ACT4 BIOSIMILARS

Act4Biosimilars **Action Plan**

www.act4biosimilars.com

Foreword

As the Act4Biosimilars Steering Committee, we're passionate about increasing patient access to potentially life-changing biologic medicines. We know that the introduction of biosimilars almost two decades ago brought this opportunity to patients. However, adoption of biosimilars remains uneven across the globe and it is crucial that action is taken to help ensure everyone can access the biologic treatments they need.

When we launched Act4Biosimilars in 2022, combined biosimilar adoption across the 30 target countries in scope of tracking was only 14% compared to the reference molecules despite nearly 20 years of biosimilar availability. This is why we established the Act4Biosimilars Mission, which aims to increase current biosimilar adoption by at least 30 percentage points, resulting in a minimum target of 44% biosimilar adoption by 2030. Setting an ambitious target like this is essential to drive global change as every percentage point gained could mean thousands more lives are changed through greater access to medicines.

To make this change happen, we need dedicated action from **people like you**, people who are passionate about increasing patient access to life-changing, advanced medicines. We also need a step change from multiple stakeholders globally such as payers, regulatory agencies, healthcare professionals and the patient community. By combining our efforts, we can reach our mission and **benefit patients worldwide**.

It is with this in mind that we, the Steering Committee, decided to create the Action Plan – a global roadmap that provides local stakeholders with the strategies, tools, and activities needed to leverage opportunities and overcome challenges in the 30 target countries and beyond. To ensure the Action Plan has the greatest impact as possible, we've ensured:

- The guidance it contains is applicable to every country, so that no matter where your country is on its biosimilars journey, you can use the Action Plan to drive change.
- The format takes a consistent approach to increase biosimilar adoption, using three steps – Prepare, Act, Maintain – to guide you through the essential preparatory activities to activating change and sustaining momentum.

Only by acting together and combining our efforts globally can we achieve the Act4Biosimilars Mission to increase biosimilar adoption by at least 30 percentage points in 30+ countries by 2030. By utilizing the Action Plan our hope is that we can help you on this journey to enact change. It is with your passion and drive to achieve the Mission, that means – together, we can **Act Now**, and **Act4Biosimilars**.

Best wishes,
The Steering Committee

Act4Biosimilars Steering Committee

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Why Act4Biosimilars?

Biologic medicines have **transformed the lives** of many patients. However, with increasing pressures on healthcare systems, **not everyone is able to access the treatments** they need.

Biosimilars help more patients gain access to biologic medicines, and earlier in the patient treatment cycle. **Improved access to biosimilars leads to:**

- Increased innovation by introducing competition
- Better patient outcomes
- Improved healthcare services

Act4Biosimilars is led by a multidisciplinary Steering Committee of patient advocacy leaders, healthcare professionals, biosimilar experts and industry leaders, representing views from around the world.

Driving Biosimilar Adoption

Act4Biosimilars is a global initiative that aims to increase patient access to biologic medicines by helping to accelerate the **4As of biosimilars:**

- **Approvability**
- **Accessibility**
- **Acceptability**
- **Affordability**

The Journey to 30-30-30

Act4Biosimilars' mission is to increase global biosimilar adoption **by at least 30 percentage points in 30+ countries by 2030.**

The Action Plan

The Action Plan is the global roadmap for Act4Biosimilars, and identifies the most relevant challenges and opportunities for increasing biosimilar adoption under each of the 4As. It provides stakeholders around the world with the strategies, tools and activities needed to accelerate adoption.

Within the Action Plan there are 3 steps to help achieve the Act4Biosimilars goals

Step 1 **- Prepare:**

Laying the foundations for steps 2 and 3. Essential for building knowledge and relevant connections with key stakeholders.

Step 2 **- Act:**

Using knowledge and connections created in step 1 to recruit supporters, educate stakeholders and advocate for change.

Step 3 **- Maintain:**

Building on progress made in step 2 to maintain momentum.

