

## A lower cost, business friendly environment - Reducing the regulatory burden

*Regulation is necessary for a well-functioning economy and society, but too often the first reflex of governments has been to regulate, adding layer upon layer of costs to business. The Government will remove inefficient regulation, simplify compliance and improve regulator responsiveness to help small and large businesses thrive. As part of the Government's Industry Innovation and Competitiveness Agenda, it is removing regulation that duplicates trusted overseas processes, except in cases where unique Australian regulations can be justified.*

### Accepting trusted international standards and risk assessments

To reduce duplicative regulation, the Government will adopt the principle that if a system, service or product has been approved under a trusted international standard or risk assessment, then Australian regulators should not impose any additional requirements for approval in Australia, unless there is a good and demonstrable reason to do so. This will reduce costs and delays for businesses, increase the supply of products into the Australian market and allow regulatory authorities to focus on higher priorities.

- ▶ As a first step, the Therapeutic Goods Administration (TGA) will enable Australian manufacturers to register routine medical devices using conformity assessment certification from European notified bodies.
- ▶ Similarly, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) will better utilise and increase its acceptance of international risk assessment materials from trusted overseas regulators. This will be part of broader reform to introduce a graduated, risk-based approach to the regulation of industrial chemicals, that will streamline (and, in the case of low-risk chemicals, remove the need for) the pre-market assessment of chemicals already authorised for use in comparable countries.

#### **Streamlining the assessment of industrial chemicals as part of the National Industrial Chemicals Notification and Assessment Scheme**

Australian chemicals regulatory arrangements are complex, involving some 140 pieces of legislation, multiple agencies, and numerous regulatory decision-makers at all government levels.

The Government intends to remove regulatory barriers to the introduction of lower-risk industrial chemicals already approved overseas, while allowing resources to be devoted to assessing higher risk industrial chemicals.

Portfolios and regulators will review Commonwealth standards and risk assessment processes and objectively assess whether unique Australian standards or risk assessments are needed.

To ensure a thorough review of all regulations, ministers will be asked to write to regulators in their portfolio and key business and other stakeholders seeking their views on each of their standards and risk assessment processes against this principle. Separately, stakeholders can submit examples of unnecessary divergence from international standards at [www.cuttingredtape.gov.au](http://www.cuttingredtape.gov.au).