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IPSEN'S COMMITMENT TO DEVELOPING AN ALTERNATIVE TO ANIMAL TESTING FOR ITS BOTULINUM TOXIN

Ipsen produces a prescription drug containing a botulinum toxin type A (abobotulinum toxin A). It is primarily used for the treatment of a wide range of neurological conditions in which patients can experience uncontrollable, severely debilitating and sometimes painful muscle spasms. Despite its indications in aesthetic medicine, this medicinal product cannot be considered a "cosmetic".

To ensure drug efficacy and patient safety, regulatory authorities worldwide request all manufacturers of botulinum toxins to establish the potency of each batch they release. The manufacturing process of each toxin is unique and results in a unique final product. Consequently, it is not necessarily possible to use the same test, without modifications, for two different toxins.

To date, animal testing assay is still the only approved method to establish the potency of Ipsen's toxin. Ipsen takes the issue of animal welfare very seriously and invests in R&D to end the use of animals for testing toxins.

It is our objective to replace existing methods for this medicinal product in the foreseeable future, whilst ensuring the highest standards of product safety.

To achieve this objective, Ipsen is leveraging all possible options to implement as quickly as possible an alternative to animal testing, including collaborative research and in-licensing of technologies. Ipsen maintains a constructive and fruitful dialogue with the regulators and is working hard to answer remaining questions.

Recent progresses on which Ipsen can communicate include the following:

- Since 2010, Ipsen has decreased by about 25% the number of mice used through the use of an endopeptidase assay;
- Since April 2011 Ipsen joined forces with another manufacturer of botulinum toxin to speed up the development process of an alternative to animal testing;
- In 2012 Ipsen entered the development stage for an in vitro cell-based assay (CBA) after demonstrating its feasibility by establishing a proof of concept;
- In 2014 Ipsen met with international regulatory authorities to minimise time for approval of its animal-free method;
- In 2015, regulatory authorities requested additional data before a final submission. Ipsen is producing additional elements to ensure a full regulatory submission in the shortest possible timeframe;
- Since 2013, Ipsen invested €28 million in a life-sciences company and developed its R&D collaborations to research and develop therapies based on engineered recombinant toxins, the development philosophy of which is to use in vitro potency testing only.