INNOVATIONS JOURNALS

*Conference Proceeding*

# A Formulary Management Group Consensus

**Laila Carolina Abu Esba,[1,2,3] Hind Almodaimegh,[1,2,3] Mansoor Ahmed Khan,[3,4,5] Consuela Cheriece Yousef,[3,6,7] Hana Al-Abdulkarim,[8,9] Ali A. Al Aklabi,[2,3,10] Mohammed Al Harbi[2,3,11]**

[1]Pharmaceutical Care Department, King Abdulaziz Medical City, Ministry of National Guard, Health Affairs, Jeddah, Saudi Arabia
[2]King Saud Bin Abdulaziz University for Health Sciences, Riyadh, Kingdom of Saudi Arabia
[3]King Abdullah International Medical Research Centre, Riyadh, Kingdom of Saudi Arabia
[4]Pharmaceutical Care Department, Ministry of National Guard Health Affairs, Jeddah, Saudi Arabia
[5]King Saud bin Abdulaziz University for Health Sciences, Jeddah, Saudi Arabia
[6]Pharmaceutical Care Department, Ministry of National Guard Health Affairs, Dammam, Saudi Arabia
[7]King Saud bin Abdulaziz University for Health Sciences, Al Ahsa, Saudi Arabia
[8]Doctoral School of Applied Informatics and Applied Mathematics, Óbuda University, Budapest, Hungary
[9]Drug Policy and Economic Center, Ministry of National Guard Health Affairs, Riyadh, Saudi Arabia
[10]Internal Medicine Division, Department of Medicine, King Abdulaziz Medical City, Ministry of National Guard Health Affairs, Riyadh, Saudi Arabia
[11]Department of Anesthesia, King Abdulaziz Medical City, Ministry of National Guard, Riyadh, Saudi Arabia

Address correspondence to Laila Carolina Abu Esba (abuesbala@ngha.med.sa).

Source of Support: None. Conflict of Interest: None.

Submitted: Sep 12, 2023; First Revision Received: Nov 20, 2023; Accepted: Jan 4, 2024

Abu Esba LC, Almodaimegh H, Ahmed Khan M, et al. A formulary management group consensus. *Glob J Qual Saf Healthc.* 2024; 7:88–94. DOI: 10.36401/JQSH-23-26.



## INTRODUCTION

In 2014, the very first event that marked a significant milestone in the field of formulary management took place in Riyadh, Saudi Arabia. The conference, organized by King Faisal Specialist Hospital, brought together healthcare experts and professionals from various national and international institutions. It was a momentous occasion, one that provided a platform for the exchange of invaluable insights and sparked the interest of many in the field of formulary management.[1]

Since that historic gathering, no similar conference was organized, despite the rapid pace of evolvement of drug discovery and the need for experts in the field of formulary management. The need for continued dialogue, collaboration, and knowledge sharing in this ever-changing field has never been more apparent, and there has been a noticeable lack of research and standardization of practices.[2,3] Fortunately, as serendipity would have it, the formulary team at the Ministry of National Guard Health Affairs (MNGHA) was granted the privilege of leading this endeavor forward and was honored to organize the second formulary management conference.

Several organizations have developed tailored policies, outlining their formulary management and development processes, some of which include unique elements tailored to their specific population and services they provide.[4,5] Notably, in the year 2000, a collaborative working group in the United States, consisting of various stakeholders, developed a set of principles. These principles serve as the foundation for establishing essential components integral to a robust formulary system.[6]

Despite this, there is a notable lack of standardization and agreement among large healthcare systems globally regarding the essential elements that need to be addressed within a formulary system. The American Society of Health-System Pharmacists, in its 2021 guidelines, has outlined some of the most important standards in formulary management.[6] However, it is imperative not only to establish agreed-on practice standards but also to highlight emerging and trending issues that formulary management systems may encounter. These challenges can be regional, local, or global in nature, affecting healthcare systems in diverse ways. Collaborative efforts in sharing experiences and approaches are essential for institutions in managing their formulary systems.

