>Carter review on productivity in NHS hospitals</b> Published 11.06.2015, Available from: <a href="https://www.gov.uk/government/publications/productivity-in-nhs-hospitals">https://www.gov.uk/government/publications/productivity-in-nhs-hospitals</a>	



# UK Case Study 2: *OHPiT on the Isle of Wight*

In cases of geographic need due to isolation from specialist hospital clinics, high-tech homecare services can be **provided by the hospital trusts themselves**, without outsourcing.

For example, the NHS Isle of Wight Trust provides Out-Patient and Home Parenteral Infusion Therapy (OHPiT). This is a **community service that provides intravenous therapy** for patients referred from the hospital or from a GP in the community<sup>1</sup>.

The innovative, **cost-effective service**<sup>2</sup> operates 7 days a week, and can be **delivered both in the infusion clinic or via the comfort of the patients home**, to patients requiring antimicrobial treatment or infusion therapy.

Through the utilisation of the OHPiT service, the Trust can:

- Reduce the need for in-patient admission
- Free capacity within the hospital for more complex / critical patients
- Reduce the risk of hospital acquired infections
- Improve patient quality of life by providing comfort and choice



## Channel

Direct-to-patient

Near-to-patient

## Relevant Products

Antimicrobial treatment and medications with infusion mode of administration

## Drivers of Uptake

Behavioural

Geographically isolated from closest specialist care in mainland Britain

Financial

Cost of service covered by the NHS

Regulatory

Mandated by the Public Health England's Antimicrobial Stewardship Guidelines; Encouraged by the NHS Five Year Forward plan

## Relevant Regulation

### Carter review on productivity in NHS hospitals

Published 11.06.2015; Available from:

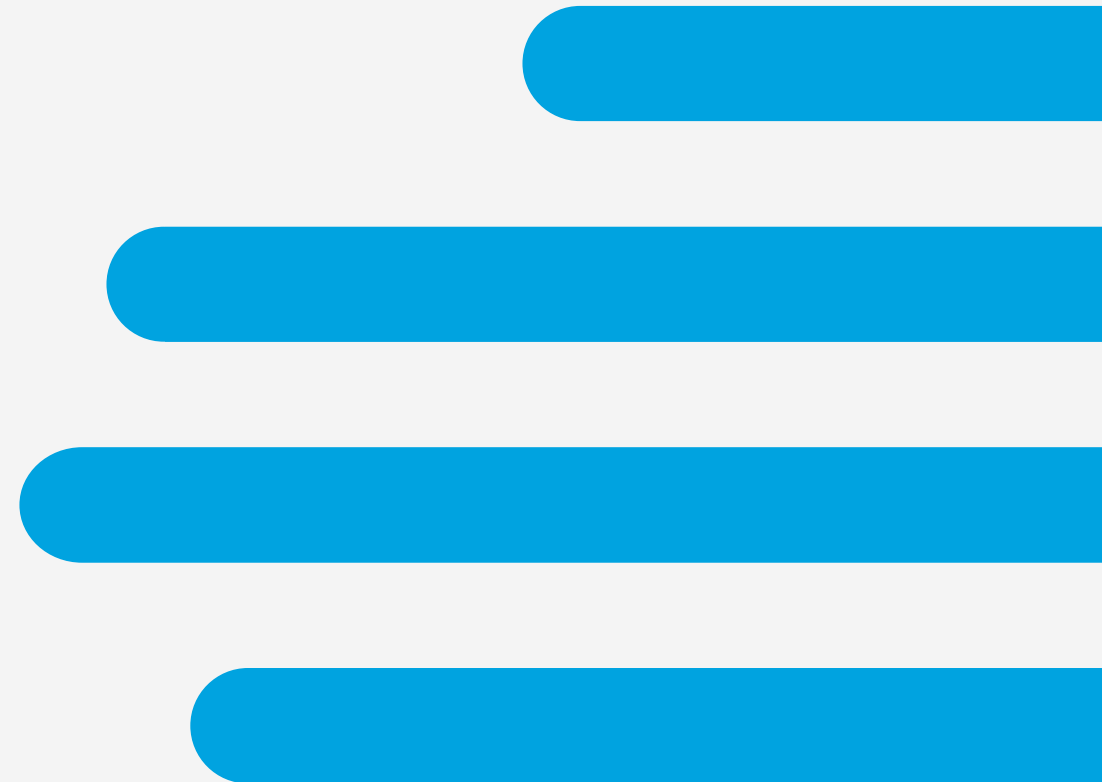
<https://www.gov.uk/government/publications/productivity-in-nhs-hospitals>

