



SMF MTIG Regulatory Services

Workstreams

Workstream	Lead	Co-Lead
Regulatory sub-committee	James Chan, Baxter	Lu Ai Ing, Roche Diagnostics
Inter Government Agency engagements	Jonathon Loo, Medtronic	Boon Theng, 3M
Software - HSA system enhancement	Charles Lim, Philips	Stanley, Carestream
Cell Therapy (CTT)	Ching Hwee Lee/Yew Meng, JnJ	Yi Sin, Zimmer
European Union Medical Devices Regulation (EU MDR)/(GN-21) & In-Vitro Diagnostics Regulation (IVDR)	Lu Ai Ing, Roche Diagnostics	Jacqueline Monteiro, Abbott (IVD) Ching Hwee, JnJ (Medical Device)
Post market	Wang Kaiye, Baxter	Shing Koon, Boston

Agenda

- European Union's Medical Device Regulations/In Vitro Diagnostic Regulation (EU MDR/IVDR)
- Singapore's Mandatory Packaging Reporting (MPR)

EU MDR/IVDR - Status

- The local association (SMF MTIG) has shared a position paper with Singapore HSA back in Mar 2020 to facilitate EU MDR/IVDR product changes.
- There has been follow-up discussions with HSA on our recommendations.
- Work is still in progress.

EU MDR/IVDR - Challenges & Recommendations

Challenges

- Foresee a ‘tsunami’ of applications from EU MDR/IVDR
- If the regulatory framework remains unchanged, it will overwhelm both the regulator/industry.

Recommendations

- For local health authority to partner with their local industry to review their regulatory framework to facilitate product changes from EU MDR/IVDR
 - Exemption for simple changes (e.g. symbols)
 - Bundling for similar changes across different products/licenses

Singapore's Mandatory Packaging Reporting – Why?

- To bring greater awareness to companies on the potential benefits for packaging reduction within their business operations
- To spur companies to take action to reduce the amount of packaging used and packaging waste disposed of, and offer flexibility for companies to implement measures
- To prepare companies for the Extended Producer Responsibility (EPR) framework for packaging waste management, which will be implemented no later than 2025
- Packaging data collected could aid in future review and development of policies and programmes on packaging waste management

Singapore's Mandatory Packaging Reporting – Who?

Companies that meet all the following criteria are required to comply with the **mandatory packaging reporting requirements** under the RSA:

- Carries on a business of supplying regulated goods in Singapore
- Meet the prescribed threshold criteria (annual turnover >S\$10m)
- Imports specified packaging as per S19(2)(a) or uses specified packaging as per S19(2)(b) of the RSA

Singapore's MPR – What?

Companies that meet the prescribed threshold criteria will be required to:

- Submit annual reports on specified packaging imported/used and 3R plan for packaging in Singapore based on prescribed requirements
- Keep records related to reports and plans based on prescribed requirements and retention period

Singapore's MPR – How?

Details of Packaging Reports and 3R Plans

Report template: (MS excel file format)

Company Name:	ABC Company			
Reporting Period*:	01-01-2021 to 31-12-2021			
Annual Turnover:	S\$10.1 million			
Packaging Material	Packaging Form	Further Details (Optional)	Weight (kg)	Remarks** (Optional)
Plastic	Beverage bottles	PET	200	
Plastic	Product packaging (rigid, excluding beverage bottle)	HDPE	400	
Plastic	Product packaging (flexible)	LDPE	200	
Composite	Others		200	Plastic-aluminium sachets
Plastic	Carrier bags	LDPE	100	
Paper	Carrier bags	Paper	200	

*Refers to the year which the packaging reported is placed on the market

**Please provide additional details if you have selected "Others" in the columns on the left (i.e. Packaging Material, "Packaging Form", "Further Details").

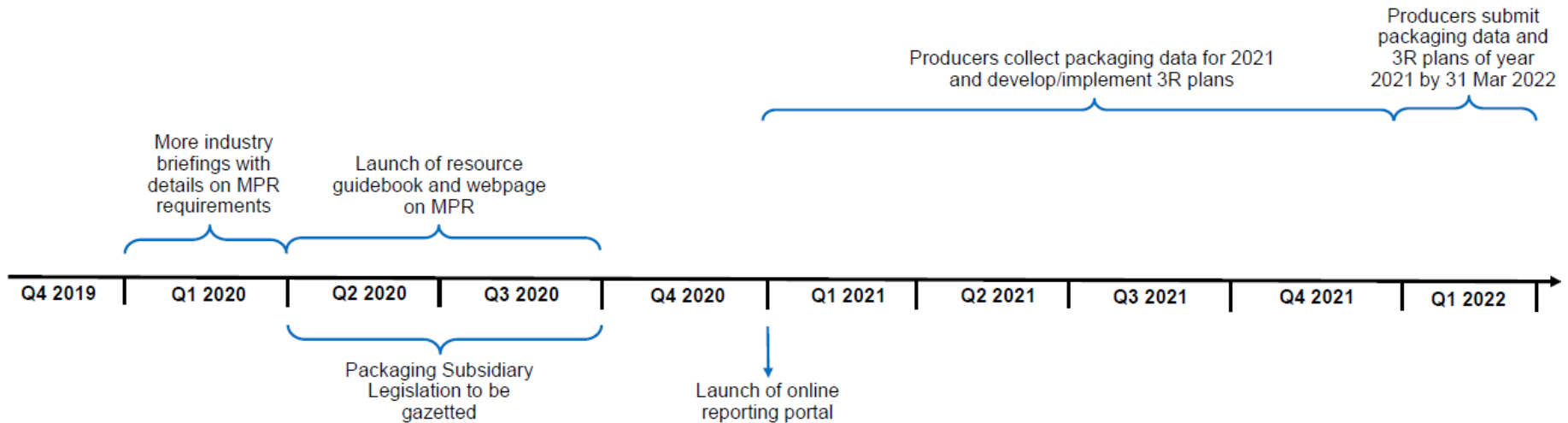
Rows can be added where necessary

3R Plans: (online web form with the following fields)

1. Types of plans:
 - Packaging reduction
 - Packaging collection for recycling
 - Packaging collection for reuse
 - Consumer outreach related to packaging 3Rs
 - Industry outreach related to packaging 3Rs
 - Use of recycled content in packaging material
 - Improving recyclability of packaging
2. Self-set targets
3. Action plans
 - Specific measures to achieve self-set targets
 - Details (e.g. specifications and photos of specific packaging)
4. Progress Update
 - Progress made against plans and targets set in previous reports
 - Explanation by Producer why targets were not met or change of targets and action plans
 - Target completion date within 3 years

Singapore's MPR – When?

8. Implementation Timeline



Update:

- In view of the current COVID-19 situation, commencement of packaging data collection for the Mandatory Packaging Reporting has been revised to 1 January 2021 instead of 1 July 2020 with the first reports to be submitted by 31 March 2022 and shall include packaging data collected from 1 January to 31 December 2021 together with the 3R plan(s).

Thank you