Goal:

Level playing field for robust dossiers

Key initiatives:

Adoption of rigorous regulatory pathways

Description:

Assist the adoption of rigorous regulatory pathways for biosimilars in countries where these are currently lacking.

Where are we today?

Rigorous regulatory pathways are vital to ensure only quality-assured biosimilars reach patients and substandard products are kept from entering the market. However, rigorous regulatory pathways for biosimilars are not in place in every country.

Where do we want to go?

The World Health Organization's (WHO) Guidelines on Evaluation of Biosimilars is a set of internationally recognized requirements to ensure only quality-assured biosimilars become available to patients. We want to ensure that all countries adhere to this standard.

Actions:

Prepare

Identify Stakeholders

Find out organizations and individuals who are involved in the decision-making process when it comes to the development and revision of regulatory pathways. Equally important, identify stakeholders who can contribute to this process, including trade associations, physician groups, and patient groups.

Listen & Learn

Compare the local regulatory pathway to the WHO's Guidelines on Evaluation of Biosimilars. Then, contact the stakeholders you have identified to understand their perspective on where the pain points are and how to drive change.

Plan

Once you have gathered insights from various stakeholders, take the time to plan your approach. Keep in mind the need to present a clear and strong value proposition supported by proof points to policy makers and health officials.

Act

Recruit & Mobilize Supporters

Encourage other stakeholders to start reaching out to policy makers and health officials. Support these stakeholders with key messages, proof points, and reference materials. Establish a continuous feedback loop to fine tune your approach.

Educate & Raise Awareness

Share best practices from other countries, including those from highly regulated countries with an established track record of success with biosimilars.

Advocate for Change

Together with other stakeholders, reach out to relevant policy makers and health officials, holding a series of meetings to share insights and materials. Be sure to always introduce new information, including case studies and news on regulatory changes impacting biosimilars.

Maintain

Maintain Momentum

Once you see movement towards change, offer support to policy makers and health officials on reviewing and providing feedback on proposed revisions, comparing them against the WHO's Guidelines on Evaluation of Biosimilars.

Goal:

Streamline biosimilars approval

Key initiatives:

Optimize regulatory review procedures

Description:

Accelerate approval and development timelines for faster introduction of biosimilars while maintaining robust standards.

Where are we today?

Regulatory review procedures may be optimized by taking into consideration the latest scientific and technological advancements as well as a growing wealth of real-world experience with biosimilars. Already, a growing number of regulatory agencies have been taking such steps, revising existing regulations and guidelines while also adding new ones.

Where do we want to go?

Biosimilar regulatory pathways must be rigorous. At the same time, it is also important that these regulatory pathways are consistently updated based on the latest best practice, data and technology and move towards a harmonized and streamlined regulatory approach, wherever possible. Doing so can support expanded biosimilar competition and achieve faster patient access to affordable, quality-assured biosimilars.

Actions:

Prepare

Identify Stakeholders

Find out organizations and individuals who are involved in the decision-making process when it comes to the development and revision of regulatory pathways. Equally important, identify stakeholders who can contribute to this process, including trade associations, physician groups, and patient groups.

Listen & Learn

Find out what local stakeholders (e.g. physician groups, patient organizations) think about the existing regulatory pathway for biosimilars and gauge their view of the level of rigor as well as efficiency. In addition, speak with local industry associations and research sources available internationally (e.g. journal articles, news media) to find out what's happening in other countries.

Plan

Based on the gathered insights, develop your approach to target policy makers and health officials and include key messages and materials to share with them. Equally important, continue to build rapport with like-minded local stakeholders based on previous conversations.

Act

Recruit & Mobilize Supporters

Before engaging policy makers and health officials, align key messages across stakeholder groups with similar interests, and work with them to incorporate key messages into their activities.

Educate & Raise Awareness

Through a series of meetings with the target stakeholders, explain the key messages supported by evidence. Share third-party materials for reference. Keep track of stakeholder feedback and questions.