In this paper, we attempted to encapsulate some of the most pivotal and enlightening thoughts shared by the speakers and attendees at that momentous conference. Their insights, expertise, and dedication to advancing the field of formulary management have left an indelible mark on our collective understanding of this critical domain.

## METHODS

### Participants

Participants for the consensus-building process were based on their expertise and experience in the field of

formulary management. A diverse group of professionals, including physicians, pharmacists, and policymakers, was chosen to ensure a comprehensive perspective. A total of eight panel members were included, all of whom had served an average of 8–10 years as pharmacy and therapeutics committee members and were involved in a variety of responsibilities related to formulary management.

### Preparation

The expert panel met regularly before the formulary management conference held in Riyadh, Saudi Arabia, to develop the agenda topics, selection of the expert speakers, and pressing issues for discussion. Although the participants prepared during the conference preparatory phase, many provided feedback to the panel, which stimulated important ideas to bring forth.

### Consensus-Building Process

The consensus-building process took place during a 2-day in-person meeting at the conference venue where topics were discussed, and constructive discussions took place. The conference was divided into several sessions, each focused on a specific aspect of formulary management, including committee formation, drug evaluation process, drug safety considerations, post-approval issues, regulatory and logistic factors, and the adoption of biosimilars and generics. Each session followed a structured format:

1. **Presentation by an expert**: A subject matter expert presented the available evidence, research findings, and best practices related to the specific topic under discussion. Each session was followed by questions from the audience.
2. **Panel discussion**: Participants engaged in open and facilitated discussions regarding the presented topics, with attendees from various institutions and experts in the field.
3. **Consensus building**: The facilitator guided the participants to propose specific statements that represented the consensus view on the topic.
4. **Documentation**: Detailed notes and minutes of each session were recorded, including the key points of discussion and areas of consensus. All panel members reviewed the key points and provided feedback if they had any amendments. The final draft was circulated by email and approved by all panel members.

### Data Analysis

Following the consensus meeting, the recorded notes, recommendations, and minutes were analyzed to compile a comprehensive report summarizing the consensus reached on each topic. This report served as the basis for the development of the final consensus document.

The draft consensus document was circulated to all participants for review and feedback. Participants had the opportunity to suggest revisions or clarifications. After incorporating their input, the final consensus was compiled and is outlined as follows.

## RESULTS

There are key features, concepts, and practices that a successful formulary system needs to adopt. In the following we highlight the themes that emerged during the conference, where a consensus was reached regarding their importance.

### The Role of Formulary Management in Value-Based Healthcare

Formulary management is a critical component of the healthcare system. In our ever-changing landscape, ensuring the safe, effective, and cost-efficient use of medications is paramount. Value in healthcare is described as the measured improvement in a patient's health outcomes for the cost of achieving that improvement.[7] Formulary management is pivotal in embracing value-based healthcare, guaranteeing patient access to the most effective and cost-efficient medications based on measurable health outcomes. However, the concept of value-based healthcare within formulary management faces challenges, such as defining value, measuring therapeutic outcomes, and incorporating patient-centered care into the decision-making processes.[8]

The role of a formulary manager extends far beyond a job; it is a calling demanding dedication, passion, and commitment to improving the lives of patients. It requires ongoing learning and adaptation to new technologies, medications, and practices. It calls for a profound understanding of the healthcare system and collaborative work with healthcare professionals.

Every drug selected for the formulary has the potential to lead to life-changing outcomes for patients, and each time cost savings are made in the selection process, there are opportunities to invest in other technologies and services that enhance patient care. "Value," as envisioned, is about the outcomes that matter most to patients relative to the cost of achieving them. Yet, the growing burden in pharmaceutical spending and its impact on all healthcare systems challenges this equation. It is recognized that we are not living in a cost crisis in healthcare but rather we are living in a value crisis in healthcare.