### Antimicrobial prescribing and stewardship competencies

Published 09.13; Available from:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/253094/AR\\_HAIPrescrcompetencies\\_2\\_.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/253094/AR_HAIPrescrcompetencies_2_.pdf)

# Near-to-patient delivery in UK hospitals





# Specialist hospitals have the option to run satellite units in near-to-patient locations

*The satellite units are run in existing brick-and-mortar sites with the required capabilities*

They are normally founded by a specialist clinic within a larger hospital

- Common locations include community hospitals and local medical centres
- Most commonly available for renal care and dialysis, however also popular for oncology and haematology care
- **Medicines are supplied by the specialist trust** either directly (through its own pharmacy) or indirectly (invoiced from the host site pharmacy)

### Drivers of Uptake

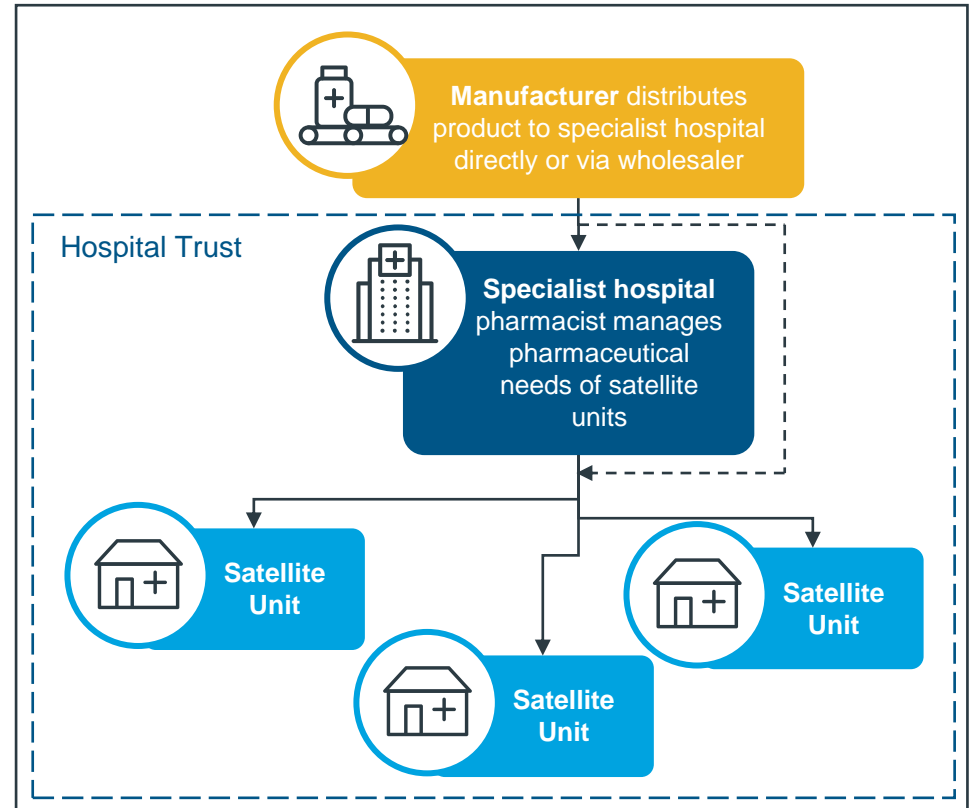
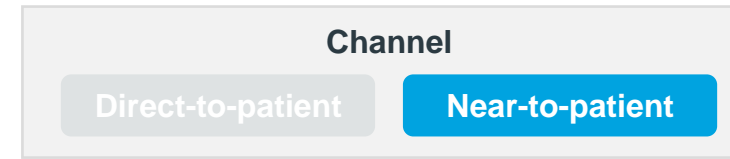
Behavioural

Fulfils need generated by lack of local specialist clinics in the UK healthcare system, and provides highly specialised tertiary services closer to the patient

Financial

Cost for care remains with the specialist trust, simplifying the funding stream

➔



**Relevant regulations**

**Health and Social Care Act 2012**  
 Enacted 27.03.2012, Available from:  
<https://www.legislation.gov.uk/ukpga/2012/7/contents/enacted>

