Regulatory Data Protection (RDP)

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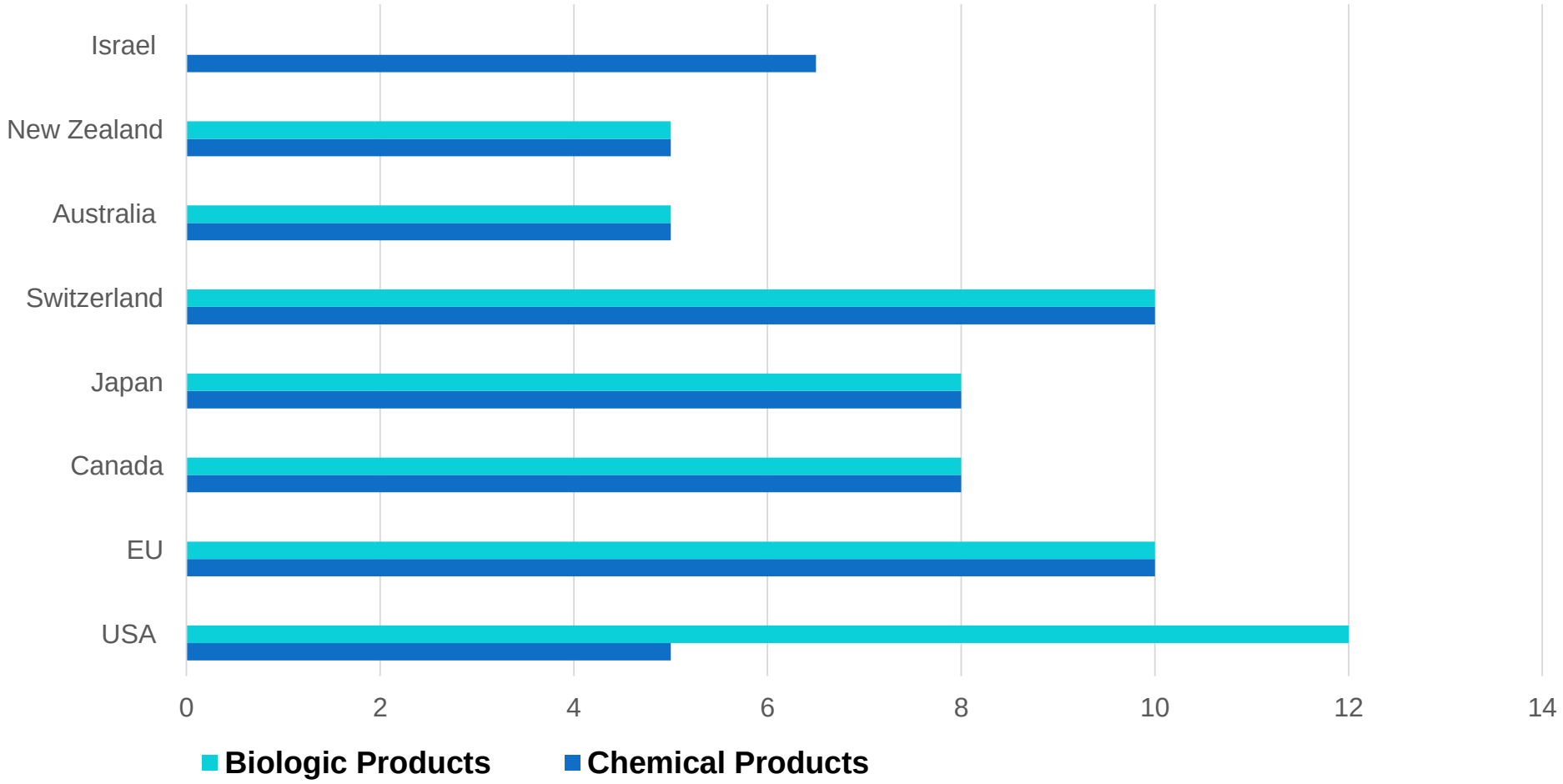
Regulatory Data Protection for Chemical & Biologic Drugs

Years of Regulatory Data Protection (RDP)



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Regulatory Data Protection for Biologic Drugs

Robust protection of IP is an essential part of a regulatory environment which encourages innovation

- Encouraging clinical trials
- Early access to pharmaceuticals
- Increasing foreign direct investments (FDI)

Israel must adopt IP protection which is in-line with international standards

- Data Exclusivity grants stronger protection than marketing exclusivity
- Most countries grant strong protection, including some form of data exclusivity
- Israel must adopt strong RDP in-line with the highest international standard

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Regulatory Data Protection for Biologics - International Survey

	Data exclusivity	Marketing exclusivity	Total	
 USA	4	8	**12**	YEARS
 EU	8	2	**10**	YEARS
 SWITZERLAND	10	-	**10**	YEARS
 CANADA	6	2	**8***	YEARS

*According to the new trade agreement recently signed between Canada and USA, the regulatory exclusivity period to be granted to original biological drugs will be at least 10 years from the date of marketing approval granted to that drug in the member country.

 JAPAN	8	-	**8**	YEARS
 AUSTRALIA	5	-	**5**	YEARS
 NEW ZEALAND	5	-	**5**	YEARS

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Regulatory Data Protection for Biologics - International Perspective

European Commission report, March 2018

"The Commission also identified a separate category of countries, where IP enforcement gives rise to concern and where developments need to be closely monitored. ***This category of countries includes Israel, Kuwait, Paraguay, South Africa, United Arab Emirates and Uruguay.***"

National Trade Estimate, March 2019

"The United States remains concerned with ***certain deficiencies that remain with respect to Israel's protection of IPRs. … Israel lacks adequate protection against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for biologic pharmaceuticals..***"

Source: United States, USTR, National Trade Estimate, March 2018; European Commission, "Report on the protection and enforcement of intellectual property rights in third countries", March 2018

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