Incorporating value-based assessment tools developed by various associations within the drug decision processes has been described. Tools such as the National Comprehensive Cancer Network (NCCN's Evidence Blocks) and the European Society for Medical Oncology-Magnitude of Clinical Benefit Scale can be useful for formulary decision-makers.[9,10] There have also been recent efforts shared on how to apply a multi-tier value-based formulary within a health plans, and interest in such approaches is growing and supported.[11,12]

The emergence of innovative contracting opportunities commonly known as managed entry agreements and their

subtypes, such as outcome-based agreements, in which a specific efficacy outcome may be a rule for reimbursement, mandates a better understanding of how to implement them and developing policies related to their execution. Formulary managers need to build awareness in negotiating skills, how to develop terms of such contracts, and methods of implementing them, which can be very challenging; however, many workshops and learning opportunities are available.[13,14]

## Formulary Committee Formation

Developing a value-based formulary hinges on several key factors. First and foremost is the establishment of an effective formulary committee, commonly referred to as the pharmacy and therapeutics committee (P&T). This committee plays a central role in ensuring the alignment of the formulary with value-based principles; institutions have recognized the importance of coordinating the processes of these committees and organizing the streamlining of its responsibilities.[15–17] In addition, with the complexity of new emerging extremely expensive therapies, large institutions have examined developing subcommittees with more specialized members and focused tasks.[18]

Efficiency in formulary management development is contingent on the formulation and leadership of an adept team. This entails selecting individuals with the requisite expertise, fostering collaboration, and providing clear guidance on the committee's objectives and decision-making processes.

To drive continuous improvement, benchmarking against the practices and experiences of similar committees is invaluable. In addition, it is crucial to define the role of each committee member within the process. In essence, developing a value-based formulary necessitates a well-structured committee, proficient leadership, insights from best practices, and a defined role for each member in the decision-making journey.

Efforts have been made to outline standards and practices of the P&T committee, describing the structure and functions of such committee.[6,19] The sophistication of these committees can vary widely based on the size of the institution and population it serves. The MNGHA's formulary committee described some of the features of its process and structure in previous publications, which was also shared in detail during the conference.[20,21]

Challenges faced by the committee, as described by many members, include limited time allocated for pharmacists to evaluate a drug and constraints on the time allocated for P&T members to review the literature related to a drug discussion. In addition, there is a need for greater higher management support in providing extra working slots and/or compensation for overtime. Addressing these challenges is crucial for ensuring the committee can make well-informed and timely decisions.

Addressing conflicts of interest within drug formulary committees is critical for maintaining transparency and safeguarding the best interests of patients and institutions. Committee members should voluntarily disclose any conflicts of interest they may have before meetings, and chairs must play a pivotal role in recognizing and managing these conflicts. Having clear, written policies and procedures for conflict identification and management is essential. Some organizations choose to use multilayered committees to enhance decision-making and mitigate conflict of interest.[22]

Physicians within these committees serve a vital role in advocating for practical and convenience-related aspects of therapies, aligning with the principles of evidence-based practice that stress the importance of assessing the applicability of the evidence to unique patient populations. In addition, physicians must ensure that research findings are representative and beneficial to the patients served by the committee and call to localize clinical trials to reflect the diversity of their population.

## The Drug Evaluation Process

The drug evaluation process is a crucial aspect of the formulary decision-making process, aiming to ensure that all members have the resources available to make an informed decision. The transition from evidence-based medicine to value-based medicine emphasizes the importance of not only considering clinical evidence but also the overall value that a drug provides to patients and healthcare systems. Here are some key points and considerations in this process:

### *Formulating comprehensive evaluations*

Evaluators must develop a systematic and comprehensive approach to evaluating drugs. This includes evaluating clinical trial data, real-world evidence, economic analyses, and patient-reported outcomes. A well-rounded assessment provides a more holistic view of a drug's value.

### *Literature search and data navigation*

The first step in drug evaluation is a comprehensive literature search. Drug evaluators should be well-versed in using advanced search tools and strategies to gather the best available evidence.

### *Interpreting statistics*

Understanding statistics is imperative for drug evaluators. They should be able to identify the strengths and limitations of different study designs and statistical methods. It is also important to recognize that statistical significance does not always equate to clinical significance.

