Expanding EPR Laws Targeting Unused Medicines and Used Medical Devices

Pharmaceutical EHS Counsel Roundtable

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BEVERIDGE & DIAMOND PC

Topics

Global EPR tracking project

EPR for pharmaceuticals

- Brazil status update

EPR for medical devices

- Ghana's new law
- Chile multi-product EPR

Basel Convention initiatives on pharmaceutical wastes

SAICM work on EPPPs

EPR Regulatory Tracking Project

Objective

- Track development of proposed and enacted EPR legislation affecting pharmaceutical companies

Scope

- Medicines, sharps, combination products (i.e., medical devices, including batteries), and packaging
- EPR legislation targeting brand owners, importers and manufacturers
- 2016 focus on major jurisdictions of Latin America and Asia
- 2017 added Eastern Europe and Africa

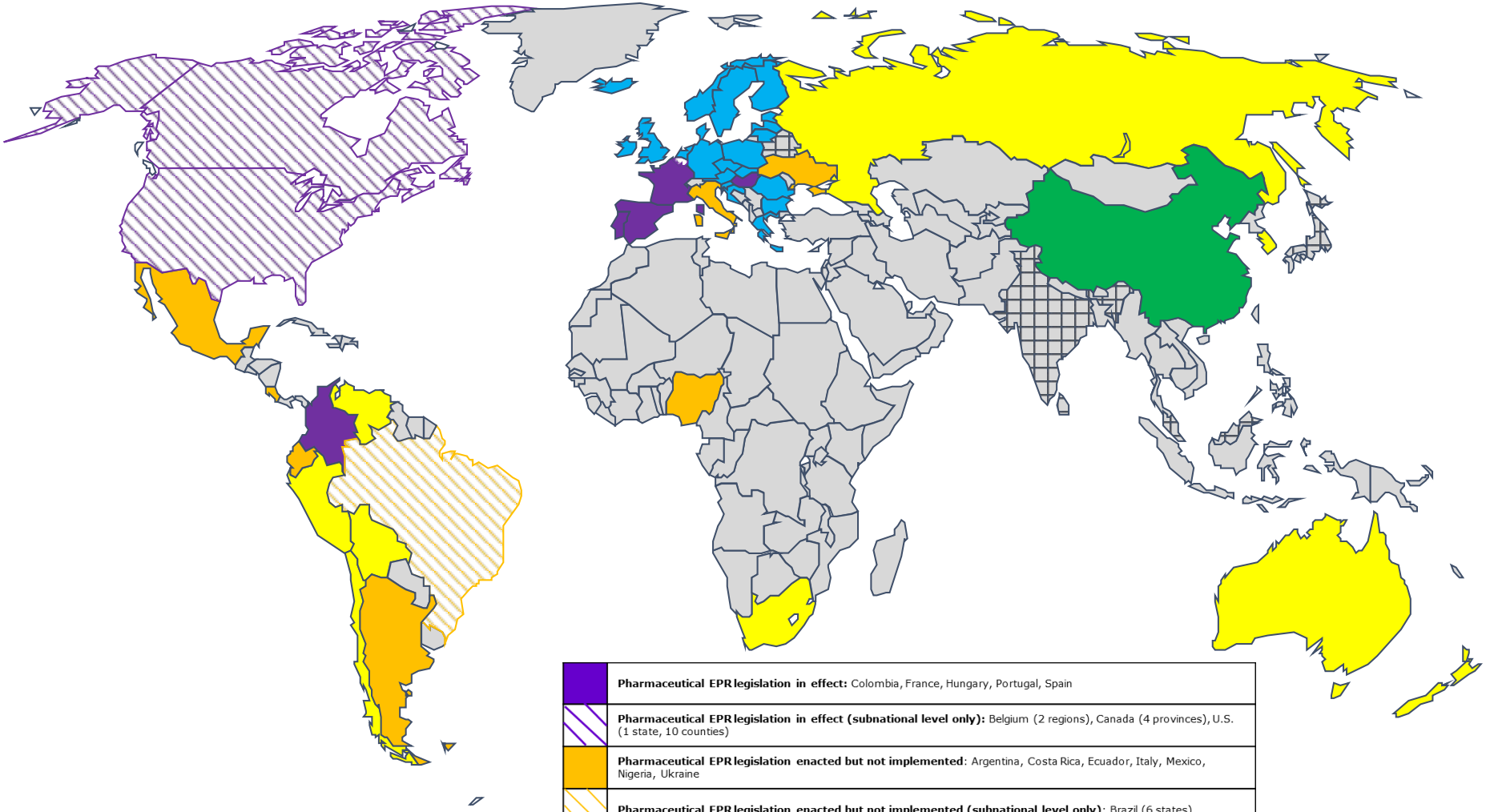
Format

- Global EPR summary reports in matrix form (updates: March, August, November)
- Global EPR maps
- Alerts on major developments
- Teleconference after each report

Participation

- 2016: 6 companies
- 2017: 9 companies
- 2018: ???

