

Regulated Product Submission (RPS)







About us

- The MC approved a work item extension in 2021 to update the Table of Contents and develop a dynamic template
- Working group members: Australia, Botswana, Brazil, Canada, China, Dominican Republic, Egypt, European Union, EU Notified Bodies, Japan, Nigeria, Saudi Arabia, Singapore, South Korea, Tanzania, UK, USA, WHO





Ongoing work

- After the updates to N9 and N13 were completed in 2024, the working group is developing a dynamic template that leverages the updated Table of Contents requirements of N9 and N13
- Members discussed barriers integrating dynamic template data into their systems and potential solutions such as conversion tools
- Discussions on governance and maintenance are still ongoing to address challenges such as update cycles