### *Comparative trials*

When evaluating comparative trials, there must be a critical assessment of the choice of comparators. Vigilance is required to recognize irrelevant comparators or disadvantaged ones.

### *Composite endpoints*

Caution is needed when dealing with composite endpoints in clinical trials. If the significance of a trial is primarily driven by a less valuable component to patients, it may not reflect the true clinical benefit of the drug. In

addition, the choice of each individual component of a composite endpoint should be sound, and results of each component examined separately to conclude the overall benefit.

***Surrogate endpoints***

Recognizing that surrogate endpoints, although often used in clinical research, do not always translate into meaningful clinical value. Evaluators should consider whether the surrogate endpoint correlates with important patient outcomes. This may require examining basic evidence related to disease pathophysiology and quality of evidence linking the surrogate marker to an expected benefit.

***Common statistical misconceptions***

Understanding common statistical misconceptions is vital for drug evaluators. *P* values should not be used in isolation to determine clinical importance, and they do not convey the size of the effect. Relative risk can exaggerate findings, and absolute risks provide a clearer picture. Moreover, it's crucial to differentiate between correlation and causation.

The drug evaluation is a multifaceted process that requires a combination of clinical expertise, statistical acumen, and a patient-centered approach. As healthcare systems are transforming to value-based care, drug evaluators play an important role in ensuring that the right drugs are selected for formularies, taking into account not only their clinical efficacy but also their overall value. In addition, untraditional aspects of a drug evaluation, such as the effect a pharmaceutical may have on the environment, indicates the multiple issues the committees may need to address and incorporate into their evaluation.[23]

## Drug Safety from a Formulary Perspective

Drug safety is a vital aspect of formulary management, and it involves multiple stages, from pre-market assessment to post-marketing surveillance. During the evaluation of drugs for formulary inclusion, limited information is often available about their safety profiles, and committees might not discuss the safety profile thoroughly. There is a need for greater standardization and guidance from committees concerning the management of risks associated with drugs at all stages.[2] Here are some key considerations for evaluating and ensuring drug safety within a formulary system.

***Drug safety assessment upon formulary addition consideration***

Before a drug is approved and added to a formulary, thorough evaluation of the safety profile and assessing the safety data from available studies should be conducted. This includes reviewing data from clinical trials and real-world studies and assessing the risk-benefit ratio.

***Risk mitigation strategies***

The drug evaluating committee should be aware of any risk mitigation measures developed by the country's drug regulatory body to address specific safety concerns associated with certain drugs. For example, the Saudi Food and Drug Authority (SFDA) developed the regulatory framework known as the Risk Minimization Measures (RMM). This framework closely resembles the U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategy program and the European Medicines Agency's risk-management plan. The purpose of RMMs is to introduce interventions aimed at preventing or mitigating the occurrence of adverse reactions associated with exposure to a medicine or to reduce their severity or impact on the patient. Components of the SFDA RMM may include patient cards, patient guides, healthcare provider guides or checklists, and Dear Healthcare Provider letters. Implementation of these measures requires collaboration between regulatory agencies, the pharmaceutical industry, healthcare providers, and patients. There is also a growing emphasis on digitalizing the RMM components to facilitate access to the safety information.[24,25]

***Post-marketing surveillance***

Because randomized controlled trials are not powered to identify all safety concerns, post-marketing surveillance can help detect safety issues that have not been recognized and that can shift the benefit versus risk ratio. The formulary committee has a significant role in monitoring and addressing new safety concerns and considering whether adjustments to formulary inclusion or utilization criteria are necessary.[26]

***Medication use evaluations (MUEs)***

MUEs can be a valuable tool for monitoring drug safety. These evaluations involve a systematic review of the medication's safety and effectiveness, and can identify local safety issues (e.g., higher risk groups based on genetic or ethnic background, inappropriate practices resulting in safety concerns, or cultural aspects influencing risk vs benefit of a drug). The committee can help identify potential issues and inform decision-making.

