## The EU Pharmacovigilance Risk Assessment Committee: early year experiences

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The PRAC is central to the new EU pharmacovigilance framework. The European Committee mandated to handle a wide range of pharmacovigilance procedures means that EUpharmacovigilance has become truly European.It The workload of the new regulation has been challenging and the administrative burden has not yet been reduced. However, this is an important change in EU pharmaceutical sector since the creation of the EMEA.
The implementation of the EudraVigilance system to become the single point of receipt of adverse drug reactions and for the PSUR repository to become established and the creation of PASS and PAES will be of pivotal importance for a more comprehensive pharmacovigilance system.
The workload of the PRAC has increased significantly with an increasing number PSURs and RMPs each month. For the first time, a legal basis for a very important tool in pharmacovigilance – the signals – has been established. The PRAC has introduced a systematic evaluation process of all signals which are identified and – following an initial evaluation by the PRAC rapporteur – has sufficient strength to be prioritised for plenary discussion in the PRAC.