Pharmaceutical EPR Legislation



	Pharmaceutical EPR legislation in effect: Colombia, France, Hungary, Portugal, Spain
	Pharmaceutical EPR legislation in effect (subnational level only): Belgium (2 regions), Canada (4 provinces), U.S. (1 state, 10 counties)
	Pharmaceutical EPR legislation enacted but not implemented: Argentina, Costa Rica, Ecuador, Italy, Mexico, Nigeria, Ukraine
	Pharmaceutical EPR legislation enacted but not implemented (subnational level only): Brazil (6 states)
	EU-level legislation requiring pharmaceutical collection, but not necessarily EPR: All EEA countries that lack specific pharmaceutical EPR legislation
	Multi-product EPR legislation with potential to cover pharmaceuticals: Australia, Bolivia, Chile, New Zealand, Peru, Russia, South Africa, South Korea, Venezuela
	Proposed EPR legislation with potential to cover pharmaceuticals: China
	Researched, but no pharmaceutical EPR legislation identified: Belarus, India, Israel, Japan, Malaysia, Singapore

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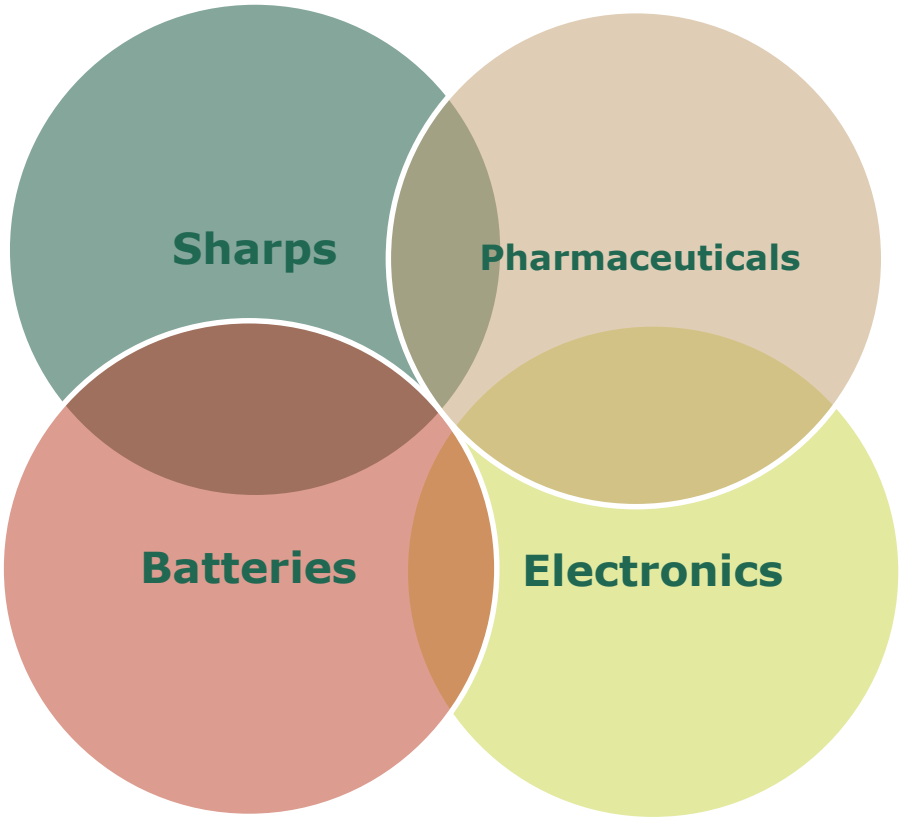
Brazil Pharmaceutical EPR

- **Federal**
  - Ministry attempted to require industry take-back agreement in 2013.
  - Industry factions disagree over cost allocation; dispute federal authority.
  - 13 bills to clarify federal authority now pending in Congress (recent movement at committee level).
- **São Paulo**
  - Included pharmaceuticals in 2015 take-back regulation.
  - Implementing rules were due in 2016 (absence unexplained).
- **Paraná**
  - Take-back obligations in effect since 2013.
  - Industry-run program has launched.
- **Other legislation**
  - 10 more states and 100+ municipalities are active.
- **Voluntary programs**
  - Several operating across much of the country.
  - In 2015, one program expanded to cover sharps.

