KEY MESSAGES ON COMPULSORY LIABILITY INSURANCE FOR MANUFACTURERS OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTIC DEVICES

Insurance Europe supports the aim of the European Commission (EC) to create conditions for safe, effective and innovative medical devices and *in vitro* diagnostic medical devices and it fully embraces the objective of ensuring a high level of health protection for citizens. However, Insurance Europe is seriously concerned about the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee's suggested amendments introducing compulsory liability insurance for medical device manufacturers into the EC's proposals for Regulations on medical devices[1] and on *in-vitro* diagnostic devices[2]. Such EU-wide compulsory insurance would not, in fact, minimise the potential harm caused to consumers by these devices.

Insurance Europe would like to draw policymakers' attention to the negative effects that the introduction of EU-wide compulsory liability insurance could have for manufacturers of medical devices and for citizens.

An EU-wide compulsory insurance system will not prevent fraudulent cases such as the Poly Implant Prothèse (PIP) case

- Incidents such as the fraudulent PIP breast implant case should be prevented. However, an EU-wide compulsory liability insurance system is an ineffective response to the PIP case.
- Compulsory insurance will not provide the solution to cases similar to PIP for the following reasons:
  - Insurers do not cover the liability of perpetrators of crime, fraud or dishonesty against the acts they have committed.
  - To cover the above acts via liability insurance would enable criminals to be protected from their crimes. This has a wider implication for the public interest, as persons might be more inclined to commit such acts with the belief that they would be protected by insurance.
- The PIP case happened in a compulsory insurance regime that has been in place in France since 2002.
- In light of what is covered by product liability insurance, the PIP case clearly demonstrates that EU-wide compulsory insurance is not the appropriate solution for making medical devices safer throughout Europe and/or ensuring adequate compensation for personal injury arising from similar fraud.

Compulsory insurance will not improve the existing insurance cover for injured citizens

- Insurance plays a socially useful role in transferring the risk of damage caused by defective products in order to help ensure compensation to injured parties. Yet the existence (or non-existence) of insurance cover is not a factor in determining liability.
- Aside from cases of crime, fraud or dishonesty, which insurers do not cover, liability insurance will only cover product defect claims if the claimant can establish that:
  - the product was defective
  - the defect caused the harm
- Even if made compulsory, general product liability policies do not cover:
  - cases in which the manufacturer has behaved fraudulently or recklessly
  - cases in which the injury is caused by improper installation of the medical device by a third party (eg distributor, hospital staff) rather than the manufacturer
  - the basic costs of recall, such as withdrawing or repairing the device
  - the cost to the health systems for treatment, operations and diagnostic procedures for patients as a result of defective or malfunctioning medical devices (because these costs would surpass the insurance policy limit)

1 COM 2012 (542)
2 COM 2012 (541)

- Liability insurance policies are subject to financial limits and accordingly establish a maximum amount that can be paid during a determined period of time.

EU-wide compulsory insurance will not reflect the manufacturer's genuine risk and could lead to inadequate covers and higher costs

- EU-wide compulsory insurance can compel low-risk medical device manufacturers to purchase far more cover than necessary, as the mandated cover must accommodate all levels of risk and will thus factor in the highest-risk medical devices. The result will be a substantial increase in insurance premiums for low-risk medical devices and thus increase the cost of even the most basic medical devices, such as spectacles or knee braces.
- Under a compulsory system in the EU, some manufacturers may seek to distribute to non-EU areas where insurance is not compulsory. The outcome will be more limited choice of medical devices for European consumers.
- Any difficulty in obtaining the mandated cover will also hamper medical device innovation, thereby depriving consumers of the immense benefits of new and revolutionary products.
- The uptake of the insurance will need to be constantly monitored to ensure legal compliance with the compulsory law. The excessive and unnecessary costs of this bureaucratic monitoring will ultimately impact consumers via increased spending by public authorities.
- Under a voluntary insurance system, insurers can design insurance cover that most adequately reflects the manufacturer's risk profile. The benefit of tailor-made insurance products is particularly relevant for the medical devices sector in light of its heterogeneity, ranging from small exposures like disposable gloves to advanced devices such as medical implants.

The insurance market for medical devices is currently a functioning market

- EU-wide compulsory insurance is not only undesirable but also unnecessary. On a voluntary basis medical device manufacturers already can — and do — take out adequate insurance cover as a means of protecting themselves against possible claims.
- By setting mandatory standards that are configured at EU level rather than through individual risk assessments by insurance experts, compulsory insurance would disrupt a market that is currently functioning and offering risk-appropriate insurance cover.

Solution: Improving the safety of medical devices to ensure a high level of consumer protection

- The focus of the EU should be on ensuring the highest protection of consumers through the prevention of reckless and criminal acts involving the manufacturing and distribution of medical devices.
- Actions could include:
  - systematic control, approval and/or certification procedures by professional licencing authorities
  - harmonisation of device safety standard processes
  - high level of transparency about the prevention and safety measures introduced by manufacturers
  - enhanced vigilance and market surveillance
- Proper risk management processes should be relied on to ensure higher safety standards. **Insurance is not a substitute for the introduction of such safety measures.**
- A voluntary insurance system enables insurers to encourage their policyholders to engage in risk management in exchange for more favourable policy conditions. An EU compulsory insurance regime will remove this contractual flexibility.