Advocate for Change

Invite like-minded stakeholders to participate in meetings with the target stakeholders, sharing with them relevant perspectives from a diverse range of stakeholder groups.

Maintain

Maintain Momentum

Once the target stakeholders have expressed interest, continue engagement and offer support in drafting and reviewing relevant legislations and/or policies, involving other stakeholders in this process.

Goal:

Create biosimilars markets

Key initiatives:

Improve peer-to-peer exchange between HCPs and patient advocates

Description:

Elevate trust in biosimilars via increased peer-to-peer exchanges among HCPs and patient advocates.

Where are we today?

Peer-to-peer engagement is critical towards improving HCP and patient confidence in biosimilars. However, peer-to-peer engagement may be limited in certain geographies. This may be due to low interest in biosimilars from HCPs and patients, lack of information due to language barriers, or lack of events and other opportunities to engage with peers.

Where do we want to go?

Active peer-to-peer exchanges should be factored into local HCP and patient engagement, so that they have sufficient information to make confident, informed treatment decisions resulting in positive treatment experiences.

Actions:

Prepare

Identify Stakeholders

Identify local key opinion leaders (KOLs), patient advocacy groups, and local registries that collect biosimilar real world evidence (RWE), as well as medical event organizers and academic publications that deal with biosimilars.

Listen & Learn

Reach out to the identified stakeholders to gather their perspectives and insights related to local awareness of biosimilar RWE. Collect and analyze local materials, such as journal articles and newsletters from patient advocacy and HCP groups, that mention biosimilars. Identify how biosimilars are characterized and on which aspects local stakeholders tend to focus most.

Plan

Based on gathered insights, work with a local industry association to identify opportunities to amplify RWE and stimulate conversation among HCPs and patients.

Act

Recruit & Mobilize Supporters

Work with a local industry association to collect international and local RWE via its member companies. Encourage local KOLs and patient advocacy groups to tap into their international network to identify topics or issues that could be shared with their local peers.

Educate & Raise Awareness

Motivate local HCP and patient advocacy groups to disseminate relevant information via events, publications and newsletters to their individual members.

Advocate for Change

Propose local industry associations and their member companies sponsor local non-promotional events dedicated to presenting and discussing biosimilar treatment experiences.

Maintain

Maintain Momentum

Stay in touch with local KOLs, HCP groups, and patient advocacy groups, sharing updated RWE and other insights on biosimilar treatment experience.

Goal:

Strong policies for transitioning to biosimilars

Key initiatives:

Moving from forced transitions to informed transitions

Description:

Change disinformation-based misperception of biosimilar transitions by raising awareness of the safety, efficacy and socio-economic benefits of switching.

Where are we today?

Patients across a growing number of countries have been transitioning from reference medicines to biosimilars. Although real-world evidence (RWE) has supported the safety and efficacy of biosimilars and the savings generated have been widely documented, patient awareness is low.

Where do we want to go?

Biosimilar transitions should be informed for all stakeholders involved. HCPs and patients should be comfortable with biosimilar transitions, based on confidence in the treatment quality of biosimilars and the socio-economic relevance of increasing biosimilar adoption.

Actions:

Prepare

Identify Stakeholders

Identify stakeholders who are impacted by biosimilar transitions (e.g. physicians, payers, patients).

Listen & Learn

Engage the identified stakeholders to understand different stakeholder perspectives of biosimilar transitions.

Plan

Based on gathered insights, identify knowledge gaps within each group of target stakeholders, namely HCPs and patient organizations, and develop an outreach plan to address these gaps.

Act

Recruit & Mobilize Supporters

Collaborate with industry associations and their member companies to develop key messages and educational content that would resonate with local target stakeholders.

Educate & Raise Awareness

Raise awareness among the target stakeholders on the safety and efficacy of transitioning by leveraging RWE, while raising awareness of the socio-economic benefits of biosimilars by referencing international and local case studies.

Advocate for Change

Encourage HCPs and payers to prioritize patient education on biosimilars prior to transitioning or starting on biosimilars.

