P3: PROSTATE CANCER FORUM 2025

Perspectives, Possibilities, Progress

POST-MEETING SUMMARY SLIDES

An Expanding Role for Pharmacists: Tackling adverse events and drug-drug interactions

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Dr Vikash Dodhia, Mount Vernon Cancer Centre

This promotional meeting was organised and funded by Bayer PLC. Bayer products were discussed at this meeting.
Prescribing Information for products mentioned can be found at the end of the presentation.
This meeting was intended for UK healthcare professionals (HCPs) and the intended recipient only.

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Disclosures

Diana Matthews

- Bayer
- Astellas
- Janssen

Vikash Dodhia

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  - Baxter Healthcare Ltd
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  - AstraZeneca Ltd
  - Bristol-Myers Squibb Pharmaceuticals Ltd
  - Roche Products Ltd
  - Janssen-Cilag Ltd
  - Astellas Pharma Ltd

NUBEQA (darolutamide) is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease or with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy or with mHSPC in combination with docetaxel

Nubeqa (darolutamide) Summary of Product Characteristics.

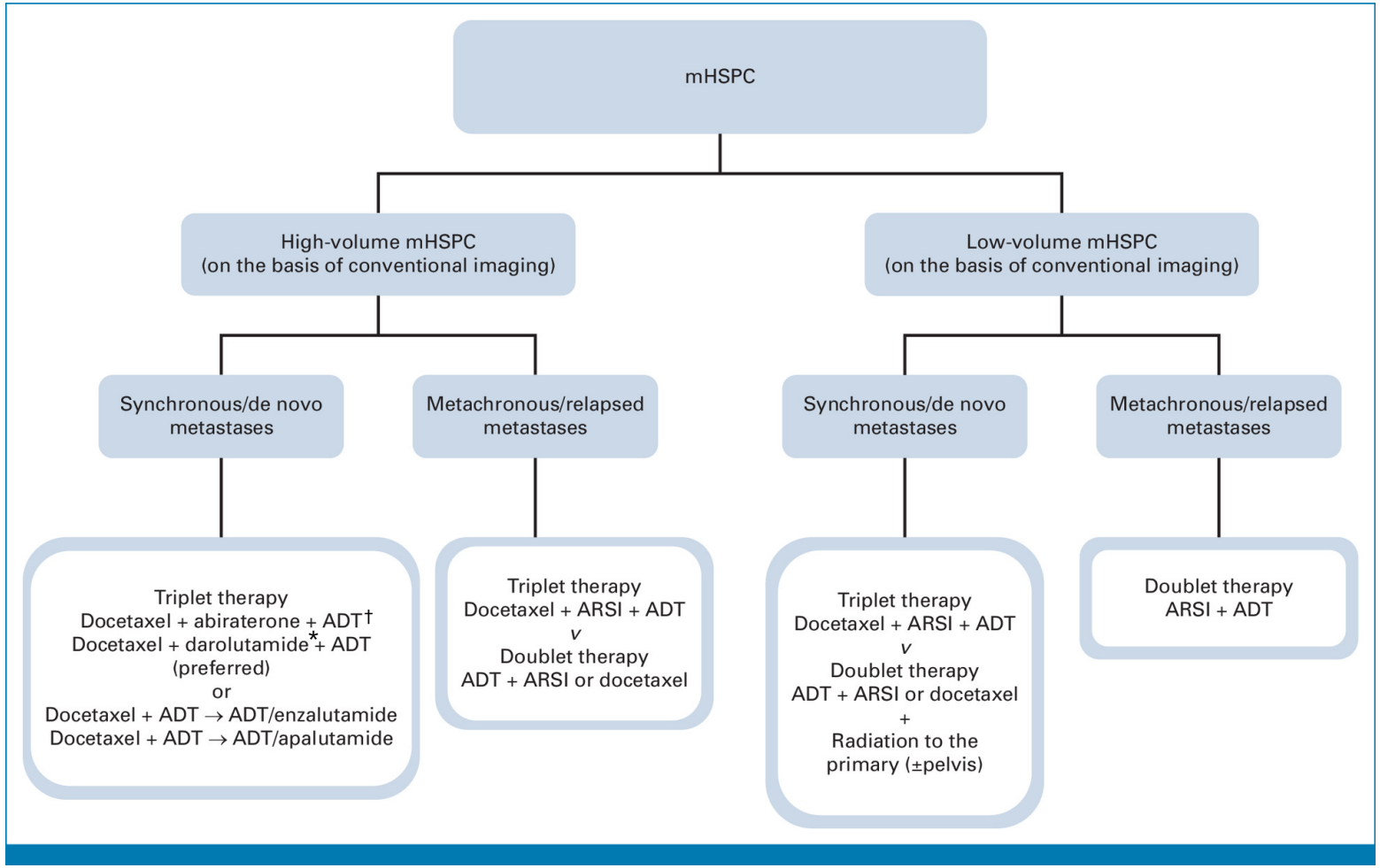
Overview

This presentation will cover:

- Treatment landscape in PCa and rise of polypharmacy in aging PCa population
- Management of side-effects from PCa treatment
- DDIs to avoid, including those due to CVD comorbidities management
- Case study: Management of polypharmacy and DDIs
- Role of hospital pharmacist in management of patients with advanced PCa
- Benefits and barriers to establishing an NMP cancer service
- Case study: Mount Vernon Cancer Centre NMP Joint Working Project

ADT, androgen-deprivation therapy; CVD, cardiovascular disease; DDIs, drug-drug interactions; NMP, non-medical prescriber; PCa, prostate cancer.

Treatment landscape for mHSPC



*Darolutamide is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease or with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy or with mHSPC in combination with docetaxel. †Abiraterone + docetaxel + ADT is not licensed in the UK

ADT, androgen deprivation therapy; ARSI, androgen receptor signalling inhibitor; mHSPC, metastatic hormone-sensitive prostate cancer; nmCRPC, non-metastatic castration resistant prostate cancer.

McManus HD, et al. J Clin Oncol. 2023;41(20):3576-3579.

Polypharmacy in men with prostate cancer

- Due to the ageing population, an increasing number of men with prostate cancer are presenting with co-morbidities
- With multiple specialisms involved in their care, potentially no-one takes overall responsibility
- This may lead to suboptimal polypharmacy and could result in poorer therapeutic outcomes
- Involvement of expert pharmacists is important to ensure lifelong personalised care and appropriate polypharmacy

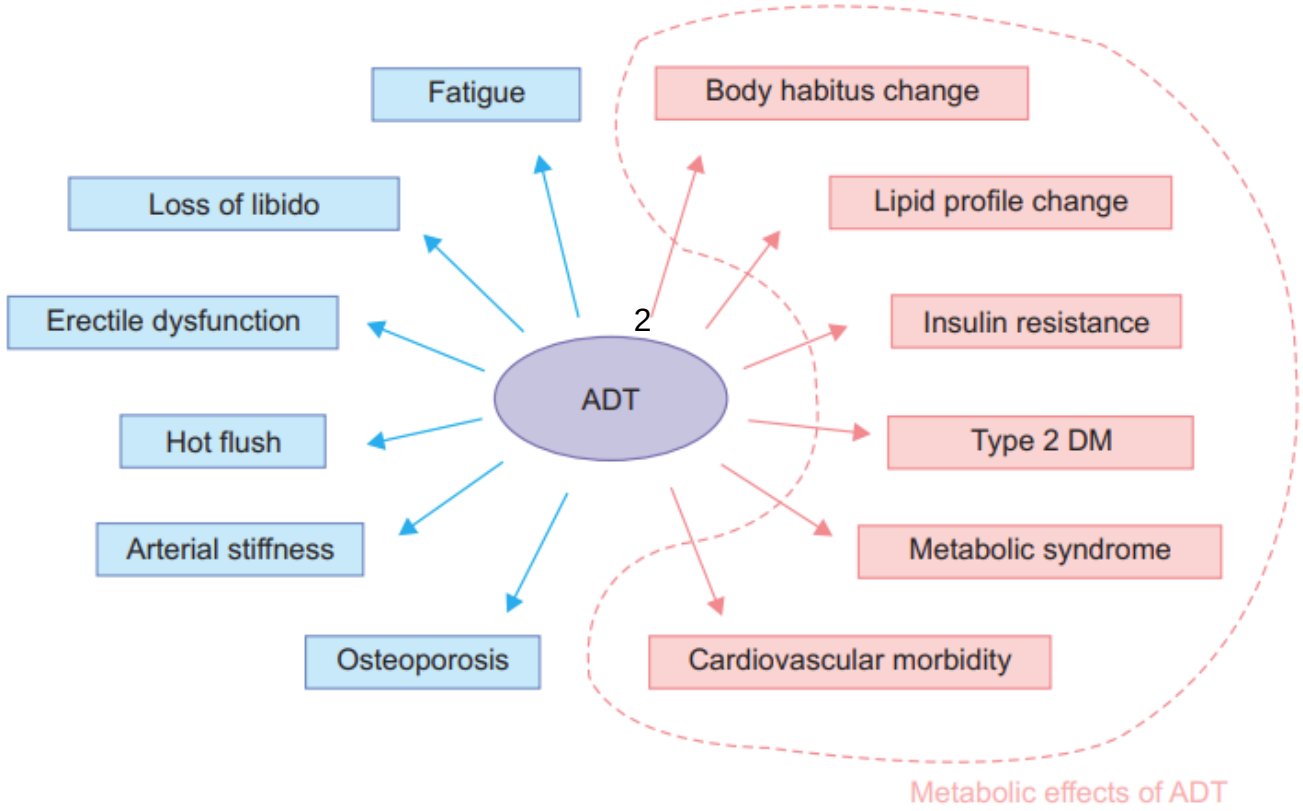
Williams J, et al. Clinical Pharmacist. 2018;10(1):DOI:10.1211/PJ.2018.20204093.