**The Human Medicines Regulations**  
 Enacted 14.12.2012, Available from:  
<https://www.legislation.gov.uk/uksi/2012/1916/introduction>

# Alternatively, mobile units can be deployed to avoid the need for physical sites

Channel

Direct-to-patient

Near-to-patient

*These have the added benefit of being able to move between locations throughout the week, providing wider coverage*

Mobile units are run by a specialist hospital trust, and the medicines are dispensed through the hospital pharmacist

- Most commonly deployed for administration of chemotherapy using specialist equipment in remote locations
- Typically staffed by a team of nurses, with the doctors and pharmacists remaining at the hospital site



## Drivers of Uptake

Behavioural

Need for oncology care in remote locations without nearby brick-and-mortar sites with the required capabilities

Financial

Cost for care is managed through the specialist trust rather than local sites, simplifying the funding stream





# UK Case Study 3: *Christie Hospital at Bolton and Salford*

In North West England, The Christie NHS Foundation Trust is operating a **mobile chemotherapy unit** (Bolton) and a **satellite unit** (Salford) to provide chemotherapy and other systematic anti-cancer treatments (SACT) to patients

The system is flexible and allows additional supportive treatments to be supplied through satellite unit host sites by access to the full range of Trust services

## Mobile Chemotherapy Unit



**Service:** Launched in 2013, specialist outreach service provides cancer treatment administered by specialist Christie **chemotherapy nurses** employed by the Royal Bolton Hospital in 5 different locations throughout the week

**Location(s):** Rochadale, Trafford, Chadderton, and Bolton

**Capacity:** 4 treatment Chairs; 1,700 treatments per year

## Satellite Unit



**Service:** The Christie **Chemotherapy nurses** travel to Salford once a week to deliver selected cancer treatments to patients living in the Salford area

**Location(s):** Haematology Unit at Salford Royal NHS Foundation Trust

**Capacity:** 3 treatment chairs; 480 treatments per year

### Channel

Direct-to-patient

Near-to-patient

### Relevant Products

A wide range of oncological products, including Trastuzumab

### Drivers of Uptake

Financial

Cost covered by The Christie Foundation

Behavioural

Deployed near-to-patient in remote locations where there is no suitable nearby hospital site

### Relevant Regulation

#### Homecare Medicines Services Framework

Published 01.09.17; Available from:

<https://www.commercialsolutions-sec.nhs.uk/frameworks/homecare-medicines-services>

#### Antimicrobial prescribing and stewardship competencies

Published 09.13; Available from:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/253094/AR\\_HAIprescrcompetencies\\_2\\_.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/253094/AR_HAIprescrcompetencies_2_.pdf)



# UK Case Study 4: *Lloyds Healthcare Centre*

Co-located within a LloydsPharmacy and delivered by a **specialist nursing team**, patients can now opt to **receive infusion or injection treatment** in a local LloydsPharmacy Healthcare Centre

The innovative, integrated community service offers to **improve patient experience** by providing easier and more convenient access to traditional hospital-based treatment, whilst **transforming hospital capacity**

- Each healthcare centre must provide an agreed clinical governance framework with the relevant NHS trust
- The first Lloyds infusion centre was launched in Scunthorpe, England, in partnership between the Northern Lincolnshire and Goole NHS Foundation Trust