***Managed entry agreements (MEAs) and risk sharing agreements (RSAs)***

When there is uncertainty surrounding the risk-benefit balance of a drug, the formulary committee can consider incorporating specific drug safety concerns into MEAs or RSAs. These agreements can help to manage the financial risk associated with uncertain outcomes.[27]

## Formulary Post-Approval Process

The formulary post-approval processes within formulary management are just as important as the initial evaluation. These processes ensure the continuity of care within an institution. Here are some key aspects of post-approval formulary management.

***Monitoring utilization***

Continuously monitoring the use of drugs on the formulary is essential to identify trends and to ensure formulary committee members are informed of changes. This

includes monitoring stocks, estimating initial stocks required, observing prescribing trends, and forecasting changes in the utilization of drugs being replaced.[28]

***Handling appeals and restrictions***

Handling appeals from healthcare providers and the industry, as well as implementing restrictions based on the committee's decisions, is an ongoing process. Thorough discussions should take place regarding the justifications behind restriction decisions, whether rooted in high costs, safety concerns, or abuse potential. Clear methods for implementing these restrictions should also be decided on.[29]

***Leveraging automation***

Automation tools can streamline formulary decisions, including automated prior authorization systems, electronic prescribing information, enforcement of restrictions, building customized alerts and system monitoring tools, and utilization management tools that help ensure compliance with formulary policies.[30]

***Procurement issues***

Collaborating closely with procurement teams is crucial to ensure the availability of drugs on the formulary. Formulary committees need to communicate with procurement experts to address supply chain issues, manage drug shortages, and ensure medications are consistently available while minimizing wastage.

***Drug regulations and compliance***

Staying up-to-date with drug regulations and compliance requirements is essential. For example, in Saudi Arabia, adherence to multiple bodies is expected within the procurement process, such as Expenditure & Project Efficiency Authority, the Local Content and Government Procurement Authority, and the National Unified Procurement Company.[31–33]

## Biosimilars and Generics

Optimizing pharmaceutical spending through strategic implementation of biosimilars and generics is a key role in formulary management.[34] Exploring the opportunities and expectations associated with biosimilar/generic switching at an institutional level is therefore vital. Biosimilar switching provides a key opportunity in cost savings; however, issues that institutions should consider when contemplating a switch to a biosimilar include the following.[35–38]

***Thorough product evaluation***

Rigorous evaluation of biosimilar products is essential. This involves reviewing regulatory approval, examining evidence on efficacy and safety from approval trials, switching studies, and post-marketing experiences. In addition, factors such as dosage form differences and patient convenience that may vary between the reference and biosimilar products should be taken into account. Some large healthcare institutions may consider forming a biosimilar subcommittee to streamline the work.[38–41]

***Institutional considerations***

Each institution must assess the feasibility and significance of interchangeability and switching within their specific healthcare setting. Understanding how product excipients can impact patient outcomes highlights also the need for a holistic approach to evaluation.

***Appropriateness of extrapolation***

Deciding whether to extrapolate data from one indication to another should be based on robust scientific evidence and clinical judgment. In some cases, maintaining both the reference and biosimilar products may be necessary to ensure adequate treatment options for specific patients (e.g., pediatrics).

***Manufacturer's history***

Reviewing the track record of the biosimilar manufacturer and history of recalls and shortages are key in ensuring a reliable and consistent supply chain.

***Pharmacoeconomic impact***

Assessing the impact of biosimilar adoption is fundamental to justify the switch. It involves analyzing the potential savings and overall financial implications for the institution.

***Stakeholder engagement***

Engaging various stakeholders, including healthcare providers, and patients, is essential to ensure a smooth transition to biosimilars or generics. Open communication and addressing concerns are critical to gain support and trust.

***Pharmacovigilance requirements***

Implementing robust pharmacovigilance measures is necessary to monitor the safety and efficacy of biosimilars or generics post-switch.