Maintain

Maintain Momentum

Stay in touch with target stakeholders to regularly gather feedback on educational content, and work with trade associations to update educational content.

Goal:

Clear medical guidelines

Key initiatives:

Promote effective medical guidelines

Description:

Educate relevant stakeholders on how to prescribe and access biosimilars in the local market.

Where are we today?

For patients who need more affordable treatment options, there should be greater transparency about accessing biosimilars. However, due to potential complexities around local health systems and lack of transparency around how they plan to roll out biosimilars, patients can have difficulty finding more affordable treatment.

Where do we want to go?

Patients should be given sufficient information to navigate the health system to access lower cost medicines. Patients should know when and how to ask physicians to prescribe lower cost biosimilars, while physicians should be able to make informed prescribing decisions supported by guidance from HCP groups.

Actions:

Prepare

Identify Stakeholders

Identify decision-making stakeholders when it comes to determining treatment choice for patients.

Listen & Learn

Speak with local patient organizations to get an understanding of the patient journey to access biosimilars. Get in touch with HCPs and infusion centers to identify the prescribing and administration process for biosimilars.

Plan

See how widely available biosimilars are by checking government and hospital procurement information as well as formularies of private insurance companies. Familiarize yourself with local government policies and regulations and HCP group guidelines relevant to biosimilars, such as those on substitution and transitioning.

Act

Recruit & Mobilize Supporters

Partner with a local trade association to develop an educational leaflet on guiding patients and HCPs to identify the most affordable path to biosimilar access. Work with patient organizations to identify specific patient needs when accessing biosimilars.

Educate & Raise Awareness

Inform patient organizations about the lower cost of biosimilars, how they can benefit the health system, and who benefits from these savings.

Advocate for Change

Encourage patient organizations to distribute non-promotional leaflets to their individual members. Encourage the trade association to distribute the leaflets to HCP groups via its member companies.

Maintain

Maintain Momentum

Work with trade associations to identify when to update leaflets based on timing of new regulations and policies related to the procurement and prescription of biosimilars.

Goal:

Respond to loss of market exclusivity

Key initiatives:

Improve awareness of biosimilar availability

Description:

Ensure local decision-making stakeholders are aware of availability dates for new biosimilars with upcoming patent expiry.

Where are we today?

Biosimilars continue to be introduced across new therapeutic areas and for new indications, widening treatment choice for HCPs, offering lower price treatment options for healthcare systems, and broadening access for patients. However, stakeholders are often unaware of upcoming biosimilar availability and loss of exclusivity dates, creating challenges to health systems and HCPs with regards to planning and resource allocations.

Where do we want to go?

Availability of individual biosimilar products should be communicated to the relevant stakeholders in a timely manner*. Payers (e.g. tender authorities, hospitals, insurers) should be given sufficient time to include upcoming biosimilars into their budgetary and procurement planning, while HCPs, particularly in disease areas new to biosimilars, should be given biosimilar education in advance of initial biosimilar availability.

* To ensure compliance with local regulations, a local legal assessment should be carried out prior to launching any initiative, or alternatively activities should commence once the medicine has received marketing authorization.

Actions:

Prepare

Identify Stakeholders

Work with a local industry association to identify stakeholders (such as HCPs, payers and patients) who may be most interested in biosimilar availability.

Listen & Learn

Work with an industry association and its member companies to collect publicly available information on the status of relevant biosimilar development programs, including companies involved, development timelines, and clinical trial status and results.

Plan

Work with local industry associations and their member companies to determine upcoming availability dates for patent expiry for molecules with ongoing biosimilar, as well as agree on when and how to communicate this information.

Act

Recruit & Mobilize Supporters

Using the gathered information, develop materials that cover patent expiry and the development status of relevant biosimilar candidates, including timelines.

Educate & Raise Awareness

Work with an industry association to distribute the materials to the target stakeholders.

Advocate for Change

Focus on increasing transparency around exclusivity.

