

World Pharmacy Council Member Survey Report: SPECIALTY MEDICATIONS

July 2020

Introduction

Across June and July 2020 the WPC surveyed its member organisations on the topic of Specialty Medications. Building on a background paper on this issue published for WPC members in May 2020 (see <https://www.members.worldpharmacycouncil.org/specialty-medications>), this survey sought to better understand the scope, market conditions, regulations, restrictions and potential for change with regard to these complex (and often high cost) medicines. The objective is to enable a compelling case to be built for the clinical and patient care benefits of community pharmacies dispensing specialty and biologic products for their patients.

This report provides a summary of the responses and, as an Appendix, a table detailing the individual responses to each question.

The results show that there is a consistent international view that greater accessibility to these medicines through community pharmacies would be beneficial for patients. However, there is little consistency regarding the regulatory treatment of individual drugs. The report highlights that some countries are making progress to improve the accessibility to these medicines. Portugal, for example, has been able to build a case through an initial focus on HIV medications and through changes made as part of the national Covid-19 response. Ireland has a High Tech Drugs scheme that is supported by the IPU, and a pilot study there is trialling the supply of hepatitis C medicines through community pharmacies. The USA is unfortunately experiencing the opposite trend, with a tightening of availability being driven largely by the market power of some participants, rather than by consideration of patient benefit.

Summary of responses

To see the questions and the detailed responses, see the Appendix to this report.

Terminology (Question 1)

“Specialty medications” was confirmed to be an American terminology, however there was no common term across WPC countries for this category of drugs. Given the USA’s size and its leading position in the introduction of new therapies, the term specialty medications (or specialty drugs) is the most commonly used on the internet (based on Google). While it is unlikely that a change in terminology will have any real bearing on pharmacy’s role, WPC members may wish to consider whether the WPC’s use of this term promotes an unwanted (and, in most cases, unwarranted) view that involvement in these medicines should be a niche that is not open to all pharmacies. That said, the only terminology in any WPC country that does not hold this niche connotation is “High Tech Drugs” as used in Ireland.

Scope (Question 2)

Seven out of eight WPC members considered that the definition suggested in the survey was appropriate. However, given the key role the USA plays in this area, the NCPA’s differing viewpoint must be taken into account. The recommendation is therefore that the simple, broad definition from a WPC standpoint becomes:

A registered drug that targets a rare or highly complex medical condition and/or requires complex clinical monitoring.

The above is broadly in line with other definitions on the internet (although there is no consistent definition, which was the reason for the question). Although the drugs are often biologics and/or require special handling or special administration, this is not always the case. Also, although usually high cost, and often with special rules or conditions regarding prescribing or payment, this is not always the case and – as pointed out by the NCPA – should not be a determinant on its own.

Comparison of regulations and restrictions for specific medicines (Question 3)

Of the eight drugs in the sample, only Humira can be dispensed through community pharmacies in all eight WPC countries. Each of the other seven drugs have regulations or restrictions that are inconsistent between WPC members. Where there are restrictions on dispensing, in most cases the justification used by the payer is based on patient safety implications and the regular reviews that the patient may need to undergo. However, as the safety implications and monitoring requirements should be the same in each country, and every one of these drugs can be dispensed through community pharmacy in at least one country, it is likely that different approaches to cost control may be the overriding factor in many cases. Market structure also plays a major role.

In the Appendix to this report, the answers to Question 3 have been colour coded so the differences can be easily identified.

Main barriers to supply through community pharmacy (Question 4)

The main barriers to supply of specialty medications through community pharmacy fall into two categories - clinical and payer-related. In some cases the small and/or specific population groups and requirement for specialist care results in niche rather than whole-of-network network community pharmacy dispensing. In the USA the situation is exacerbated by some payers having their own pharmacy network which receives preferential conditions or exclusivity. Non-USA members should take note of the USA experience, including the current trend toward “specialty-lite” drugs in lower price ranges – such as insulin and ondansetron – beginning to be moved into the specialty tier of formularies and therefore away from most independent community pharmacies.