ADT – adverse effects

- Men on ADT may experience a number of mental, physical and metabolic side-effects which can significantly impact their quality of life[1,2]
- The most severe complications of ADT are metabolic syndrome, cardiovascular morbidity, depression and bone resorption[1]
- Regular follow-up, including monitoring of serum testosterone, creatinine, liver function, metabolic parameters and mental health at 3–6 month intervals is advised[1]

Adverse effects of Androgen Deprivation Therapy (ADT)

Inside the dotted line represents metabolic effects of ADT



ADT, androgen deprivation therapy; DM, diabetes mellitus.

1. Crawford ED et al., EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5; 2. Choi SM, et al. Korean J of Urol. 2015;56(1):12-18.

ARPIs – adverse effects

Percentage of patients experiencing adverse events in pivotal ARPI trials

	Enzalutamide		Apalutamide		Darolutamide		Abiraterone acetate	
	(PROSPER)[1*]	*(ARCHES)*[2*]	*(SPARTAN)*[3#]	*(TITAN)*[4]	*(ARAMIS)*[5]	*(ARASENS)*[6*]	*(COU-AA-301)*[8]	*(LATITUDE)*[9,10]
Fatigue	46%	32.2%	30.4%	19.7%**	12.1%¶	33.1%	47%	13%
Risk of falls	18%	10.1%	15.6%	7.4%*	4.2%*	6.6%	n/d	n/d
MSK events	34%†	39%	15.9%‡	17.4%‡	n/d	n/d	30%‡	n/r
Seizures	<1%	n/r	0.2%‖	0.6%*	2%*	0.6%	n/d	n/d
Hypertension	18%	14.3%	24.8%	17.7%**	6.6%¶	13.7%[7]	11%*	37%
Rash	n/r	3.8%	23.8%	27.1%*	2.9%*[7]	17.3%	6%	n/r
Fracture	18%	13.5%	11.7%‖	n/r	4.2%*	7.5%	n/r	7%##
Deranged LFTs	n/r	5.9%	n/r	n/r	n/r	2.8%††	11%*	16%
CV Events	6%	4.4%	n/r	n/r	n/r	10.9%	16%*	n/r
Hypothyroidism	n/r	n/r	8.1%	6.5%*	n/r	n/r	n/r	n/r
Hypokalaemia	n/r	n/r	n/r	n/r	n/r	n/r	15%	20%

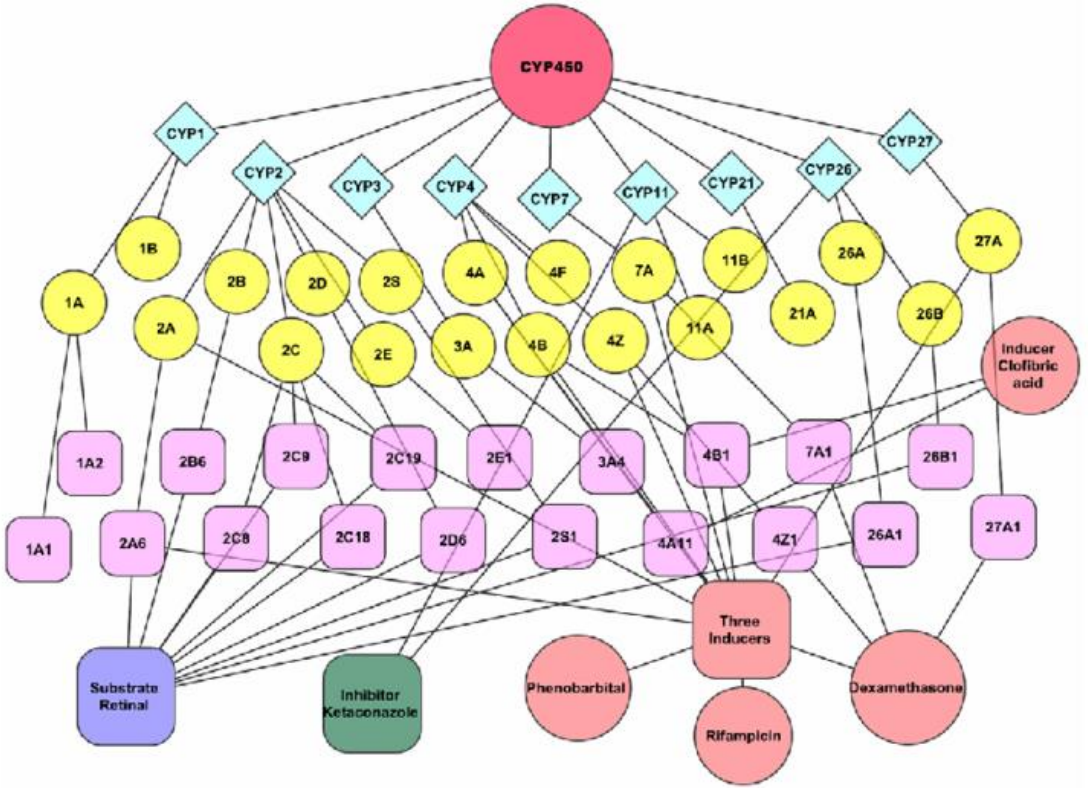
These are not head-to-head comparison studies – data presented side by side for illustration purposes only.

*AEs of special interest. #AEs that occurred in ≥15% of patients in either group. ¶AEs that occurred in ≥5% of patients in either group. ‖Other AEs of interest. **Events reported in ≥10% of patients in either group or events of grade ≥3 reported in ≥10 patients in either group. †Musculoskeletal events included back pain, arthralgia, myalgia, musculoskeletal pain, pain in extremity, musculoskeletal stiffness, muscular weakness, and muscle spasms. ‡AEs for arthralgia only. ††Selected grade 3 or 4 AE. ##Osteoporosis, including osteoporosis-related fractures. AE, adverse event; ARPIs, androgen-receptor pathway inhibitors; CV, cardiovascular; LFTs, liver function tests; MSK, musculoskeletal; n/d, not done; n/r, not reported.

1. Sternberg CN, et al. NEJM. 2020;382:2197–206; 2. Armstrong AJ, et al. J Clin Oncol. 40:1616-1622; 3. Smith MR, et al. NEJM. 2018;378:1408–18; 4. Chi KN, et al. NEJM. 2019;381:13–24; 5. Fizazi K, et al. NEJM. 2019;380:1235–46; 6. Smith MR, et al. NEJM. 2022;386:1132–1142; 7. Darolutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/11324/smpc/ (accessed April 2025); 8. Fizazi K, et al. Lancet Oncol. 2012;13:983–92; 9. Fizazi K, et al. NEJM. 2017;377:352–60; 10. Fizazi K, et al. Lancet Oncol. 2019;20(5):686–700.

The CYP450 family

- Mainly expressed in the liver
- Responsible for the metabolism of approximately 90% of drugs
- Convert lipophilic substances into hydrophilic form to facilitate the elimination
- In most cases drug metabolism reduces therapeutic effect



Basith S, et al. Arch Pharm Res. 2010;33(9):1289-91.

Zhao M, et al. Int J Mol Sci. 2021;22;12808.

Metabolism of ARPIs

	Enzalutamide[1]	Apalutamide[2]	Abiraterone[3]	Darolutamide[4]
Substrate	**CYP2C8** **CYP3A4**	**CYP2C8** CYP3A4	CYP3A4	CYP3A4 P-gp
Inhibitor		**CYP2C8** **CYP2B6**	**CYP2D6** CYP2C8 CYP3A4	**BCRP** **OATP**
Inducer	**CYP3A4** CYP2C9 CYP2C19	**CYP3A4** **CYP2B6** **CYP2C19** CYP2C9, OAT, BCRP, P-gp		CYP3A4

ARPIs, androgen receptor pathway inhibitors; BCRP, breast cancer resistance protein; OATP, organic anion transporting polypeptides.

1. Enzalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/10318/smpc/ (accessed April 2025); 2. Apalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9832/smpc/print (accessed April 2025); 3. Abiraterone. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14566/smpc/ (accessed April 2025); 4. Darolutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/11324/smpc/ (accessed April 2025).

Anti-hypertensives

- ACEis – carboxylesterases, UDP – Glucuronosyltransferases[1]
- ARBs – CYP2C9 & CYP3A4 (Losartan), OATP (valsartan)[2]
- CCB – CYP3A4[1]
- B-blockers – CYP2D6, CYP3A4 (bisoprolol)[1]

	Enzalutamide[3]	Apalutamide[4]	Abiraterone[5]	Darolutamide[6]
Substrate	CYP2C8 CYP3A4	CYP2C8 CYP3A4	CYP3A4	CYP3A4 P-gp
Inhibitor		CYP2C8 CYP2B6	CYP2D6 CYP2C8 CYP3A4	BCRP OATP
Inducer	CYP3A4 CYP2C9 CYP2C19	CYP3A4 CYP2B6 CYP2C19 CYP2C9, OAT, BCRP, P-gp		CYP3A4

ACEis, angiotensin-converting enzyme inhibitors; ARBs, angiotensin-II receptor blockers; B, beta; CCB, calcium channel blockers; UDP, uridine diphosphate.

1. Zisaki A, et al. Curr Pharm Des. 2015;21(6):806-22; 2. Bolek H, et al. ESMO Open. 2024;9(11):103736; 3. Enzalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/10318/smpc/ (accessed April 2025); 4. Apalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9832/smpc/ (accessed April 2025); 5. Abiraterone. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14566/smpc/ (accessed April 2025); 6. Darolutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/11324/smpc/ (accessed April 2025).

Lipid lowering drugs

- Simvastatin – OATP, CYP3A4[1]
- Atorvastatin – OATP, CYP3A4[1]
- Pravastatin – OATP[1]
- Rosuvastatin – OATP/BCRP[1,6]

	Enzalutamide[2]	Apalutamide[3]	Abiraterone[4]	Darolutamide[5]
Substrate	**CYP2C8** **CYP3A4**	**CYP2C8** CYP3A4	CYP3A4	CYP3A4 P-gp
Inhibitor		**CYP2C8** **CYP2B6**	**CYP2D6** CYP2C8 CYP3A4	**BCRP** **OATP**
Inducer	**CYP3A4** CYP2C9 CYP2C19	**CYP3A4** **CYP2B6** **CYP2C19** CYP2C9, OAT, BCRP, P-gp		CYP3A4

BCRP, breast cancer resistance protein; OATP, organic anion transporting polypeptides.

1. Neuvonen PJ, et al. Clin Pharmacol Ther. 2006;80(6):565-81; 2. Enzalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/10318/smpc/ (accessed April 2025); 3. Apalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9832/smpc/ (accessed April 2025); 4. Abiraterone. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14566/smpc/ (accessed April 2025); 5. Darolutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/11324/smpc/ (accessed April 2025); 6. Mao Q and Unadkat J. AAPS J. 2014;17(1):65–82.

Anti-coagulants

- Warfarin – CYP2C9, CYP3A4[1.2]
- Apixaban – CYP3A4, P-GP[2]
- Rivaroxaban – CYP3A4, P-GP[2]
- Dabigatran - P-GP[2]
- Edoxaban - P-GP[2]

	Enzalutamide[3]	Apalutamide[4]	Abiraterone[5]	Darolutamide[6]
Substrate	**CYP2C8** **CYP3A4**	**CYP2C8** CYP3A4	CYP3A4	CYP3A4 P-gp
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Inducer	**CYP3A4** CYP2C9 CYP2C19	**CYP3A4** **CYP2B6** **CYP2C19** CYP2C9, OAT, BCRP, P-gp		CYP3A4

P-GP, P-glycoprotein.

1. Warfarin. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14333/smpc/ (accessed April 2025); 2. Sikorska J, et al. Eur Cardiol. 2017:12(1):40–45; 3. Enzalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/10318/smpc/ (accessed April 2025); 4 Apalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9832/smpc/ (accessed April 2025); 5. Abiraterone. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14566/smpc/ (accessed April 2025); 6. Darolutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/11324/smpc/ (accessed April 2025).

Case study

Patient: RS

- 78-year-old man
- ECOG PS 2

Diagnosis

- Metastatic prostate cancer (bone and nodal mets)
- G 5+3=8
- Presenting PSA: 181 ng/ml

PMHx

- IHD
- T2DM
- AF

DHx

- Alfuzosin
- Atenolol
- Atorvastatin
- Apixaban
- Glyceryl trinitrate
- Isosorbide mononitrate
- Metformin
- Omeprazole
- Ramipril

PCa treatment

- ADT + enzalutamide

*Fictitious case based on speaker experience.

ADT, androgen deprivation therapy; AF, atrial fibrillation; DHX, drug history; ECOG PS; Eastern Cooperative Oncology Group Performance Status 2; G, Gleason; IHD, ischaemic heart disease; mets, metastases; PCa, prostate cancer; PMHx, past medical history; prostate-specific antigen; RS; T2DM, type 2 diabetes mellitus.

Outcomes

- BP monitoring requested, patient to get own monitor
- Started bisphosphonate and calcium and vitamin D (GP asked to continue)
- Atorvastatin switched to rosuvastatin (GP asked to continue)
- Apixaban switched to edoxaban (GP asked to continue)
- Edoxaban levels checked 2 weeks after the switch (within range for AF)
- Advice on symptoms of GORD and report if getting worse
- Letter to GP to notify of the changes and update on treatment including the increased CV risk and possible impact on diabetes

*Fictitious case based on speaker experience.

AF, atrial fibrillation; BP, blood pressure; CV, cardiovascular; GORD, gastro-oesophageal reflux disease.

Role of the hospital pharmacist

- 1960's: dispensing and manufacturing[1]
- 1970-1980's: ward pharmacy duties[1]
- Nuffield Report (1986): clinical pharmacy[2]
  - Contribution to prescribing decisions
  - Monitoring and modifying drug therapy
  - Counselling patients
  - Involvement in clinical trials
- 1999 (2nd Crown Report): new groups of professionals could apply for prescribing rights in specific areas (nurses)[4]
- 2003: Pharmacist Supplementary Prescribing[5]
- 2006: Pharmacist Independent Prescriber (2009 – unlicensed; 2012 – CDs)[5]

"by helping to ensure patient safety and appropriate use of medicines, clinical pharmacy services could prove to be cost-effective"[3]

CDs, controlled drugs.

1. Olalekan K. Hospital pharmacists' contribution: a perspective. Available at: https://hospitalpharmacyeurope.com/news/hospital-pharmacists-contribution-a-perspective/#:~:text=Up%20until%20the%20mid%201960s,prescription%20charts%20brought%20pharmacists%20out (accessed May 2025); 2. Turner P. The Nuffield Report: A Signpost for Pharmacy. BMJ (Clinical Research Edition).1986;292:1031-1033; 3. Child D, Cooke J and Hey R. Clinical Pharmacy. In Hospital Pharmacy. Pharmaceutical Press 2011. 4 Crown J. Department of Health. Review of Supply and Administration of Medicines. Final report, Crown 2. March 1999. 5. Baqir W, et al. European Journal of Hospital Pharmacy. 2012;19:487-488.

Anticipated growth in demand for cancer services

- The gap between the future demand for cancer services and the specialist oncologist workforce will widen from 15% to 21% by 2028[1]
- SACT demand is growing with approximately 6–8% growth per year with only a 3.5% growth in consultant workforce[1]
- By 2026 all newly qualified pharmacists will hold prescribing qualifications[2]
- Utilising NMP pharmacists to reduce this gap is urgently required

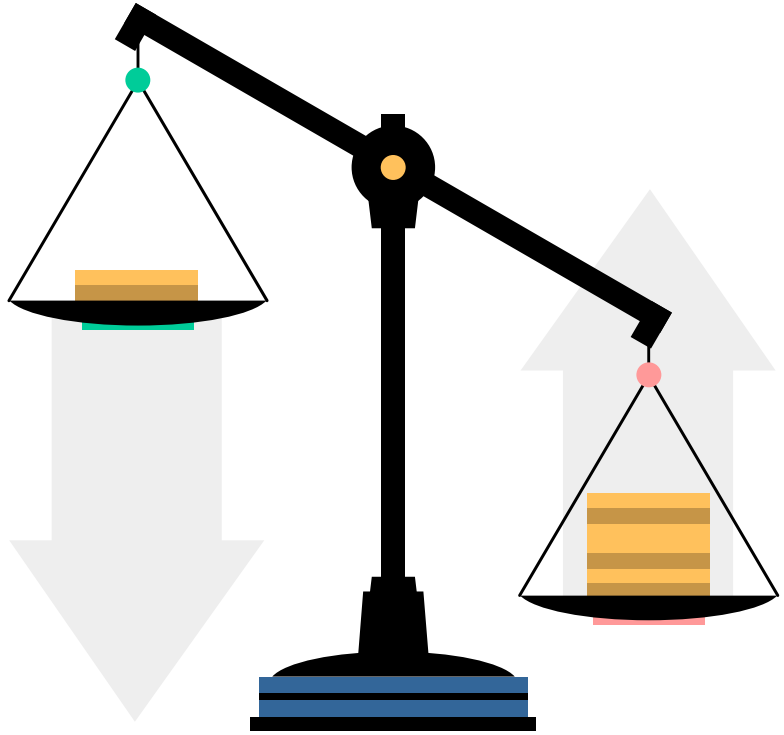
NMP, non-medical prescriber; SACT, systemic anti-cancer therapy.