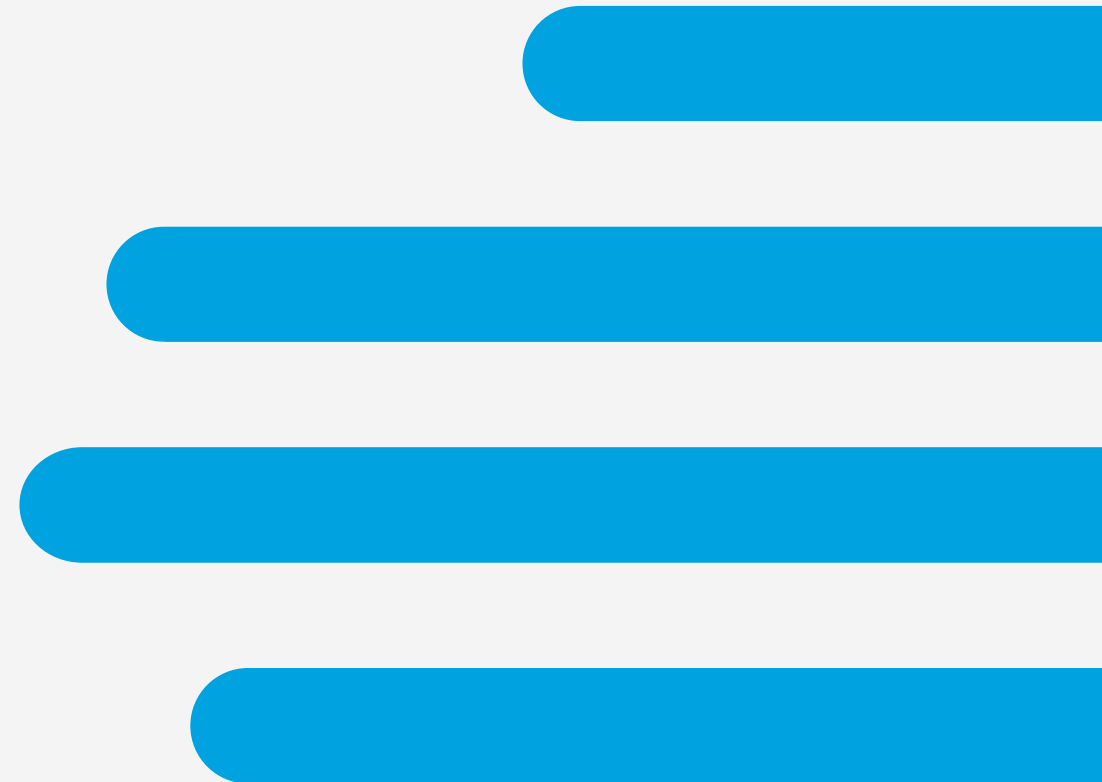
The project has been **commissioned by the NHS**, and paid for by a combination of trusts, clinical commissioning groups, and pharmaceutical companies

LloydsPharmacy  
**Clinical  
Homecare**











Channel	
Direct-to-patient	<b>Near-to-patient</b>
Relevant Products	
A wide range of hospital prescribed medicines	
Drivers of Uptake	
<b>Financial</b>	Private homecare providers are VAT-exempt, providing a 20% saving on cost
<b>Regulatory</b>	Mandated by Carter Report; Hospital-drug outpatient management encouraged
Relevant Regulation	
<b>Homecare Medicines Services Framework</b> Published 01.09.17; Available from: <a href="https://www.commercialsolutions-sec.nhs.uk/frameworks/homecare-medicines-services">https://www.commercialsolutions-sec.nhs.uk/frameworks/homecare-medicines-services</a>	
<b>Carter review on productivity in NHS hospitals</b> Published 11.06.2015, Available from: <a href="https://www.gov.uk/government/publications/productivity-in-nhs-hospitals">https://www.gov.uk/government/publications/productivity-in-nhs-hospitals</a>	
<b>The Human Medicines Regulations</b> Enacted 14.12.2012, Available from: <a href="https://www.legislation.gov.uk/ukxi/2012/1916/introduction">https://www.legislation.gov.uk/ukxi/2012/1916/introduction</a>	

# Closing Remarks



# Several different models for bringing hospital drugs to a location closer to the patient have been identified

*The local success of each model depends on suitability to the local market, as well as a range of identified regulatory, financial, and behavioural factors*

	Model	Example in practice	Relative success
<b>Direct-to-patient</b> Delivery of hospital medicines to the patients home	<b>1. Outsource provision of homecare to third-party providers</b>	 <b>UK Case Study #1</b> Comprehensive homecare offering managed and coordinated by dedicated NHS pharmacy staff, with products dispensed and delivered by private, third-party homecare providers	
	<b>2. Develop hospital in-house homecare capabilities</b>	 <b>UK Case Study #2</b> Development of a community infusion service by Hospital Trusts for outpatients requiring intravenous therapy in rural areas	
<b>Near-to-patient</b> Delivery of hospital medicines at a site nearer to the patients home	<b>3. Enable development of hospital external sites</b>	 <b>UK Case Study #3</b> Infusion sites in hospital satellite units and mobile units, managed through the specialist hospital pharmacy	
	<b>4. Transition hospital products into retail channel and administer through outpatient clinics</b>	 <b>Germany Case Study #1</b> Specialist care provided through office-based clinicians, and outpatient clinics, with medicines dispensed through the German retail pharmacy channel	



# Thank you

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