Arguments made to allow or enable supply through community pharmacy (Question 5)

Most WPC members reported that they had put forward a range of arguments in favour of greater supply of specialty medications through community pharmacies. There was consistency across countries in terms of the arguments used. These included:

- patient accessibility and convenience due to proximity and geographical distribution of community pharmacies
- more equitable, easier, and faster access to all medicines, avoiding unnecessary trips to the hospital
- hospital is a higher risk environment (especially in a pandemic situation)
- professional competencies exist
- maintains better continuity and completeness of treatment for patients, and integration of records
- expenditure control (in some countries reimbursement arrangements mean that supply through hospital is cheaper, however when looked at in terms of whole-of-cost – inclusive of related costs of hospital involvement – this may not be the case)
- relationship of trust with patients

Ireland’s government body (the Health Service Executive) specifies that the High Tech Drug arrangements in that country “are designed to provide a quality community based service to patients, by ensuring the active involvement of community pharmacists in the dispensing of High Tech medicines, that were previously supplied in the main through Hospitals or Community Health Offices.”¹

Despite the benefits of broader accessibility, in the USA the recent trends have been towards more restrictive access to speciality drugs. Some payers are requiring multiple types of accreditation for pharmacies. There has been some pushback on this, including through statutory means – such as in Louisiana, where “an insurer or pharmacy benefit manager shall not require any license, accreditation, affiliation, or registration other than those required by federal or state government.” The state of Maryland Insurance Administration conducted a report examining the impact of the definition for specialty pharmacy adopted by the state. This report showed the negative consequences faced by independent community pharmacies resulting from the definition.

Recent trends or changes to regulations or arrangements (Question 6)

Several WPC member countries have had positive progress in recent years.

In Australia there has been expanded access through community pharmacy for clozapine, HIV antiretrovirals, hepatitis B and C medicines, IVF medicines and Growth Hormone.

The IPU is satisfied overall with the High Tech Drugs scheme. Notably, a new centralised online hub for prescribing, ordering and reimbursing High Tech Drugs (HTD) has been put in place recently. The Health Service Executive’s website states that “the development of the HTD hub specifically arises as a result of PCRS [Primary Care Reimbursement Service] requirement for improved governance, assurance and probity for the HTD spend. The hub will allow orders to flow through to suppliers and will enable the tracking of drug journey and stock through the process. The system will follow and track the journey of the prescription, order and product across the main stakeholders: Consultant/GP - Patient - HSE PCRS – Pharmacy – Supplier.”² Separately, Ireland is conducting a pilot study into the supply of Hepatitis C medications through community pharmacy.

Portugal has also seen some significant developments. The findings of the recent HIV Drug Pilot study showed that changing the dispense setting from the hospital to the community pharmacy generated higher satisfaction with the service provided and greater convenience and comfort on the trips to the pharmacy. There is now a move to extend this study to include other drugs and therapeutic areas, such as oncology, multiple sclerosis, immunosuppression, renal failure, and haemophilia. This project was formally suspended due to Covid-19. However, the problems associated with Covid-19 triggered a separate initiative whereby specific dispensing policies and regulations regarding specialty medicines were published to allow patients to obtain them through the community pharmacy of their convenience or even at home. With this update, from 23rd March until 31st May, it was possible to establish a nationwide response called the Green Light Operation, that allowed patients to ensure their treatment continuity and to avoid unnecessary travelling to the hospital. Green Light Operation was a multidisciplinary and structured operation that involved more than 2,270 community pharmacies, 33 hospitals, pharmaceutical wholesalers, healthcare professionals and pharmaceutical stakeholders, endorsed by both Pharmaceutical and Medical Societies. With this project it was possible, in less than 3 months, to allow more than 12,500 patients to obtain their medicines in a community pharmacy, avoiding 1.4 million of kilometers previously travelled by patients.

As mentioned under Question 5, in the USA access to specialty medications and patients using these drugs has become more restrictive. There has been an emergence of dedicated specialty pharmacies (especially owned by Pharmacy Benefit Managers, or PBMs) and increases in restricted specialty pharmacy networks. The NCPA summarises the main points and problems as follows:

- Several legend drugs are now considered specialty such as insulin and ondansetron. Because of cost or association with “specialty” disease states, we are seeing more drugs moved to the specialty tier of payer formularies.
- Increased prevalence of mail order.
- Addition of specialty tier formularies.
- Limited distribution appears to be more prevalent because of the volume of newer drugs coming to market.

¹ <https://www.hse.ie/eng/staff/pcrs/about-pcrs/>

² ibid

- Evolving biosimilar market. Patent lawsuits have prohibited the launch of many biosimilar medications; however, many brand patents will expire in the next several years allowing biosimilars into the market.
- There has been an increase in co-pay cards that utilize accumulator or maximizer methods, which are meant to be patient financial assistance tools for affording specialty medications. However, these co-pay solutions may actually be detrimental to a patient's longer-term ability to afford these medications.