Maintain

Maintain Momentum

Stay in touch with local industry association to identify new and updated information. Update materials to ensure accuracy and relevance.

Goal:

Fair and accurate information - fighting disinformation

Key initiatives:

Drive publication of authoritative local educational content

Description:

Convince and support locally trusted organizations (e.g. health bodies, patient advocacy groups) to develop, endorse, and support the dissemination of biosimilar educational content

Where are we today?

In some countries, locally trusted organizations (e.g. health bodies, patient advocacy groups) have developed their own educational content on biosimilars, ensuring there is a single, trusted source of information on the topic. However, this is not widespread and with multiple stakeholders involved, it is not always clear who has the responsibility for such educational efforts. In turn, inaccurate or questionable biosimilar content can be widespread.

Where do we want to go?

In every country, HCPs, patients, and payers considering biosimilars should have unbiased, accurate, and scientifically sound information on biosimilars, so that stakeholders can make informed decisions.

Actions:

Prepare

Identify Stakeholders

Identify trusted organizations that publish biosimilar educational content, such as industry associations, patient organizations, and physician groups.

Listen & Learn

Reach out to those organizations to gather their insights on how they develop and distribute biosimilar educational content. If possible, find out what type of feedback they have received on such content.

Plan

Form a coalition of like-minded stakeholders who are willing to play an active role in developing and/or reviewing educational content. Collaborate to identify a target organization with a high level of trust among local healthcare stakeholders that could publish biosimilar educational content.

Act

Recruit & Mobilize Supporters

Organize meetings and roundtables between your coalition and the target organization in order to reach consensus on the need for biosimilar educational materials developed by the government organizations and endorsed by local HCP groups.

Educate & Raise Awareness

Highlight adverse impacts of disinformation and the value of trustworthy educational content to prevent disruptions to biosimilar adoption.

Advocate for Change

Reach out to the target organization, sharing case studies on biosimilar education initiatives in other countries and their positive impact throughout the biosimilar adoption process.

Maintain

Maintain Momentum

Once the target organization decides to pursue biosimilar educational materials, offer support by developing and reviewing content. Add value by leveraging your coalition's expansive knowledge and perspectives. Encourage the coalition organization to distribute educational materials to their individual members and encourage them to promote the educational materials through their events and meetings.

Goal:

Share experience of biosimilars use across countries

Key initiatives:

International exchange on biosimilar real-world evidence

Description:

Activate local sharing of biosimilar treatment experience from other countries.

Where are we today?

Biosimilar use continues to grow worldwide, and the availability of biosimilar RWE has increased in parallel. However, awareness and use of biosimilar RWE remains varied, and not always factored into stakeholders' opinions on biosimilars and their treatment decisions.

Where do we want to go?

In countries where biosimilars are available, local stakeholders should have sufficient evidence when forming their opinions on biosimilars. Local stakeholders should have basic knowledge of biosimilar RWE, and RWE should be regularly shared and updated among local stakeholders.

Actions:

Prepare

Identify Stakeholders

Identify local patient groups and HCP groups, representing physicians, nurses, and pharmacists.

Listen & Learn

Collect and analyze local materials such as journal articles and newsletters from HCP groups that mention biosimilar treatment experience from other countries, particularly those based on RWE.

Plan

Work with a local industry association to collect international RWE via its member companies. Establish an outreach plan to target local patient and HCP groups. Also, ensure RWE not only covers efficacy and safety, but also quality of life, patient access, and population health outcomes.

Act

Recruit & Mobilize Supporters

Work with local patient and HCP groups to disseminate information on international biosimilar treatment experience and RWE via events, publications, and notifications to their individual members.

Educate & Raise Awareness

Encourage local industry associations and their member companies to organize or sponsor local events dedicated to presenting and discussing international biosimilar patient treatment experience and RWE.

Advocate for Change

Encourage local KOLs to refer to international biosimilar RWE when addressing issues related to patient treatment and to leverage their international KOL network to identify relevant RWE studies.

