



INTERNATIONAL GENERIC AND  
BIOSIMILAR MEDICINES ASSOCIATION

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Committee  
Welcoming Remarks at IGBA 25<sup>th</sup> Annual Conference - Plenary (Orlando)  
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- It's my honor to address you all here today as the inaugural chairman of the IGBA CEO Advisory Committee – **a body that could hardly have been founded at a more appropriate time.**
- As Jonathan Kimball said, it's hard to overstate just how much IGBA has changed in recent years, and how far IGBA has come as an organization. But we still have a long way to go, and **we will need to work together to get there.**
- From the Covid pandemic to the war in Ukraine, the last few years have thrown the world more historical curve-balls than many people experience in a lifetime.
- Which raises the obvious question: **what have we learned from all this?**
- From my perspective, deeply anchored in global healthcare, there have been **two main learnings.**
- The first is that the public and policymakers have become truly aware, for the first time in decades, of the **critical systemic relevance of off-patent medicines**, which provide the vast majority of the world's medicines at a fraction of the cost.
- This is a huge silver lining and, to mix my metaphors atrociously, we need to grab it with both hands.
- However, old habits die hard, and there are still substantial challenges facing this critical industry, as governments and healthcare systems worldwide continue to focus on **prioritizing cost savings, even at the ultimate expense of security of supply.**
- Which brings me to the second learning: **the need for clear, cross-sectorial coordination of global healthcare policy, including a clear "seat at the table" for the off-patent industry.**
- This is true at many levels. **First, the national level does matter, because many policies – like politics in general – are still local.**



- I don't have to tell anyone in this room about the need for hard and concerted work to prevent significant unintended consequences resulting from some provisions of the otherwise well-intentioned **Inflation Reduction Act**.
- And there are plenty more examples at national level, ranging from the need to avoid damaging US market economics (the proposed BLOCKING Act) through to the ongoing battle to prevent punitive additional taxes on biosimilars in the UK (the so-called VPAS legislation).
- **My thanks go to our national and regional associations**, and the invaluable work they are already doing to address these key issues.
- But what's common to all these challenges is that **we as an industry need to get beyond just explaining our viewpoints to becoming valued advisors** to policymakers.
- This is about working together to develop win-win solutions for all concerned.
- But the biggest challenges, and the biggest opportunities, lie **not on the national, but on the international stage**.
- Today's complex global healthcare challenges, from driving equitable access across geographies to ensuring the continued efficacy of antibiotics, **simply cannot be solved by individual players, or even nations**.
- That's why our industry needs to work with governments, international agencies and policymakers to create a **framework for truly global healthcare policies**.
- So **which policies should we be focusing on?**
- As science-based companies, I believe **we should always start with the science**.
- For instance, there is enormous potential to lower development costs, particularly for more complex biosimilar medicines, and speed time to market by **breaking through the web of national regulatory requirements and introducing universal scientific standards** such as a global comparator product...
- ... not to mention a tailored approach to clinical development of biosimilars that truly reflects the underlying science.
- As I always like to point out, there is no real difference between the **comparability principle** underlying approval of changes in the originator biologic manufacturing processes and the **biosimilarity principles** underlying the initial approval of biosimilars.
- Moving beyond the regulatory field, we all need to pull together and collectively think bigger and bolder about how best to **anticipate and plan for future pandemics, to mitigate the**



**global spread of antimicrobial resistance, or to jointly address the threat of older diseases** we thought we had under control but are now returning with a vengeance – e.g., cholera and TB.

- Last but not least, we have to play our part to **ensure the medicines we produce every day actually reach the people who need them.**
- There are many complex factors underlying the current supply shortages of critical medicines in many countries, particularly life-saving antibiotics. Our first task as industry is to do what we can by **making necessary investments to ramp up production where possible.**
- At the same time, I fully recognize that many players, particularly smaller companies, are simply not in a position to do so economically, given current market economic frameworks where critical medicines are treated like commodities, but without the ability to pull the price lever when external costs shoot up.
- That's why we have to **make our voice heard now** and provide advice on how to ensure our health systems stay viable and sustainable for the public sector, patients and companies, both at national and at international level.
- To come back to my starting point, I'm pleased to see that – as with the early Covid supply crunch – the **current shortages are spurring signs of government action**, at least in some key European markets.
- And it's also **heartening to see growing media understanding** of the underlying issues, including a strong and comprehensive summary run by Reuters just last week. Indeed, the latter may be doing more than a little to drive the former.
- This is one area where I am **hopeful that our recently-initiated closer interaction with the WHO could create opportunities for greater joint initiatives** on the global stage. It's early days, and we will need to discuss this in more detail before saying more, but I'm greatly looking forward to our ongoing collaboration through 2023 and beyond.
- To conclude and leave the stage to our wonderful array of speakers and panelists, I would just stress that, whatever our differences, there are **two underlying concepts** everyone both in and beyond our industry should be able to unite around.
- The first is that, in economic terms, **healthcare is the ultimate global good.**
- The second, which follows directly from the first, is that **ensuring healthcare for all is an investment, not a cost.**
- Thank you and have a great conference!