Changes that should be made (Question 7)

The Pharmacy Guild of Australia believes that, while still requiring specialist prescribing and/or oversight, more patients should have the freedom to have prescriptions dispensed at their community pharmacy or hospital of choice.

The Pharmacy Guild of New Zealand would like to encourage more suppliers of high cost medicines to sponsor programmes such as the AbbVie Care Pharmacy programme³ (sponsored by AbbVie Ltd) for the supply of Maviret through community pharmacy. More high cost medicines could be available earlier and more easily accessed by New Zealanders, through suppliers collaborating with PHARMAC and utilising programmes similar to the AbbVie programme.

Portugal is building on the recent positive outcomes that have been shown through the HIV drugs pilot and the Covid-19 Green Light Operation. The ANF consider it to be extremely important to ensure regulatory changes and an adequate funding scheme to enable the dispensing of these medicines in community pharmacies according to patients' preferences, even after the pandemic.

The Spanish Pharmaceutical Council considers that there should be community pharmacy dispensing of medicines even where they are for hospital diagnosis and outpatient use, avoiding unnecessary visits to the hospital and added costs to the national Health System. There should be reinforcement of the collaborative model for dispensing hospital medicines in outpatient pharmacies.

In the USA, the NCPA considers the priorities for change to be:

- Eliminating the need for multiple accreditations to be part of a payer network.
- Removing cost/price of medications from regulation/statute.
- Allowing profession of pharmacy to determine one definition for specialty medicine and specialty pharmacy.
- Removing mail order requirements by allowing patients to choose where they receive their medications.
- Reducing the number of limited distribution medications and increase number of medications that can be dispensed by community pharmacies (not specialty pharmacy only).
- Disallowing patient steering to PBM owned specialty pharmacies.

Accreditation specific to specialty medications – is it required and is it supported? (Question 8)

The responses to the final survey question were mixed. Australia and Ireland do not have accreditation specifically for these drugs, and do not consider this to be necessary in future. New Zealand and Portugal do have accreditation and see it as being important, while Spain supports accreditation in future as part of expanding the access to these drugs through community pharmacy. The USA has the deepest and most complex experience with accreditation and it is worth considering the NCPA's entire response, copied below:

- "Yes, there are currently accrediting organizations for specialty pharmacy in our country. Generally, accreditation can be beneficial from an oversight and quality perspective. Accreditation can be a tool to become a better operator. However, it is expensive and is being used as a way to limit networks of specialty pharmacies. Often more than one accreditation is needed even though the requirements to achieve each accreditation are similar, but nuanced. Accreditation also depends upon how drugs are categorized. Drugs that really should be in a "specialty" category (as we suggest above) might justify some accreditation but for drugs arbitrarily categorized by a payer as specialty, accreditation may not be justified."

³ <https://abbviecarepharmacy.co.nz/>

APPENDIX: Table of compiled responses

	Australia	Denmark	Ireland	New Zealand	Portugal	Spain	UK	USA
QUESTION 1 What term is most commonly used for specialty medicines in your country?	Specialised medicines or Highly Specialised Drugs	No name	High Tech Drugs	High cost medicines	Specialty medications, High-Cost Therapy, Hospital Medicines	Medicines with reserves in prescription or dispensation	Specialised medicines	Specialty medications
QUESTION 2 While recognising that there may always be exceptions to any definition, is the following an appropriate definition to determine whether a medicine is a specialty medication? <ul style="list-style-type: none"> • A specialty medication is a registered drug which has two or more of the following characteristics: • It is for the treatment of a complex medical condition that requires ongoing clinical supervision. • It targets a small, specific patient population. • It is a complex molecule or molecules (for example, the drug is a biologic). 	Yes	Yes	Yes	Yes	Yes	Yes	No: Remove “It is a high cost medicine.” Remove “There are special rules or conditions from payers (government or insurer) before prescribing and/or payment can occur.” Medications are medications. They are used to treat disease. What makes certain medications “special” is the prevalence of the disease state, the complexity of managing the disease, and any specific handling, administration, and monitoring requirements associated with these medications beyond the capabilities of normal dispensing practices. Cost and prescribing and/or payment rules can be arbitrary and therefore should not be associated with the definition.	