***Post-switching education***

Comprehensive education and support to healthcare professionals and patients is vital. It helps them understand the reasons for the switch, manage expectations, and use the new products effectively. Various means of education can be approached such as in-services or emails.

***Real-world evidence studies in extrapolated indications of biosimilars***

Generating real-world studies of biosimilars in the extrapolated indication is encouraged to improve the confidence and trust of health care professionals and patients on biosimilars.

## Pharmacoeconomics and Defining Value

Pharmacoeconomics and defining value are crucial aspects of formulary management. Policymaking, local industry development, health technology assessment (HTA), and cost-effectiveness assessments all play a role in defining value and influencing the decisions made regarding which pharmaceuticals to include in the formulary. These factors are integral to ensuring access to

effective and cost-efficient healthcare interventions for the population.

The evolving healthcare landscape in Saudi Arabia, driven by the Saudi Vision 2030 goals,[42] has profound implications for formulary management. Here are some of the key points that shape this landscape.

***PESTEL indicators***

Improvement in Saudi Arabia's ranking across PESTEL indicators signifies the nation's commitment to progress in various dimensions, including politics, economics, society, technology, environment, and legal aspects. These improvements can influence healthcare policies and investments, affecting formulary management decisions.

***Regulatory updates***

Regulatory updates focusing on privatization, patient-centric care, and digital transformation are shaping the healthcare landscape in Saudi Arabia. These changes may impact the availability of healthcare services, technologies, and pharmaceuticals, thereby influencing formulary management strategies.

***Maximizing local content***

Efforts to maximize local content in healthcare, including pharmaceuticals, reflect a move toward self-reliance and sustainability. This can have implications for drug procurement and formulary decisions, as supporting local industries becomes a priority.

***National medicines policy***

The development of a national medicines policy with priorities such as institutional cohesion, cost containment, secure medicine supply, and the growth of the local pharmaceutical industry indicates a comprehensive approach to pharmaceutical management. These priorities can directly affect formulary decisions, pricing, and access to medications.

***Health Technology Assessment (HTA)***

The progress toward a highly effective national HTA body is significant. HTA plays a crucial role in assessing the value and cost-effectiveness of healthcare interventions, including pharmaceuticals. The interplay between HTA recommendations and formulary management decisions indicates a data-driven approach to drug inclusion.

***Cost-effectiveness threshold***

The effort to publish the first paper on a cost-effectiveness threshold specific to Saudi Arabia demonstrates a commitment to evidence-based decision-making.[43] Such thresholds can guide formulary management by determining which treatments offer the best value.

## CONCLUSION

In conclusion, formulary management in Saudi Arabia has evolved significantly, with a focus on patient-centered care, evidence-based decision-making, and adaptability in a changing healthcare landscape. Key insights presented herein include the importance of defining value, the role of effective formulary committees, and transition from evidence-based to value-based medicine.

The rapidly evolving healthcare landscape has underscored the importance of formulary management in ensuring access to cost-effective and high-quality medications. Challenges such as enhancing the drug evaluation process, drug safety, conflict of interest, regulatory and logistic considerations, and the adoption of biosimilars and generics are among the specific fields that formulary committee members need to continue working in to improve patient outcomes.

## Acknowledgment

The authors thank all of the speakers who contributed their valuable time and expertise at the formulary management conference: Ahmad Jazeri, Ahmed Al Jedai, Esraa Al Tawil, Ghada Mardawi, Hussain Al Omar, Johara Al Koraishi, Mashael Alaskar, Mathew Grissinger, Mohammed Abdelshafy, Murtada Haleem, Sakra Balhareth, Samar Al Moaiseib, Tariq Al Hawassi, Waad Al Ghamdi, Wafaa Al Suwairi, Yazed Al Ruthia.