Medical Device EPR

- Complicated issues of definition and scope
- No EPR legislation dedicated to medical devices *per se*
- 4 types of EPR measures can cover some medical devices:
  - Sharps
  - E-waste
  - Batteries
  - Pharmaceuticals



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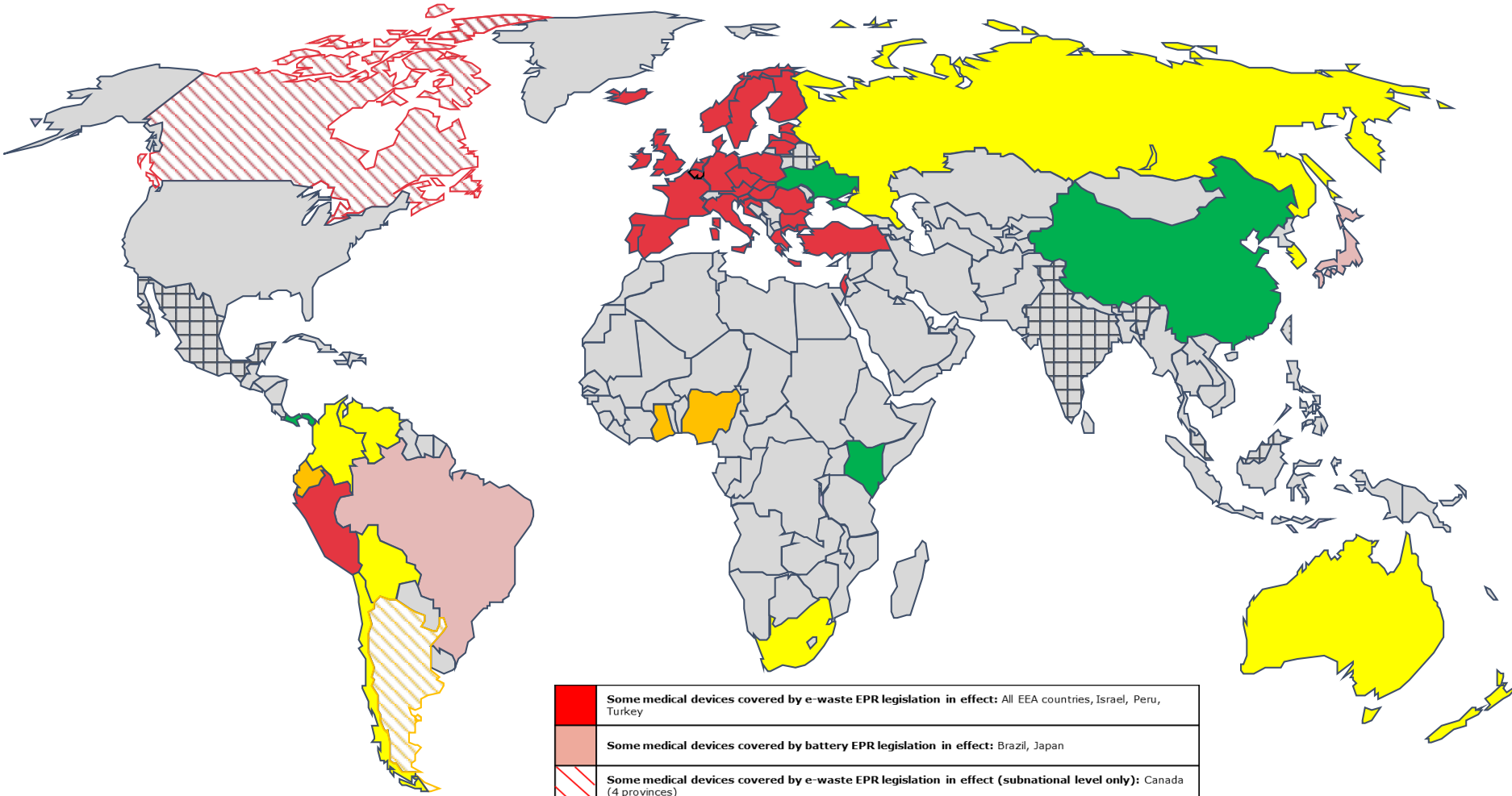
Medical Device EPR Legislation