1. The Royal College of Radiologists. Clinical Oncology UK Workforce Census Report (2023). Available from: https://www.rcr.ac.uk/media/j5jmhpju/rcr-census-clinical-oncology-workforce-census-2023.pdf (accessed April 2025); 2. NHS England. Update on Independent Prescribing in Community Pharmacy Pathfinder Programme (2024). Available from: https://www.england.nhs.uk/long-read/update-on-independent-prescribing-in-community-pharmacy-pathfinder-programme/#update-on-independent-prescribing-in-community-pharmacy-pathfinder-programme (accessed April 2025).

Benefits and barriers to establishing a non-medical prescriber service

Benefits[1]

- MDT workload
- Clinic capacity
- Patient satisfaction
- HCP satisfaction
- Workforce retention



Challenges and barriers[2]

- **Finance**
- Workforce
- Training and competency
- Core service requirements
- HCP resistance

HCP, healthcare professional; MDT, multidisciplinary team; NMP, non-medical prescriber.

1. Hg HWW, et al. BOPA Symposium 2022. Poster; 2. Armstrong A. J Prescribing Practice. 2023;5(1):18-25.

Bayer – objectives of Mount Vernon Cancer Centre joint working project

A stronger partnership with the NHS and potential to share	**Increased number of prostate out-patient clinic consultations**
A richer understanding of planning and implementing prostate cancer services	**Frees up time for consultants to see more complex cases**
Improve the prostate cancer quality of care and patient satisfaction	**Improve patient services by implementing a stratification mechanism that will enable patients to be seen in the right clinic for their needs**
Increase compliance and adherence to treatment	**Improve prostate patient satisfaction of the service at the MVCC**
Access to anonymised and aggregated service level and patient satisfaction data for future joint working projects	**Shared learning to encourage similar service innovation**
	Business case illustrating benefits and evidence for a long-term financially sustainable service

MVCC, Mount Vernon Cancer Centre.

Bayer. Collaborative Working Executive Summary (RP-UN-ONC-GB-0088). 2022. Available at: https://www.bayer.co.uk/sites/bayer_co_uk/files/MVCC_Executive_Summary_June_2022(Jan_2023_start_date).pdf (accessed April 2025).

Levers – finance[1,2,*]

- Consultant and other HCP vacancies
- Temporary workforce expenditure
- Financial efficiencies through workforce skill mix
- Private patient services
- **Working with industry partners**

*Speaker's own opinion.
HCP, healthcare professional.
1. Armstrong A. J Prescribing Practice. 2023;5(1):18-25; 2. Uppal Z et al. Journal of Prescribing Practice. 2024;6(9):382-392.
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Levers – core service demands and workforce*

- Oncology pharmacy heavily focused on drug preparation and delivery (aseptics)
- SACT (chemotherapy) pathway optimisation
  - Technician-led SACT ordering and supply
  - Bespoke vs. on the shelf
- Oncology workforce strategy and job design
  - Technical vs. clinical services

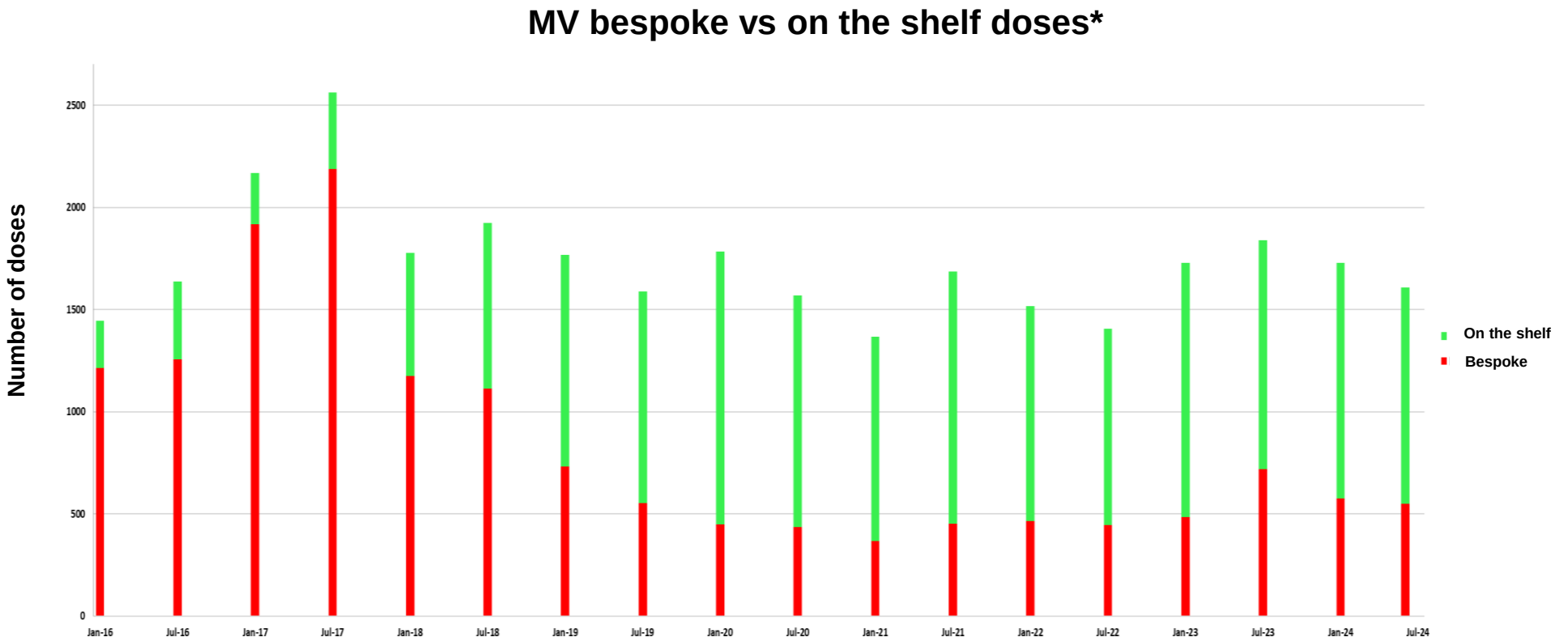
*Speaker's own opinion.
SACT, systemic anti-cancer therapy.

Levers – core service demands and workforce*

- Upskill pharmacy technician workforce towards technician-led core services
  - Right person for the right role
  - Medicines supply, medicines counselling, electronic prescribing systems
- Underutilisation of existing non-medical prescribers in current services
  - Start small and grow?
  - Redistribute duties among the team

*Speaker's own opinion.
SACT, systemic anti-cancer therapy.

Bespoke vs. on the shelf doses



*Local data.
MV, Mount Vernon.