	Australia	Denmark	Ireland	New Zealand	Portugal	Spain	UK	USA
<ul style="list-style-type: none"> It is a high cost medicine. There are special rules or conditions from payers (government or insurer) before prescribing and/or payment can occur. 								
QUESTION 3 The following table lists some medicines that are widely considered to be in the specialty category. Please indicate the prescribing and dispensing status of these drugs in your country by completing the shaded cells in the table.								
Humira (adalimumab) FDA approved since 2002 Arthritis, Crohn's Disease Injection	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy – but only to a hospital not to patients outside hospital	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy
Revlimid (lenalidomide) FDA approved since 2005 Multiple myeloma, lymphoma Oral	Can only be dispensed through community pharmacy if the pharmacy has a special licence or accreditation	Can be dispensed though any community pharmacy – but only to a hospital not to patients outside hospital	Legally can be dispensed in any pharmacy but not yet approved for reimbursement by the Health Service Executive and	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy	Cannot be dispensed through community pharmacy	Can only be dispensed through community pharmacy if the pharmacy has a special licence or accreditation	Cannot be dispensed through community pharmacy

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			thus will never be dispensed					
Keytruda (pembrolizumab) FDA approved since 2014 Cancer Injection	Can only be dispensed through community pharmacy if the pharmacy has a special licence or accreditation	Can be dispensed through any community pharmacy – but only to a hospital not to patients outside hospital	Legally can be dispensed in any pharmacy but not approved for reimbursement by the Health Service Executive and thus will never be dispensed. It is supplied directly and used within hospital clinics for individual patients who have patient-specific approval	Can only be dispensed through community pharmacy if the pharmacy has a special licence or accreditation	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy
Eylea (afibercept) FDA approved since 2011 Macular degeneration/edema Injection (intraocular)	Can be dispensed through any community pharmacy	Can be dispensed through any community pharmacy – but only to a hospital not to patients outside hospital	Legally can be dispensed in any pharmacy but not approved for reimbursement by the Health Service Executive and thus will never be dispensed. It is supplied directly within hospital clinics and must be administered by a qualified physician experienced in administering intra-vitreal injections	Can be dispensed through any community pharmacy	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy
Clozaril (clozapine) FDA approved since 1989	Can only be dispensed through community pharmacy if the pharmacy has a special licence or accreditation	Can be dispensed through any community pharmacy	Cannot be dispensed through community pharmacy	Can only be dispensed through community pharmacy if the pharmacy has a special licence or accreditation	Can be dispensed through any community pharmacy	Can be dispensed through any community pharmacy	Can only be dispensed through community pharmacy if the	Can only be dispensed through community pharmacy if the pharmacy has a special licence or accreditation

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Schizophrenia Oral							pharmacy has a special licence or accreditation	
Imbruvica (ibrutinib) Schizophrenia 2013 Lymphoma/leukemia Oral	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy – but only to a hospital not to patients outside hospital	Can be dispensed though any community pharmacy	Not a funded medicine in NZ	Cannot be dispensed through community pharmacy	Can be dispensed though any community pharmacy	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy
Harvoni (ledipasvir & sofosbuvir) 2014 Hepatitis C Oral	Can be dispensed though any community pharmacy	Not available in Denmark	Currently running a pilot project with the Health Service to supply Hep C meds through community pharmacy	Can only be dispensed through community pharmacy if the pharmacy has a special licence or accreditation	Cannot be dispensed through community pharmacy	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy	Can be dispensed though any community pharmacy
Orkambi (lumacaftor & ivacaftor) 2015 Cystic fibrosis Oral	Can only be dispensed through community pharmacy if the pharmacy has a special licence or accreditation	Not available in Denmark	Can be dispensed though any community pharmacy	Not a funded medicine in NZ	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy	Cannot be dispensed through community pharmacy
QUESTION 4: If specialty medicines are not commonly dispensed through community pharmacies, what are the main reasons for this (for example, are there specific barriers such as regulations, policies, market structures, staffing, remuneration, or others)?	<ul style="list-style-type: none"> - Policy matters which restrict where prescriptions can be prescribed, dispensed and claimed - Small and/or specific population groups and requirement for specialist care which usually results in niche rather than network community pharmacy dispensing - Administrative barriers which risk pharmacists 	Regulation Policies	From Health Service website: Arrangements are in place for the supply and dispensing of High Tech medicines through Community Pharmacies. Such medicines are generally only prescribed or initiated in hospital and	PHARMAC is the government health agency in New Zealand that decides which medicines are available to New Zealanders in a way that is affordable and accessible. When these medicines are listed in the Pharmaceutical Schedule and dispensed as publicly funded medicines through community pharmacy, PHARMAC will set the prescribing and dispensing criteria which must be met. When new medicines in this category are approved for funding by PHARMAC but not listed in the Pharmaceutical Schedule, the remuneration to community pharmacy is a barrier to dispensing through this channel.	Pharmacological characteristics and public health reasons; reimbursement rules and expenditure control through tendering, centralized purchases, and price negotiation.	Our legislation foresees that Ministry may reserve the reimbursement of certain medicines to their dispensing at hospitals. Therefore, these medicines are not usually reimbursable if dispensed at community pharmacies,	The current structure means that any speciality medicines are initiated through the secondary or tertiary sector. Some, as highlighted above, can then go on to be prescribed and dispensed in the primary care setting. Any	Specific examples of barriers include: <ul style="list-style-type: none"> • Prior Authorization and step-therapy requirements by payer(s). These can be cumbersome and time consuming and can delay patient time to therapy. • Limited distribution by manufacturer – only certain wholesalers have access to distribute • Accreditation – sometimes multiple