	Some medical devices covered by e-waste EPR legislation in effect: All EEA countries, Israel, Peru, Turkey
	Some medical devices covered by battery EPR legislation in effect: Brazil, Japan
	Some medical devices covered by e-waste EPR legislation in effect (subnational level only): Canada (4 provinces)
	Some medical devices covered by e-waste EPR legislation, enacted but not implemented: Ecuador, Ghana, Nigeria
	Some medical devices covered by e-waste EPR legislation, enacted but not implemented (subnational level only): Argentina (Buenos Aires province)
	Multi-product EPR legislation with potential to cover medical devices: Australia, Bolivia, Chile, Colombia, New Zealand, Russia, South Africa, South Korea, Venezuela
	Proposed EPR legislation with potential to cover medical devices: China, Kenya, Panama, Ukraine
	Researched, but no medical device EPR legislation identified: Belarus, Costa Rica, India, Malaysia, Mexico, Singapore

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Ghana Medical Device / Sharps EPR

- Hazardous and Electronic Waste Control and Management Act 2016
  - Product scope defined by HS codes
    - Includes various medical devices: e.g., therapeutic respiration apparatus, pacemakers, other **devices worn, carried or implanted in the body, syringes, needles, catheters, and cannulas**
  - Producer obligations:
    - Importers, manufacturers, distributors and retailers must take back and manage their end-of-life products
    - Importers and manufacturers must also pay a **per-product fee to obtain a permit to import or sell** listed products
    - Distributors and retailers must register with the Ministry and **retain a copy of the receipt of the fee for each product**
  - Awaiting implementing regulations and designation of an "External Service Provider" to collect fees

Chile Multi-Product EPR Law

- Law 20920/2016
  - EPR and recycling framework law
  - Covers "priority products," including: electrical devices, batteries, consumer product packaging
  - Many implementing regulations under development
- Resolution 483/2017
  - Required **all importers to register and report on prior-year sales and take-back** of covered products by July 31, 2017 (batteries) or September 30, 2017 (devices and packaging)
  - Compliance rate: high for battery importers; low for other categories (e.g., estimated 0.5% of importers of packaged products)

Basel Convention EPR Manual

- Prepared by Expert Working Group on Environmentally Sound Management
- Intended as a guide & stimulus for EPR legislation
  - Likely to influence government policies worldwide
  - List of products subject to EPR includes pharmaceuticals
- Revised draft presented at COP-13 (May 2017)
  - Not well developed, lacks industry perspective
  - Primary focus on mandatory, fee-based, collective schemes
- Basel Secretariat **invites comments on the revised draft by November 30, 2017**
- **New guidance expected at COP-14 (2019)**

SAICM EPPP Initiative

- **S**trategic **A**pproach to **I**nternational **C**hemicals **M**anagement (SAICM): voluntary initiative organized by the United Nations Environment Programme
- Sep.–Oct. 2015: Adopted Environmentally Persistent Pharmaceutical Pollutants (EPPP) as an Emerging Policy Issue
- EPPP Work Plan originally expected in 2016 (overdue)
- Release of plan and regional work next year will likely raise the profile of EPPP issues among governments

UNEA-3 Meeting in December

- Pharmaceuticals are mentioned throughout **the UNEA report, Towards a Pollution Free Planet**, which is the major discussion document of the UNEA meeting in December
- Pharmaceuticals/antibiotics are identified as a major source of pollution resulting from manufacturing (see p.12)
- Pharmaceuticals (antibiotics, microorganisms) are identified as a source of land and soil pollution (focus on agriculture)(see p. 17-18 of the report)
- Pharmaceuticals are also mentioned as a source of freshwater pollution – "The increasing presence of pharmaceuticals, antimicrobials and new micro-pollutants in water are also emerging concerns (Hardell et al. 2003)" (see p. 22)
- An intervention point to address water pollution: "Reduce the use of antimicrobials, including antibiotics in the livestock sector, to avoid unintended releases into the environment and food chain . . ." (see p. 52)
- References to increased antimicrobial resistance.

Thank you!

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