Maintain

Maintain Momentum

Stay in regular contact with local patient and HCP groups and KOLs, sharing updated international RWE and other insights into biosimilar treatment experience.

Goal:

Involve patients in treatment decisions

Key initiatives:

"Switch On" patient education

Description:

Encourage patient education by HCPs (e.g., physicians, nurses, pharmacists) when starting patients on biosimilars, including both new and transitioning patients.

Where are we today?

When patients hear from their HCPs about starting on or transitioning to a biosimilar, they may be unfamiliar with biosimilars. HCPs are well positioned to address patient concerns. However, there may be discrepancies in the prevalence and quality of patient education on biosimilars.

Where do we want to go?

Patients should feel comfortable using biosimilars without confusion, and we can make things better by encouraging HCPs to take the time and resources to provide biosimilar education to patients.

Actions:

Prepare

Identify Stakeholders

Speak with HCP groups and health officials to identify any existing policies or regulations on patient education. Identify the relevant government organizations as well as policy makers and public health officials who oversee such legislations or policies.

Listen & Learn

Liaise with patient organizations, asking them to share individual patient experience when transitioning to biosimilars, focusing on the timing, quality, and provider of biosimilar education. Ask them to share any biosimilar educational content to which individual patients have been exposed.

Plan

Identify local patient organizations and representatives who advocate for HCPs, including pharmacists, to pay greater attention to monitor patient experience with biosimilar education and collaborate in developing an engagement plan.

Act

Recruit & Mobilize Supporters

Together with patient organizations, hold introductory meetings with HCP groups and relevant policy makers and health officials. Share patient concerns around transitioning without sufficient educational support and propose solutions. Highlight relevant case studies from other countries.

Educate & Raise Awareness

Encourage patient organizations to raise awareness among various healthcare stakeholders, including HCPs and health officials. Encourage peer-to-peer patient education, as many patients value and seek out the opinion and perspectives of other patients.

Advocate for Change

Play a mediating role between government stakeholders and HCPs, with the aim of facilitating the creation of a practical solution.

Maintain

Maintain Momentum

Once policy makers have decided to take action to encourage HCPs to educate patients on biosimilars, support the policy makers in generating consensus among other decision-makers and influencers within government. Following the introduction of the relevant legislation or policy, encourage patient organizations to conduct regular patient surveys to track impact and propose refinements.

Goal:

Open dialogue between producers, tenderers & insurers

Key initiatives:

‘Biosimilars for the Greater Good’

Description:

Identify and raise awareness of health system benefits resulting from biosimilar savings.

Where are we today?

Biosimilars have brought value to stakeholders globally. Through lower prices, patients have benefited from greater affordability of treatment and expanded access. Health systems have used biosimilar savings towards the improvement of health infrastructure and procurement of advanced medicines. However, awareness of such benefits and their impact on patient outcomes remains low, thereby limiting stakeholder appreciation of the greater impact of biosimilar adoption.

Where do we want to go?

Support the long-term sustainability of biosimilars through greater understanding and appreciation for the value proposition of biosimilars.

Actions:

Prepare

Identify Stakeholders

Identify the local stakeholders who may have benefitted from biosimilars, such as HCPs, payers, and health officials.

Listen & Learn

Work with a variety of local stakeholders who were previously identified to collect evidence of biosimilar savings being used for health system investments. Such examples can include upgrading hospital infrastructure and procuring advanced medicines.

Plan

Based on gathered information, develop materials that focus on the scale of biosimilar savings, their specific benefits to health systems, and how they have benefited patients by increasing the number of patients treated.

Act

Recruit & Mobilize Supporters

Form a coalition with organizations that are involved in supporting biosimilar adoption. This can include public and private payers and trade associations.

Educate & Raise Awareness

Through seminars and meetings, educate other stakeholders, including government, HCPs, and patients, on the biosimilar value proposition.