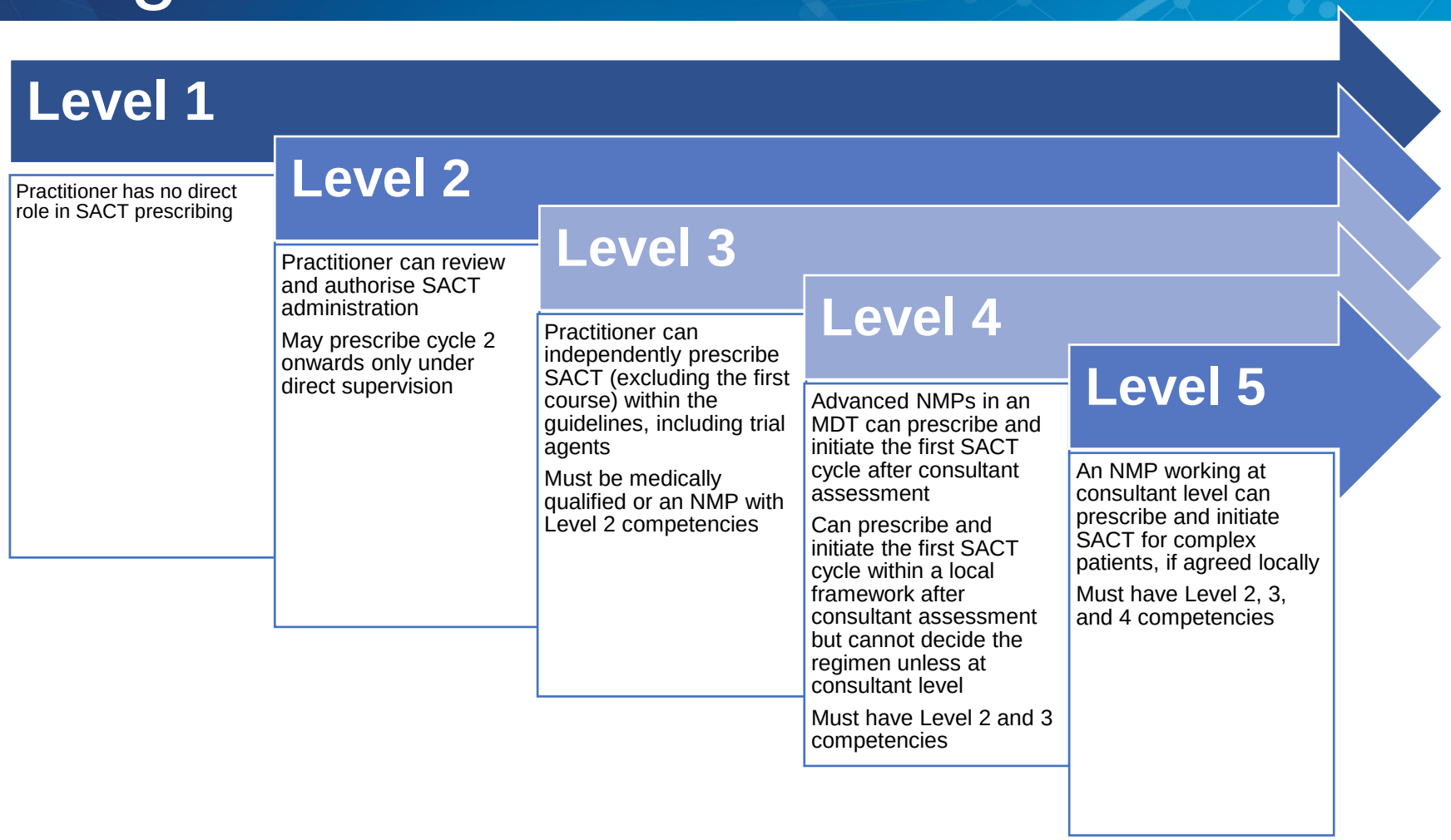
Levers – training and competencies

- Pharmacist present in all outpatient oncology clinics*
  - Building relationships
  - Developing MDT working
  - Supporting with toxicity and drug interaction management
  - Dealing with reimbursement questions
  - Building the pathway to non-medical prescribing
- Career pathway for pharmacist and pharmacy technicians at recruitment[1,2]
  - Accurate forecasting of training requirements
  - Non-medical prescribing built into all career pathways for pharmacists

*Speaker's own opinion.

1. Armstrong A. J Prescribing Practice. 2023;5(1):18-25; 2. Uppal Z et al. Journal of Prescribing Practice. 2024;6(9):382-392.

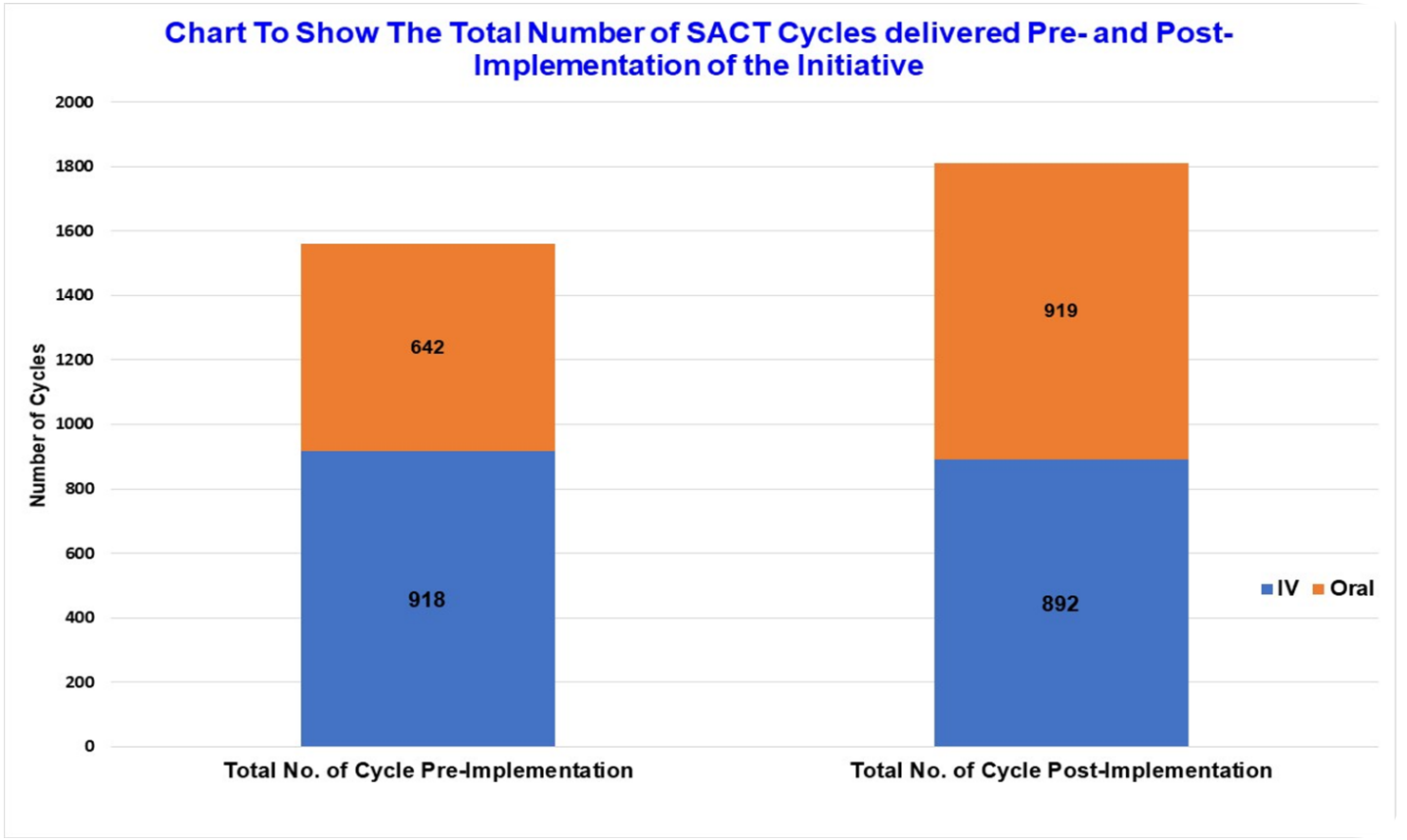
Prescriber competencies for reviewing and prescribing SACT



NMP, non-medical prescriber; SACT, systemic anti-cancer therapy.

UK SACT Board. Prescriber competencies for reviewing and prescribing Systemic Anti-Cancer Therapy. 2023.Available at: https://www.uksactboard.org/_files/ugd/638ee8_1ce28c94342f4cd095b6a373d0859280.pdf (accessed April 2025)

Levers – healthcare professional resistance



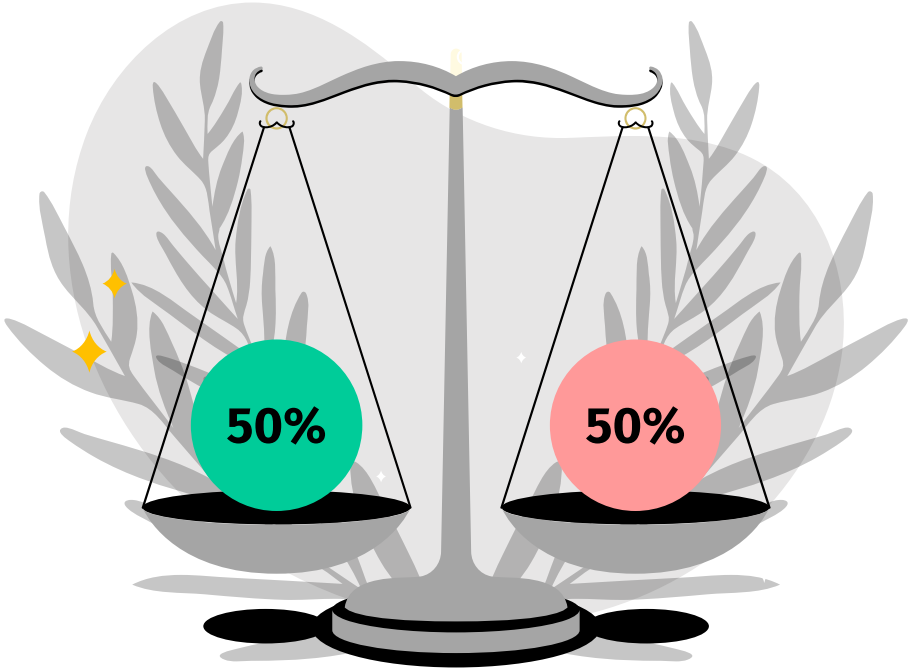
HCP, healthcare professional; IV, intravenous; SACT, systemic anti-cancer treatment.