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	<p>losing money, including:</p> <ul style="list-style-type: none"> ○ Pricing anomalies ○ Claiming anomalies ○ Ordering and delivery inconsistencies <p>The business risks associated with high-cost medicines along with the lack of familiarity due to smaller volumes has limited take up in community pharmacy.</p>		<p>would include items such as anti-rejection drugs for transplant patients or medicines used in conjunction with chemotherapy or growth hormones. The medicines are purchased by the Health Service Executive and supplied through Community Pharmacies for which Pharmacists are paid a patient care fee: the cost of the medicines and patient care fees are paid by the PCRS.</p>			<p>independently of its prescription conditions (could be a prescription for hospital use, for hospital diagnosis or a normal one). In addition, these medicines falls under the double pricing scheme, public reimbursed price if dispensed under a public prescription and other price if dispensed under a private prescription, the latter being higher price than the first. This legislation responds mainly to economic criteria. Only the medicines classified as hospital use only by the Spanish Medicine Agency follow clinical criteria.</p>	<p>barriers tend to be centred around patient safety implications and the regular reviews that the patient may need to undergo.</p>	<p>accreditations are required by payer(s)</p> <ul style="list-style-type: none"> • Cash flow/inventory management – pharmacies reluctant to keep high cost medications stocked, prefer “just-in-time” ordering • Mail order requirements by payer – this is a patient choice and potential safety issue. If a patient prefers to pick up their medication at the pharmacy, they should be allowed. If medications are delivered to a patient’s home, but require certain storage requirements, there are risks of leaving medications in a non-controlled environment. • Specific reporting/documentation requirements by manufacturer(s) and/or payer(s). This could include REMS program reporting and lab and adherence monitoring. • Restricted payer network(s) and/or patient steering. Payers are steering patients away from community pharmacies by having them fill not only their specialty medication(s) but also their other medications at an “in-network” specialty pharmacy.

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								<ul style="list-style-type: none"> No standard formularies. Each payer has their own formulary and certain medications maybe be on a specialty tier for one payer but not another. “Specialty lite” – these are medications that cost between ~\$600 - \$1,000. Some medications such as insulin are beginning to be classified into this category and being moved to specialty tiers on payer formularies. <p>*As you can see, most of the issues above are payer related. Payers with competing specialty pharmacies want to keep the business for themselves.</p>
<p>QUESTION 5: Please briefly summarise any arguments that have been put forward by your organisation (or others in your country) to support the supply of specialty medicines through community pharmacy.</p>	<p>The main argument for dispensing through community pharmacy is patient accessibility and convenience. However, to achieve supply through any community pharmacy, there needs to be:</p> <ul style="list-style-type: none"> Adequate remuneration Addressing all administrative anomalies so specialised medicines can be readily dispensed and claimed in community pharmacies Training and resources for dispensary staff to raise awareness of clinical and administrative arrangements with dispensing specialised medicines 		<p>From Health Service website: These arrangements are designed to provide a quality community-based service to patients, by ensuring the active involvement of community pharmacists in the dispensing of High Tech medicines, that were previously supplied in the main through Hospitals or Community Health Offices.</p>	<p>Proposals for supply of these type of medicines through community pharmacy in New Zealand is generally through PHARMAC consultations, which we normally support as we are keen for community pharmacy to be an enabler of equitable, easier, and faster access to all medicines for New Zealanders. However, we generally always request for these medicines to be funded as an original pack or where the pack must be broken, we request reimbursement for the waste so that the pharmacy does not need to carry the financial burden.</p>	<p>Proximity and convenience, geographic distribution, relationship of trust with patients, expenditure control, professional competences, treatment continuity.</p>	<ul style="list-style-type: none"> Improve d accessibility to medication due to the proximity and accessibility of the pharmacy Improve d medication outcomes due to comprehensive analysis of patient health information accessible to the community pharmacy 	<p>We continue to highlight the clinical expertise of the community pharmacist as the expert in medicines. This, added to the accessibility to the patient, presents community pharmacy as the ideal setting to support the supply of speciality medicines through community pharmacy.</p>	<p>Multiple states have taken legislative action to restrict PBMs from requiring additional licensure or accreditation beyond that which is required by state and federal regulations. EX. Louisiana statute – “An insurer or pharmacy benefit manager shall not require any license, accreditation, affiliation, or registration other than those required by federal or state government.” The state of Maryland Insurance Administration conducted a report examining the impact of the definition for specialty pharmacy adopted by the state.</p>