## References

1. Formulary Management at King Faisal Specialist Hospital and Research Center (KFSHRC). Nov 3–4, 2014, Riyadh, Saudi Arabia. Accessed Sep 5, 2023. twitter.com/formulary_mgmt
2. Schiff GD, Tripathi JB, Galanter W, et al. Drug formulary decision-making: ethnographic study of 3 pharmacy and therapeutics committees. *Am J Health Syst Pharm*. 2019;76:537–542.
3. Durán-García E, Santos-Ramos B, Puigventos-Latorre F, Ortega A. Literature review on the structure and operation of Pharmacy and Therapeutics Committees. *Int J Clin Pharm*. 2011;33:475–483.
4. American Heart Association. American Heart Association policy statement on drug formularies. Published 2018. Accessed Nov 17, 2023. www.heart.org/-/media/files/about-us/policy-research/prevention-nutrition/drug-formulary-statement-2018.pdf
5. American Academy of Family Physicians. Patient-centered formularies. Accessed Nov 17, 2023. www.aafp.org/about/policies/all/patient-centered-formularies.html
6. AMCP Partnership Forum. Principles for sound pharmacy and therapeutics (P&T) committee practices: what's next? *J Manag Care Spec Pharm*. 2020;26:48–53.
7. Teisberg E, Wallace S, O'Hara S. Defining and implementing value-based health care: a strategic framework. *Acad Med*. 2020;95:682–685.
8. Hamad A, Elazzazy S, Bujassoum S, et al. Applying value-based strategies to accelerate access to novel cancer medications: guidance from the Oncology Health Economics Expert Panel in Qatar (Q-OHEP). *BMC Health Serv Res*. 2023;23:15.
9. Westrich K, Hydery T, Dharbhamalla V, et al. Payer perceptions and use of value assessment tools in the United States. *J Manag Care Spec Pharm*. 2023;29:582–588.