Ng W, et al. Improvements to the Melanoma Clinic through implementation of an Independent Pharmacist Prescriber. BOPA symposium 2020.

Benefits and barriers to establishing a non-medical prescriber service

Benefits[1]

- MDT workload
- Clinic capacity
- Patient satisfaction
- HCP satisfaction
- Workforce retention



Challenges and barriers[2]

- **Finance**
- Workforce
- Training and competency
- Core service requirements
- HCP resistance

HCP, healthcare professional; MDT, multidisciplinary team; NMP, non-medical prescriber.

1. Hg HWW, et al. BOPA Symposium 2022. Poster; 2. Armstrong A. J Prescribing Practice. 2023;5(1):18-25.

Implementation*

Step 1 – What does a non-medical prescriber review look like locally?

Step 2 - Training and competency

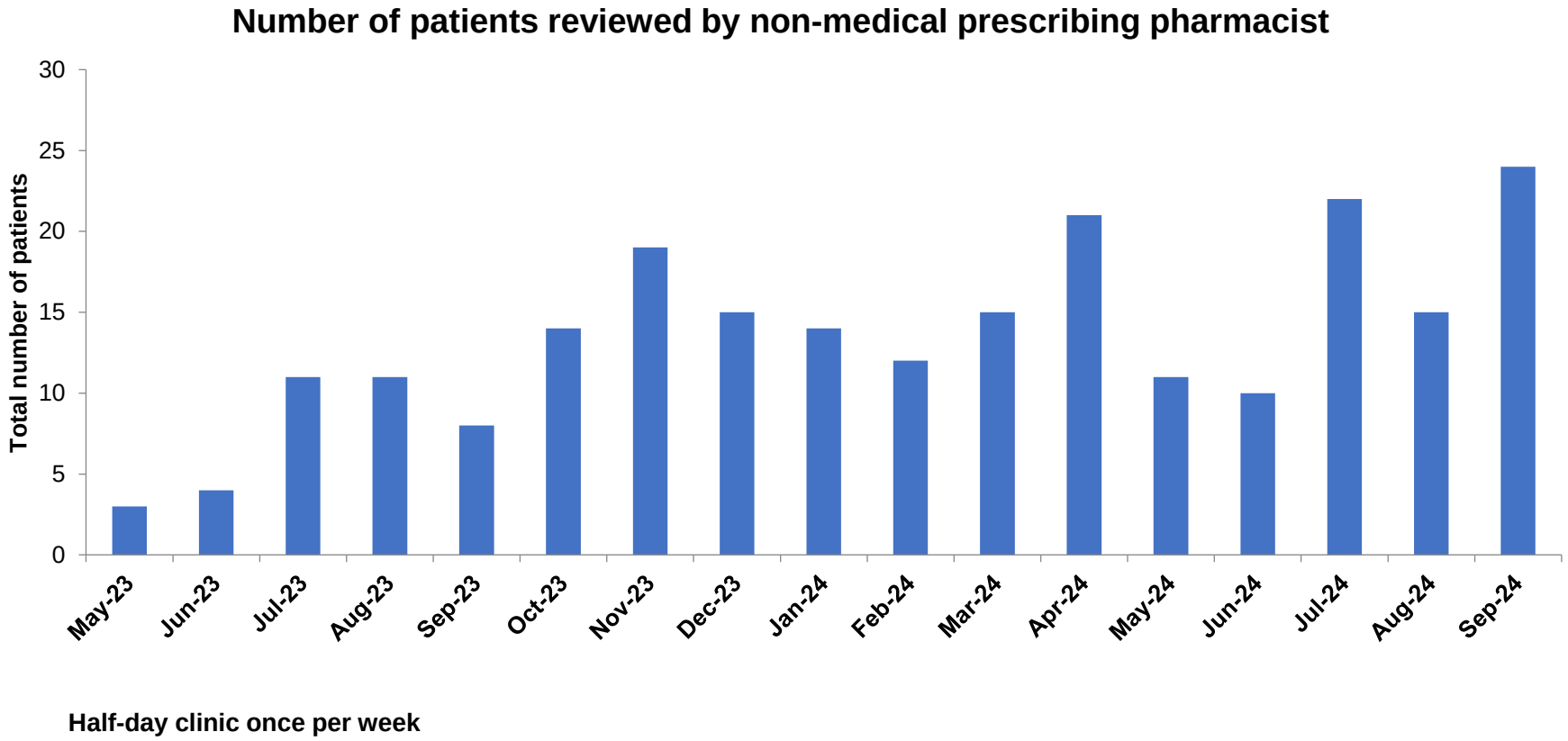
Step 3: Resource allocation

Step 4: Clinic structure and scheduling

Step 5: Sustainability and resilience

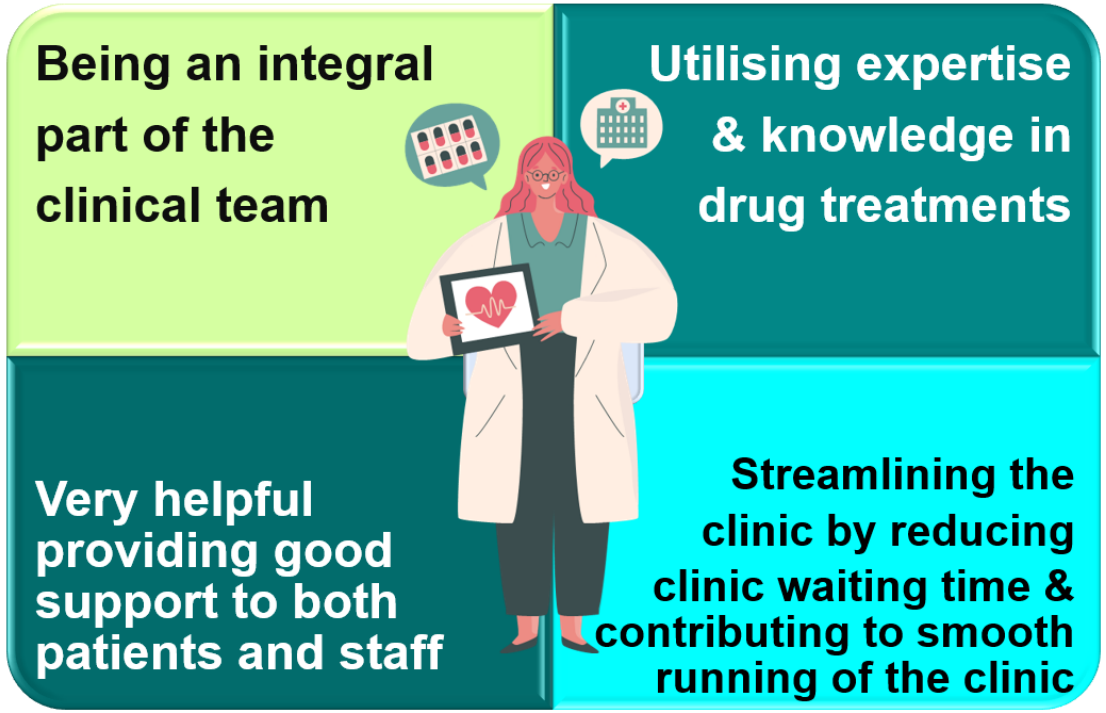
*Speaker's own opinion.