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			The scheme is coordinated centrally through the PCRS High Tech Co-ordination Unit.					This report showed the negative consequences faced by independent community pharmacies resulting from the definition. This report is attached for reference.
Question 6: In recent years, have there been any notable changes in your country to the prescribing and/or dispensing policies or regulations relating to specialty medicines in general, or for particular types of specialty medicines? If so, please describe these changes.	The Commonwealth Government has recognised accessibility through community pharmacy and has introduced a Community Access category for its Highly Specialised Drugs program and other subsidised specialised medicines program. This has expanded access through community pharmacy for clozapine, HIV antiretrovirals, hepatitis B and C medicines, IVF medicines and Growth Hormone.	No	A new centralised online hub for prescribing, ordering and reimbursing High Tech Drugs (HTD) has been put in place. From Health Service website: The development of the HTD hub specifically arises as a result of PCRS requirement for improved governance, assurance and probity for the HTD spend. The hub will allow orders to flow through to suppliers and will enable the tracking of drug journey and stock through the process. The system will follow and track the journey of the prescription, order and product across the main stakeholders: Consultant/GP -	The Named Patient Pharmaceutical Assessment (NPPA) Policy approved by the PHARMAC Board came into effect on 1 July 2013. The NPPA Policy, sets out the framework of exceptional circumstances in which PHARMAC will consider funding treatments. The provision for exceptional circumstances is an acknowledgement that there are situations in which consideration of an application for a treatment for an individual, outside of the Pharmaceutical Schedule decision making process used to consider treatments for patient populations, is warranted. Together the Pharmaceutical Schedule decision making process and the exercise of PHARMAC's discretion to consider funding in exceptional circumstances ensure there is a pathway for consideration of an individual's clinical circumstances. There are two main pathways and three circumstances which constitute PHARMAC's framework for performing its function of providing for subsidies in exceptional circumstances for pharmaceuticals not on the Pharmaceutical Schedule, by which named patients can be considered for funding under the NPPA Policy. A description of the three circumstances, the purpose of each of the two pathways, an explanation of each pathway and the prerequisite requirements that applicants need to satisfy for consideration for funding under these pathways is included in the NPPA Policy. PHARMAC will exercise its discretion to determine the most appropriate pathway for an application under the NPPA Policy based on the information that is provided. Thus, if PHARMAC receives an application that does not meet the prerequisite requirements for	In December 1st, 2016, began a pharmacy-based HIV dispensing pilot, which is currently ongoing. The project is taking place in Lisbon, with the collaboration of Curry Cabral Hospital. Patients who fulfill the inclusion criteria were invited by the hospital if they want to collect their antiretroviral therapy (ARVT) medicines at a community pharmacy chosen by the patient, or if they rather maintain the dispense at the hospital. More than 400 pharmacists attended a specific training course in order to be qualified by the Portuguese Pharmaceutical Society to participate in the study. This study has an evaluation by the Consortium CEMBE/CEA/CEFAR (please see attached Executive Summary and Poster). The findings of this study	In 2011, there was a modification in the Medicines Law in respect with the places where medicines could be dispensed. This modification established the limitation to dispense specialty medications reimbursed by the National Health System only in hospitals. Community pharmacies can dispense these medicines only with a private prescription.	No.	The following examples are notable changes that have occurred in our country over the past several years. In general, the specialty marketplace has become more restrictive. <ul style="list-style-type: none"> • Access to "specialty" medications and patients using these drugs has become more restrictive. There has been an emergence of dedicated specialty pharmacies (especially PBM owned) and increases in restricted specialty pharmacy networks. • Several legend drugs are now considered specialty such as insulin and ondansetron. Because of cost or association with "specialty" disease states, we are seeing more drugs moved to the specialty tier of payer formularies. • Increased prevalence of mail order. • Addition of specialty tier formularies. • Limited distribution appears to be more prevalent because of the volume of newer drugs coming to market.

