

Health and Social Care Committee

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Follow up action: EU drugs approval process.

At the Committee's meeting on 8 December Mick Antoniw AM asked for information on the process by which drugs are approved within the EU.

There are two processes through which drugs can be authorised within the EU is explained on the [European Medicines Agency](#) web-site and this is reproduced below for ease of reference.

To note that the European Medicines Agency is a decentralised agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union, which fall within the scope of the centralised authorisation procedure (described below).

Extract from European Medicines Agency web-site:

...In the European Union (EU), medicines can be authorised by the centralised authorisation procedure or national authorisation procedures.

Centralised authorisation procedure

The **European Medicines Agency** is responsible for the centralised procedure for human and veterinary medicines.

This procedure results in a **single marketing authorisation** that is valid in all European Union countries, as well as in Iceland, Liechtenstein and Norway.

The centralised procedure is **compulsory** for:

- human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases;
- veterinary medicines for use as growth or yield enhancers;
- medicines derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- officially designated 'orphan medicines' (medicines used for rare human diseases).

For medicines that do not fall within these categories, companies have the option of submitting an application for a centralised marketing authorisation to the Agency, as long as the medicine concerned is a **significant therapeutic, scientific or technical innovation**, or if its authorisation would be in the **interest of public or animal health**.

Applications through the centralised procedure are submitted directly to the Agency. Evaluation by the Agency's [scientific committees](#) takes up to 210 days, at the end of which the committee adopts an **opinion** on whether the medicine should be marketed or not.

This opinion is then transmitted to the **European Commission**, which has the ultimate authority for granting marketing authorisations in the EU.

Once a marketing authorisation has been granted, the marketing-authorisation holder can begin to make the medicine available to patients and healthcare professionals in all EU countries.

- More information is available on the [regulation of medicines](#).

National authorisation procedures

Each EU Member State has its own procedures for the authorisation, within their own territory, of medicines that fall outside the scope of the centralised procedure. Information about these national procedures can normally be found on the website of the national medicine authority in the country concerned.

- [National competent authorities for human medicines](#)¹
- [National competent authorities for veterinary medicines](#)²

There are also two possible routes available to companies for the authorisation of these medicines in several countries simultaneously:

- **Decentralised procedure:** companies can apply for the simultaneous authorisation in more than one EU country of a medicine that has not yet been authorised in any EU country and that do not fall within the mandatory scope of the centralised procedure;
- **Mutual-recognition procedure:** companies that have a medicine authorised in one EU Member State can apply for this authorisation to be recognised in other EU countries. More information is available via the [Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human](#) and the [Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary](#).

In some cases, disputes arising in these procedures can be referred to the Agency for arbitration as part of a [referral procedure](#).

¹ The competent authority in the UK for human medicines is the [Medicines and Healthcare products Regulatory Agency](#), an executive agency of the Department of Health, based in London.

² The competent authority in the UK for veterinary medicines is the [Veterinary Medicines Directorate](#), an executive agency of the Department of Health, based in Surrey.