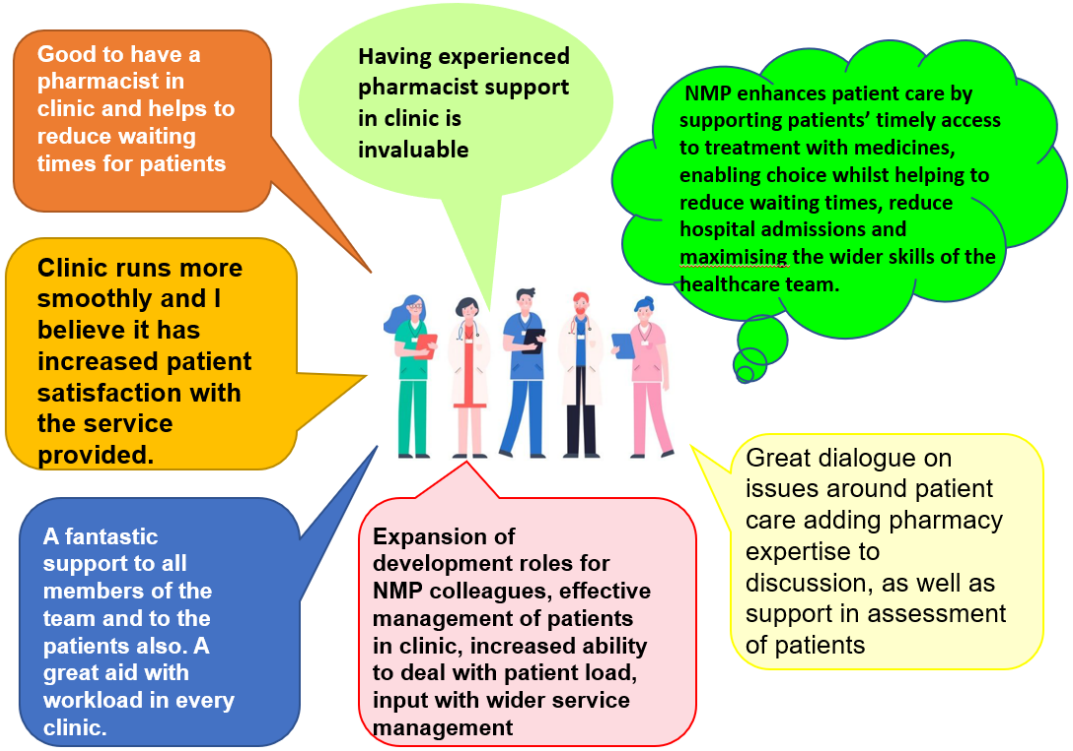
Multidisciplinary workload and clinic capacity*



*Local data.
MDT, multidisciplinary team.

Healthcare professional feedback





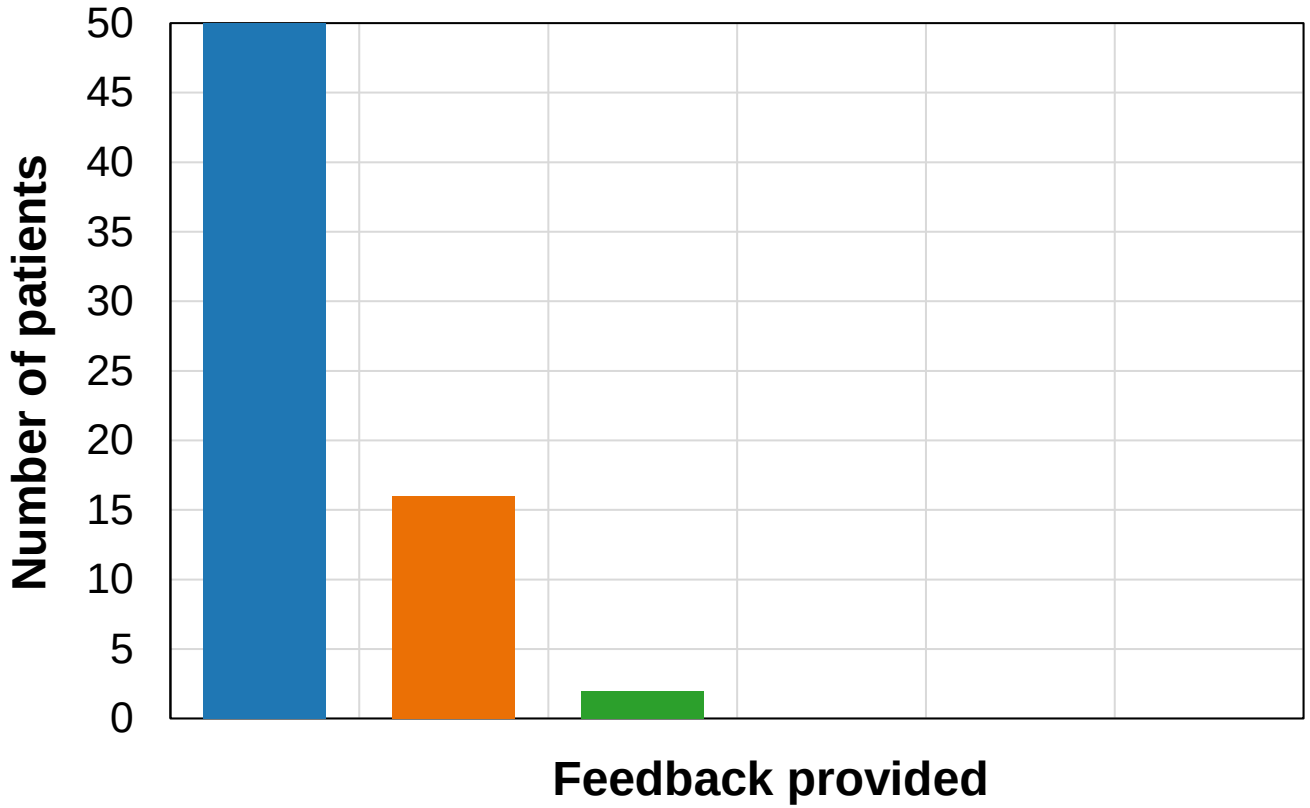
HCP, healthcare professional; NMP, non-medical prescriber.

Hg HWW, et al. BOPA Symposium 2022. Poster.

Patient feedback*

Think about your recent outpatient appointment…… Overall, how was your experience of our service?

Very good	50
Good	16
Neither good nor poor	2
Poor	0
Very poor	0
Don’t know	0



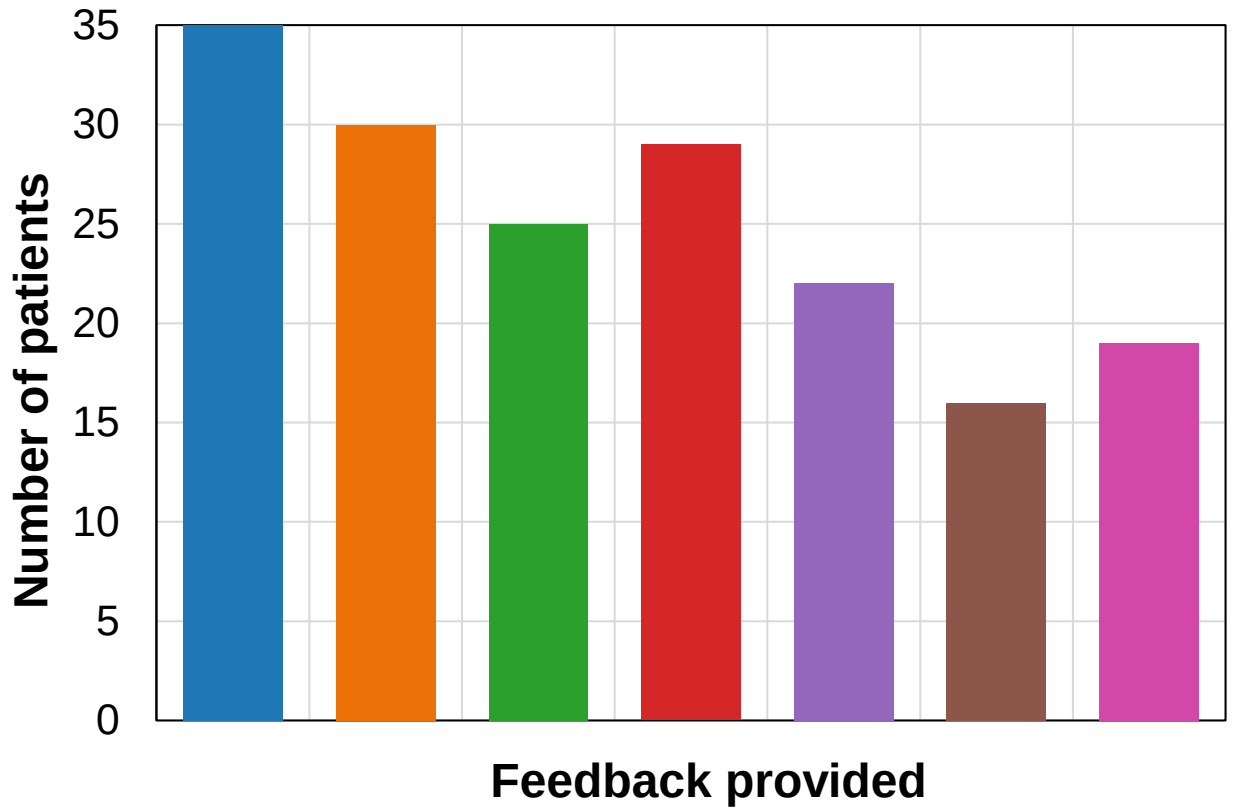
*Local data

Ng et al. Service Evaluation of the Pharmacist Independent Prescribing Clinics at a Cancer Centre. BOPA Symposium 2021

Patient feedback*

What was good about your visit?