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			<p>Patient - HSE PCRS – Pharmacy – Supplier.</p>	<p>one pathway, it will consider whether it should appropriately be considered under the alternative pathway. The NPPA Policy document can be found here, https://www.pharmac.govt.nz/assets/nppa-policy-2013-07.pdf</p>	<p>show that changing the dispense setting from the hospital to the community pharmacy generates higher satisfaction with the service provided and greater convenience and comfort on the trips to the pharmacy. After the pilot-project with Curry Cabral Hospital, ANF in collaboration with Centro Hospitalar Universitário de São João (Oporto), ADIFA (Full-Service Pharmaceutical Distributors Association) and The Portuguese Pharmaceutical Society started a new pilot-project of pharmacy-based Specialty Medicines dispensing called Farma2Care project. This project maintained the principles and requirements of the first project related with specialty medicines already announced, and introduced some novelties, as example de scope of action: beginning with HIV patients, it was planned to expand to other therapeutic areas (oncology, multiple</p>			<ul style="list-style-type: none"> • Evolving biosimilar market. Patent lawsuits have prohibited the launch of many biosimilar medications; however, many brand patents will expire in the next several years allowing biosimilars into the market. • There has been an increase in co-pay cards that utilize accumulator or maximizer methods, which are meant to be patient financial assistance tools for affording specialty medications. However, these co-pay solutions may actually be detrimental to a patient's longer term ability to afford these medications.

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					<p>sclerosis, immunosuppression, renal failure, hemophilia) and, eventually, cover all specialty medicines. Farma2Care, started on the 1st of December 2019 and until patient recruitment was suspended due to COVID-19 contingencies, 26 patients were engaged in the project to be followed-up in 19 community pharmacies. Besides these projects, it is also important to notice that during COVID-19 pandemic, specific dispensing policies and regulations regarding specialty medicines were published to allow patients to obtain their specialty medicines through community pharmacy of their convenience or even at home. With these update, from 23rd March until 31st May, it was possible to establish a nationwide response called Green Light Operation, that allowed patients to ensure their treatment continuity</p>			

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					<p>and to avoid unnecessary travelling to the hospital.</p> <p>Green Light Operation was a multidisciplinary and structured operation that involved more than 2.270 community pharmacies, 33 hospitals, pharmaceutical wholesalers, healthcare professionals and pharmaceutical stakeholders, endorsed by both Pharmaceutical and Medical Societies.</p> <p>With this project it was possible, in less than 3 months, to allow more than 12.500 patients to obtain their medicines in a community pharmacy, avoiding 1,4 million of kilometers previously covered by patients.</p> <p>In conclusion, the dispensing of specialty medicines in a community pharmacy is currently a possibility, in accordance with the provisions of joint standard DGS/INFARMED No. 03/2020 of 19th March and, after</p>			

