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As I said in Varna, Turkey has nothing to fear from its European neighbours.

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How are new medicines approved by EMA?

15/08/2018

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Find out what it takes to develop a medicine and to get it authorised

All medicines must be authorised before they can be marketed and made available to patients in the European Union (EU).

When all the relevant information has been collected from laboratory tests and clinical trials, the European Medicine's Agency's (EMA) scientific committees conduct a comprehensive scientific evaluation of the data and provide independent recommendations on medicines for human and veterinary use.

If the benefits of the medicine are greater than its risks, EMA gives the green light and recommends to the European Commission that the medicine can be marketed across the EU, as well as in the European Economic Area.

Once the medicine is on the market, the Agency continues to monitor its safety.

For an easy introduction to the evaluation and approval of medicines, watch this video.

[embedded content]

For further information, see our webpage on the authorisation of medicines in the EU.

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EIOPA publishes updated technical RFR documentation for the Danish krone and Denmark reflecting adjustments to the representative portfolios as well as the use of an option-adjusted Nykredit index

Today, the European Insurance and Occupational Pensions Authority (EIOPA) published an updated technical documentation for the calculation of the volatility adjustment to risk-free interest rates (RFR) for the Danish krone and Denmark. The risk-free rate methodology includes updated representative portfolios for the Danish krone and for the country portfolio of Denmark as well as the inclusion of option-adjustments.

The updates are based on the results of an in-depth analysis of the composition of the average Danish undertakings’ portfolio and the average Danish krone denominated (sub-)portfolio. The analysis provided further insight on the legal and economic background of the Danish covered bond market and confirmed that these assets dominate the relevant portfolios. To capture the features of Danish covered bonds in the risk-free rate methodology accordingly, henceforth an improved version (“option-adjusted”) of yield and duration data of a dedicated index for these contracts, the “Nykredit realkreditindeks”, is used in the production process of the risk-free rate.

In addition, to ensure consistency in the RFR calculation, assets reported by undertakings as being “unrated” were reallocated to the Solvency-II-inherent stepping of credit risk classes (Credit Quality Steps – CQS) by differentiating between financial and non-financial ones.

Furthermore, the technical documentation contains some minor amendments in the use of data fields of certain Markit iBoxx indices for the RFR calculation. These non-material changes for a limited number of corporate bonds were necessary to fully unify the concepts used across currencies and CQS.

The updates will be implemented with the upcoming risk-free rate production cycle for end-August 2018, to be published beginning of September 2018.

Background

Technical information relating to risk-free interest rate (RFR) term structures is used for the calculation of the technical provisions for (re)insurance obligations.

In line with the Solvency II Directive, EIOPA publishes technical information relating to RFR term structures on a monthly basis via a dedicated section on EIOPA’s Website also containing the release calendar for 2018, the RFR Technical Documentation, the RFR coding and Frequently Asked Questions.

By this publication, EIOPA ensures consistent calculation of technical provisions across Europe.

Representative portfolios are used for the calculation of the volatility adjustment to risk-free interest rates.

The information about the update of representative portfolios for the Danish krone and for the country portfolio of Denmark was published in March 2018.

The representative portfolios for all other currencies and countries are applied since end of March 2018 onwards, as announced in December 2017.

The ***volatility adjustments*** are derived from spreads of representative portfolios of assets. The representative portfolios are derived in accordance with Article 49 of Commission Delegated Regulation (EU) 2015/35.

The volatility adjustment is a measure to ensure the appropriate treatment of insurance products with long-term guarantees under Solvency II. (Re)insurers are allowed to adjust the risk-free interest rates to mitigate the effect of short-term volatility of bond spreads on their solvency position. In that way, the volatility adjustment prevents pro-cyclical investment behaviour of (re)insurers.

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