Being a good listener – feeling understood	35
Explain things clearly, informative	30
Being knowledgeable	25
Helpful	29
Was given sufficient time in the consultation	22
Showed interest in the patient's emotional needs	16
Other	19



*Local data

Ng et al. Service Evaluation of the Pharmacist Independent Prescribing Clinics at a Cancer Centre. BOPA Symposium 2021

Benefits and barriers to establishing a non-medical prescriber service

Benefits[1]

- MDT workload
- Clinic capacity
- Patient satisfaction
- HCP satisfaction
- Workforce retention

Challenges and barriers[2]

- **Finance**
- Workforce
- Training and competency
- Core service requirements
- HCP resistance

HCP, healthcare professional; MDT, multidisciplinary team; NMP, non-medical prescriber.
1. Hg HWW, et al. BOPA Symposium 2022. Poster; 2. Armstrong A. J Prescribing Practice. 2023;5(1):18-25.

Summary

- Polypharmacy in the management of patients with PCa is increasingly challenging due to the ageing population and increased likelihood of comorbidities[1]
- ADT side-effects impact patients with PCa mentally, physically and metabolically[2,3]
- Numerous DDIs including those involving ARPIs, antihypertensives, lipid lowering drugs and anticoagulants need careful consideration in patients with PCa[4-7]
- Establishment of an NMP cancer service enables pharmacists to provide expert support in clinics, freeing up time for consultants to focus on more complex cases leading to improved patient and HCP colleague satisfaction[8]

ADT, androgen-deprivation therapy; ARPI, androgen-receptor pathway inhibitor; DDI, drug-drug interaction; HCP, healthcare professional; NMP, non-medical prescriber; PCa, prostate cancer.

Williams J, et al. Clinical Pharmacist. 2018;10(1):DOI:10.1211/PJ.2018.20204093; 2. Choi SM, et al. Korean J of Urol. 2015;56(1):12-18; 3. Crawford ED et al., EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5; 4. Enzalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/10318/smpc/ (accessed April 2025); 5. Apalutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9832/smpc/print (accessed April 2025); 6. Abiraterone. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14566/smpc/ (accessed April 2025); 7. Darolutamide. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/11324/smpc/ (accessed April 2025). 8. Hg HWW, et al. BOPA Symposium 2022. Poster.

NUBEQA® (darolutamide) 300 mg film-coated tablets
Prescribing Information – United Kingdom
(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: Each film-coated tablet contains 300 mg of darolutamide. **Indication(s):** NUBEQA is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease or with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy or with mHSPC in combination with docetaxel. **Posology & method of administration:** Treatment should be initiated and supervised by a specialist physician experienced in treatment of prostate cancer. Medical castration with a luteinising hormone-releasing hormone (LHRH) analogue should be continued during treatment of patients not surgically castrated. For oral use. The tablets should be taken whole with food. ***Adults:*** 600 mg darolutamide (two tablets of 300 mg) taken twice daily, equivalent to a total daily dose of 1200 mg. When used in combination with docetaxel in mHSPC patients, the first of 6 cycles of docetaxel should be administered within 6 weeks after the start of darolutamide treatment. Treatment with darolutamide should be continued until disease progression or unacceptable toxicity even if a cycle of docetaxel is delayed, interrupted, or discontinued. If a patient experiences a ≥ Grade 3 toxicity or an intolerable adverse reaction related to darolutamide, dosing should be withheld or reduced to 300 mg twice daily until symptoms improve. Treatment may then be resumed at a dose of 600 mg twice daily. ***Children & adolescents:*** There is no relevant use of darolutamide in the paediatric population. ***Elderly:*** No dose adjustment is necessary. ***Renal Impairment:*** No dose adjustment is necessary for patients with mild or moderate renal impairment. For patients with severe renal impairment (eGFR 15-29 mL/min/1.73 m2) not receiving haemodialysis, the recommended starting dose is 300 mg twice daily. ***Hepatic Impairment:*** No dose adjustment is necessary for patients with mild hepatic impairment. The available data on darolutamide pharmacokinetics in moderate hepatic impairment is limited. Darolutamide has not been studied in patients with severe hepatic impairment. For patients with moderate and severe hepatic impairment (Child-Pugh Classes B and C), the recommended starting dose is 300 mg twice daily. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients. Women who are or may become pregnant. **Warnings & precautions:** Monitor for signs and symptoms of ischaemic heart disease. Optimise management of cardiovascular risk factors. Discontinue darolutamide for Grade 3-4 ischaemic heart disease. Seizure occurred in patients receiving darolutamide. Advise patients of the risk of developing a seizure while receiving darolutamide. Consider discontinuation of darolutamide in patients who develop a seizure during treatment. Cases of idiosyncratic drug-induced liver injury (DILI) with increases in alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) to ≥5 and ≥20 x upper limit of normal (ULN) have been reported. Idiosyncratic DILI has been reported in clinical trials and the post-marketing setting. Liver function test abnormalities were reversible upon darolutamide discontinuation. In case of liver function test abnormalities suggestive of idiosyncratic drug-induced liver injury, permanently discontinue darolutamide. The available data in patients with severe renal impairment are limited. As exposure might be increased those patients should be closely monitored for adverse reactions. The available data in patients with moderate hepatic impairment are limited, and darolutamide has not been studied in patients with severe hepatic impairment. As exposure might be increased those patients should be closely monitored for adverse reactions. Patients with clinically significant cardiovascular disease in the past 6 months including stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, and symptomatic congestive heart failure were excluded from the clinical studies. Therefore, the safety of darolutamide in these patients has not been established. Use of strong CYP3A4 and P-gp inducers during treatment with darolutamide may decrease the plasma concentration of darolutamide and is not recommended, unless there is no therapeutic alternative. Selection of an alternate concomitant medicinal product with less potential to induce CYP3A4 or P-gp should be considered. Patients should be monitored for adverse reactions of BCRP, OATP1B1 and OATP1B3 substrates as co-administration with darolutamide may increase the plasma concentrations of these substrates. Co-administration with rosuvastatin should be avoided unless there is no therapeutic alternative. In patients with a history of risk factors for QT prolongation and in patients receiving concomitant medicinal products that might prolong the QT interval, physicians should assess the benefit-risk ratio including the potential for Torsade de pointes prior to initiating NUBEQA. NUBEQA 300mg film-coated tablets contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicinal product. **Interactions:** For the effect of other medicinal products on the action of darolutamide (e.g CYP3A4, P-gp inducers and CYP3A4, P-gp and BCRP inhibitors, UGT1A9 inhibitors and docetaxel) and the action of darolutamide on other medicinal products (BCRP, OATP1B1, OATP1B3 substrates, P-gp substrates, docetaxel, CYP3A4 substrates and other medicinal products that prolong the QT interval) refer to the relevant SmPCs. **Pregnancy & lactation:** Darolutamide is not indicated in women of childbearing potential, and it is not to be used in women who are, or may be, pregnant or breast-feeding. Unknown whether darolutamide or its metabolites are present in semen. If the patient is engaged in sexual activity with a woman of childbearing potential, a highly effective contraceptive method (<1% failure rate per year) should be used during and for 1 week after completion of treatment. Unknown whether darolutamide or its metabolites are excreted in human milk. No studies in animals have been conducted to evaluate the excretion of darolutamide or its metabolites into milk. A risk to the breast-fed child cannot be excluded. There are no human data on the effect of darolutamide on fertility. Based on animal studies, darolutamide may impair fertility in males of reproductive potential. **Effects on ability to drive and use machines:** Darolutamide has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** *Adverse reactions observed in patients with nmCRPC and mHSPC* *Very common:* fatigue/asthenic conditions, neutrophil count decreased, bilirubin increased, ALT increased, AST increased, anaemia. *Common:* ischaemic heart disease, heart failure, rash, pain in extremity, fractures. *Serious adverse reactions:* cardiac arrhythmias, urinary retention, urinary tract infection, pneumonia, fractures, seizure. *Adverse reactions observed in patients with mHSPC treated with darolutamide in combination with docetaxel. Very common:* hypertension, rash, blood bilirubin increased, ALT increased, AST increased. *Serious adverse reactions:* fractures, ischaemic heart disease, seizure, febrile neutropenia, neutrophil count decreased, pneumonia. Prescribers should consult the SmPC in relation to other side effects (see section 4.8 of SmPC). **Overdose:** In the event of intake of a higher than recommended dose, treatment with darolutamide can be continued with the next dose as scheduled. There is no specific antidote for darolutamide and symptoms of overdose are not established. **Legal Category:** POM**. Package Quantities & Basic NHS Costs:** Pack of 112 film-coated tablets, £4,040. **MA Number(s):** PLGB 00010/0677. **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** June 2025

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store.
Adverse events should also be reported to Bayer plc.
Tel: 0118 206 3500, Fax: 0118 206 3703, Email: pvuk@bayer.com