

Dear madam/sir,

As NVC Netherlands Packaging Centre (ID number: 42440258570-74) we would like to react to the Public Consultation on the Delegated Act on the Principles and Guidelines of Good Manufacturing Practice for Active Substances in Medicinal Products for Human Use.

The NVC Netherlands Packaging Centre is a unique association from the Netherlands that addresses packaging in an integral manner. With its network of 14.000 individuals and over 550 member companies, NVC is leading in education and training, proactive information services and in promoting joint sustainable innovation in packaging.

Consultation item No 1:

We agree to this appraisal and approach. It is very important to include active substances in the legislation for Good Manufacturing Practice (GMP) and authenticity of medicinal products. It is impossible to ensure a product is safe and authentic, without ensuring that the supply chain is secure and tamper proof. This means that all starting materials (including active substances) should be traceable and packaged in a tamper proof way to ensure the safety and authenticity thereof.

Consultation item No 2:

No comments

Consultation item No 3:

No comments

Consultation item No 4:

As stated under Consultation item No 1, we consider it very important to give attention to the use of packaging as a means to prove that a starting material is authentic and is safe. Options that can be considered to accomplish this are tamper evident packaging (i.e. tamper evident labels of packaging that can only be opened once) or active and intelligent packaging (i.e. RFID-tags and sensors). These are efficient methods of ensuring safety and authenticity. There should not be an obligation to use a certain type of solution, since the requirements can vary for different products and different supply chains.

Consultation item No 5:

Packaging is temporarily integrating an external function and a product to enable the use of the product. In the NVC Netherlands Packaging Centre vision, packaging should contribute to the sustainable development of society. In this context, the NVC focuses on market-oriented and

innovative activities for the benefit of the entire supply chain of packaged goods. This applies to the finished consumer products (including medicinal products), but also to all the ingredients (starting materials) in the supply chain. Packaging is an efficient and cost effective way to provide leverage in the distribution, protection and providing information about the product.

Kind regards,

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