10. ESMO-MCBS Scorecards. European Society for Medical Oncology. January 2020. Accessed Nov 20, 2023. www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards
11. Chen Y, Loucks AR, Sullivan SD, et al. Designing a value-based formulary for a commercial health plan: a simulated case study of diabetes medications. *Value Health*. 2023;26:1022–1031.
12. Hung A, Sauvageau G. Formulary tiers, medication cost sharing, and transparency in bronze and silver qualified health plans in 2014 vs 2018. *J Manag Care Spec Pharm*. 2021;27:1332–1340.
13. Bouvy JC, Sapede C, Garner S. Managed entry agreements for pharmaceuticals in the context of adaptive pathways in Europe. *Front Pharmacol*. 2018;9:280.
14. Bolden T. Enhancing Managed Entry Agreement (MEA) capabilities through interactive training workshops. Remap Consulting. Jan 1, 2023. Accessed Sep 6, 2023. remapconsulting.com/managed-entry-agreements/enhancing-managed-entry-agreement-mea-capabilities-through-interactive-training-workshops/
15. Karel LI, Delisle DR, Anagnostis EA, Wordell CJ. Implementation of a formulary management process. *Am J Health Syst Pharm*. 2017;74:1245–1252.
16. Ciccarello C, Leber MB, Leonard MC, et al. ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. *Am J Health Syst Pharm*. 2021;78:907–918.
17. Leonard MC, Thyagarajan R, Wilson AJ, Sekeres MA. Strategies for success in creating an effective multihospital health-system pharmacy and therapeutics committee. *Am J Health Syst Pharm*. 2018;75:451–455.
18. Mernick F, Akrap A, MacCormack-Gagnon J. Implementation of a high-impact medication therapy subcommittee within a large academic medical center. *Am J Health Syst Pharm*. 2023;80:e46–e52.
19. Tyler L, Cole SW, May JR, et al. ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. *Am J Health Syst Pharm*. 2008;13:1272.
20. Esba LCA, Almodaimegh H, Alhammad A, et al. P&T committee drug prioritization criteria: a tool developed by a Saudi health care system. *P T*. 2018;43:293–300.
21. Esba LC. An annual formulary review strategy implemented by a Saudi Health System. *P T*. 2016;41:513–516.
22. Parker L, Bennett A, Mintzes B, et al. "There are ways . . . drug companies will get into DTC decisions": How Australian drug and therapeutics committees address pharmaceutical industry influence. *Br J Clin Pharmacol*. 2021;87:2341–2353.
23. Linder E, Wettermark B, Ovesjö ML, et al. Knowledge support for environmental information on pharmaceuticals: experiences among Swedish Drug and Therapeutics Committees. *BMC Health Serv Res*. 2023;23:618.
24. Al-Fadel N, Almutairi A, Aldhirgham T, et al. Implementation of risk minimization measures to reduce the risk of tuberculosis among tumor necrosis factor medication users. *Pharmacoepidemiol Drug Saf*. 2024;33:e5682.
25. Risk minimization measures. Saudi Food & Drug Authority. Accessed Sep 6, 2023. www.sfda.gov.sa/en/RMM
26. Abu Esba LC, Al Mardawi G, AlJasser MI, et al. Adverse drug reactions spontaneously reported at a tertiary care hospital and preventable measures implemented. *J Clin Pharm Ther*. 2021;46:460–469.
27. Jenei K, Peacock S, Burgess M, Mitton C. Describing sources of uncertainty in cancer drug formulary priority setting across Canada. *Curr Oncol*. 2021;28:2708–2719.
28. Academy of Managed Care Pharmacy. Concepts in managed care pharmacy series – drug utilization review. 2009. Accessed Nov 11, 2023. www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/drug-utilization-review
29. Park Y, Raza S, George A, et al. The effect of formulary restrictions on patient and payer outcomes: a systematic literature review. *J Manag Care Spec Pharm*. 2017;23:893–901.
30. Urbanski C, Cello R, Luby B, et al. Formulary management guiding principles for automated systems. *Am J Health Syst Pharm*. 2022;79:1599–1606.
31. Expenditure & Project Efficiency Authority website. Accessed Sep 6, 2023. expro.gov.sa
32. Local Content and Government Procurement Authority website. Accessed Sep 6, 2023. lcgpa.gov.sa/en/Pages/default.aspx
33. National Unified Procurement Company website. Accessed Sep 6, 2023. www.nupco.com/en
34. Socal MP, Cordeiro T, Anderson GF, Bai G. Estimating savings opportunities from therapeutic substitutions of high-cost generic medications. *JAMA Netw Open*. 2022;5:e2239868.
35. Ismail S, Abu Esba L, Khan M, et al. An institutional guide for formulary decisions of biosimilars. *Hosp Pharm*. 2023;58:38–48.
36. Islami MM, Khan MA, Aseeri MA, et al. Comparison of biosimilar filgrastim with innovator fligrastim for peripheral blood stem cells mobilization, collection of CD34+ stem cells, and engraftment in patients undergoing autologous and allogeneic stem cell transplantation: a single-center experience. *Ann Transplant*. 2023;28:e938585.
37. Almutairi AR, Al-Samil AM, Alsayyari A, et al. The landscape of biosimilars in Saudi Arabia: preparing for the next decade. *Expert Opin Biol Ther*. 2023;23:679–688.
38. Aschermann LM, Forshay CM, Kennerly-Shah J, Pilz J. The formulary process for biosimilar additions at a comprehensive cancer center. *J Oncol Pharm Pract*. 2022;28:185–189.
39. Kar I, Kronz M, Kolychev E, et al. Biosimilar strategic implementation at a large health system. *Am J Health Syst Pharm*. 2022;79:268–275.
40. Lam SW, Amoline K, Marcum C, Leonard M. Healthcare system conversion to a biosimilar: trials and tribulations. *Am J Health Syst Pharm*. 2021;78:2159–2163.
41. Esba LC, Yousef C, Ismail S, et al. Fixed dose combinations: a formulary decision guide. *Health Policy and Technology*. 2021;10:100500.
42. Saudi Arabia's Vision 2030. How to achieve our vision. June 2017. Accessed Mar 28, 2023. vision2030.gov.sa/en/node/125
43. Al-Jedai AH, Lomas J, Almudaiheem HY, et al. Informing a cost-effectiveness threshold for Saudi Arabia. *J Med Econ*. 2023;26:128–138.