	Australia	Denmark	Ireland	New Zealand	Portugal	Spain	UK	USA
					the end of the State of Emergency declared on 2nd May, through the provisions of The Minister of Health No. 5315/2020 of 7th May.			
<p>QUESTION 7: What changes do you (or your organisation) believe should be made in your country to enhance access to, and/or affordability of, specialty medicines for patients?</p>	<p>Change the Highly Specialised Drugs program so that there is only the Community Access category which while still requiring specialist prescribing and/or oversight, would allow patients to have prescriptions dispensed at their community pharmacy or hospital or choice. We would also like the specialised drugs to have the same Community Service Obligations as for the general subsidised medicines. Link</p>		<p>We're quite happy with the scheme that is in place since 1996.</p>	<p>We would like to encourage more suppliers of high cost medicines to sponsor programmes such as the AbbVie Care Pharmacy programme (sponsored by AbbVie Ltd) for the supply of Maviret through community pharmacy. More high cost medicines could be available earlier and more easily accessed by New Zealanders, through suppliers collaborating with PHARMAC and utilising programmes similar to the AbbVie programme or the Australian Pharma Programs.</p>	<p>Portugal has already two experiences that show that the transfer of dispensing of specialty medicines from hospitals to community pharmacies would not constitute a risk, individual and for the health service. Besides this, both project TARV (started in 2016 and currently ongoing) and Green Light Operation (from 23rd March until 31st May), have great results regarding patient satisfaction assessment studies. These studies reveal patients' satisfaction with the global community pharmacy services (including: opening hours, privacy, dignity, respect and waiting time), travel time reduction and willingness to continue to access these medicines in the pharmacy. Considering these great experiences related to specialty</p>	<p>Apply measures to promote proximity to informed access and reimbursement to medicines, in particular the dispensing in the Community Pharmacy of medicines for hospital diagnosis and outpatient use, avoiding unnecessary visits to the hospital and added costs to the national Health System. Along the same lines, reinforce the collaborative model for dispensing hospital medicines in outpatient pharmacies, launched with the Hospital Pharmacy Services. Reimbursed</p>	<p>The vast majority of the care is provided by the NHS and the patient either does not pay, or makes a negligible contribution to the funding of the medicine. The NHS has mechanisms in place to reduce the costs of all medicines to ensure affordability for the government/tax payer.</p>	<ol style="list-style-type: none"> 1. Eliminate the need for multiple accreditations to be part of a payer network. 2. Remove cost/price of medications from regulation/statute. 3. Allow profession of pharmacy to determine one definition for specialty medicine and specialty pharmacy. 4. Remove mail order requirements by allowing patients to choose where they receive their medications. 5. Reduce number of limited distribution medications and increase number of medications that can be dispensed by community pharmacies (not specialty pharmacy only). 6. Disallow patient steering to PBM owned specialty pharmacies.

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					<p>medicines already referred, it would be extremely important to ensure regulatory changes and an adequate funding scheme to enable the definitive transfer of some specialty medicines (currently exclusively dispensed in hospitals) to community pharmacies and to keep the possibility of dispensing these medicines in community pharmacies according to patients' preferences even after the pandemic. Community Pharmacists may have an important role in the dispensing of specialty medicines and may also play an important role in the improvement of the access to these medicines and potential reinforcement for reducing inequities.</p>			
<p>QUESTION 8: In your country, are there currently any accreditations for community pharmacies that relate specifically to specialty medicines</p>	<p>There are no formal accreditation requirements for approved community pharmacies to dispense pharmaceutical benefits in Australia. As part of the overarching legislation for the Pharmaceutical Benefits Scheme, approved pharmacists must meet a</p>	<p>No accreditation.</p>	<p>No, and this should not be required for pharmacies to dispense specialty medicines</p>	<p>Yes, and accreditation is supported by my organisation</p>	<p>Yes, and accreditation is supported by my organisation</p>	<p>No, but the introduction of accreditation would be a positive for pharmacy</p>		<p>Yes, there are currently accrediting organizations for specialty pharmacy in our country. Generally, accreditation can be beneficial from an oversight and quality perspective. Accreditation can be a tool to become a better</p>

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	<p>range of general dispensing related-conditions, including following the professional practice standards endorsed by the Pharmacy Board of Australia.</p> <p>As part of the process for registering a medicine for use in Australia, certain high-risk specialised medicines have additional requirements as part of their risk management strategy. Examples of this include clozapine, thalidomide, mifepristone & misoprostal which require prescribers and pharmacists to have undertaken specific training and be registered with the sponsors program.</p> <p>We have also proposed a community pharmacy service concept for specialised drugs requiring additional intervention and monitoring, including as part of a fast-tracked registration process which could provide Australians with earlier access to new and/or specialised medicines.</p> <p>Service Concept</p> <ul style="list-style-type: none"> - Community pharmacist collects and records high-quality medicine safety data according to a set protocol and using a standard platform. - Protocol involves pharmacist intervention in which pharmacist asks and assesses specific medicine safety questions - Questions are drug specific and 							<p>operator. However, it is expensive and is being used as a way to limit networks of specialty pharmacies. Often more than one accreditation is needed even though the requirements to achieve each accreditation are similar, but nuanced. Accreditation also depends upon how drugs are categorized. Drugs that really should be in a "specialty" category (as we suggest above) might justify some accreditation but for drugs arbitrarily categorized by a payer as specialty, accreditation may not be justified.</p>

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	<p>determined by an appropriate expert advisory panel based on identified and potential risks for drug</p> <ul style="list-style-type: none"> - Frequency of pharmacist intervention is drug specific (e.g. may be one intervention with initial dispensing, may involve multiple interventions over a set time) - Pharmacist records results on a suitable platform - Pharmacy remunerated based on expected time involvement (drug specific) 							