Advocate for Change

Encourage the coalition to propagate the materials by incorporating them into their respective activities, including media outreach, social media, and speaking opportunities.

Maintain

Maintain Momentum

Stay in touch with coalition members to gather additional evidence and update materials, while encouraging their regular use.

Goal:

Ensure equitable pricing

Key initiatives:

Introduce and widen adoption of sustainable biosimilar pricing policies

Description:

Instead of solely focusing on lowering price, offer support to create a sustainable pricing policy, in order to ensure rapid introduction and long-term availability of biosimilars from multiple manufacturers.

Where are we today?

The development of a single biosimilar product requires on average between USD 150 million and USD 300 million over five years.[1] Unlike generics, the high investment in development costs of biosimilars pertain to purchasing sufficient quantities of the reference medicine and conducting clinical development. Furthermore, compared to generics, the development risks are far higher, due to the complexities associated with developing biologic medicines.

Where do we want to go?

Tender authorities should take into consideration criteria beyond price and recognize value added and should award tenders to multiple winners. By doing so, they increase competition across a set of criteria, including those associated with Environmental, Social and Governance (ESG) and patient support programs.

Actions:

Prepare

Identify Stakeholders

Identify the stakeholders who define the procedures, requirements, and bid assessments for these tenders. Stakeholders may include policy makers and public health officials, as well as procurement officials within government and at hospitals.

Listen & Learn

Work with local industry associations to identify individual tenders throughout the country, particularly the tender authorities and their tender criteria.

Plan

Collaborate with industry association to develop key messages and content that outlines the benefits of sustainable pricing and multi-criteria tenders on long-term patient access to affordable biologics.

Act

Recruit & Mobilize Supporters

Work with industry associations to recruit member companies to participate and support this initiative.

Educate & Raise Awareness

Educate government stakeholders and hospitals on the growing number of multi-criteria tenders and how they have positively impacted the relevant health systems. In addition, present case studies to illustrate the range of tender criteria that are being used and suggest benchmarks.

Advocate for Change

In conjunction with local trade associations, engage government stakeholders and payers to present proposed changes to tender criteria. If necessary, organize seminars and roundtables between trade associations and relevant stakeholders to share insights and reach a consensus on the path forward.

Maintain

Maintain Momentum

Once tender authorities begin switching over to multi-criteria tenders, keep track of those making the transition, while continuing efforts to win over those that have not. Stay in touch with local trade associations, and regularly gather updated tender information from other countries.

[1] McKinsey (2021). An Inflection point for biosimilars. Available from: https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars [Accessed May 2023]

Goal:

Fair competition & swift market access

Key initiatives:

Increase local market competition

Description:

Optimize procurement processes and explore alternative tender frameworks that allow increased competition.

Where are we today?

The development of a single biosimilar product requires on average between USD 150 million and USD 300 million.[1] Unlike generics, the high development costs are associated to purchasing sufficient quantities of the reference medicine and conducting clinical development. Furthermore, compared to generics, the development risks are far higher, due to the complexities associated with developing large molecule biologics.

Where do we want to go?

Tender authorities should take into consideration criteria beyond price and consider other factors that can impact access to medicines and quality of patient care.

Actions:

Prepare

Identify Stakeholders

Identify the stakeholders who define the procedures, requirements, and bid assessments for these tenders. Stakeholders may include policy makers and public health officials, as well as procurement officials within government and at hospitals.

Listen & Learn

Work with local industry associations to identify individual tenders throughout the country, particularly the tender authorities and their tender criteria.

Plan

Collaborate with industry associations to develop key messages and content that outlines the benefits of sustainable pricing and multi-criteria tenders on long-term patient access to affordable biologics.

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Recruit & Mobilize Supporters

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Educate & Raise Awareness

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Advocate for Change

In conjunction with local trade associations, engage government stakeholders and payers to present proposed changes to tender criteria. If necessary, organize seminars and roundtables between trade associations and relevant stakeholders to share insights and reach a consensus on the path forward.

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