The Drug Commission of the German Medical Association (DCGMA) – How to make use of expert knowledge for the national pharmacovigilance system

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Background

In Germany, physicians are requested by their professional code of conduct to report adverse drug reactions (ADR) to the DCGMA. The DCGMA is a committee of the German Medical Association (GMA) focused on drug-related matters and is financed by the GMA and the National Association of Statutory Health Insurance Physicians (KBV). Approximately 170 members, mainly medical specialists from all areas of clinical medicine, serve on this commission (Figure 1).

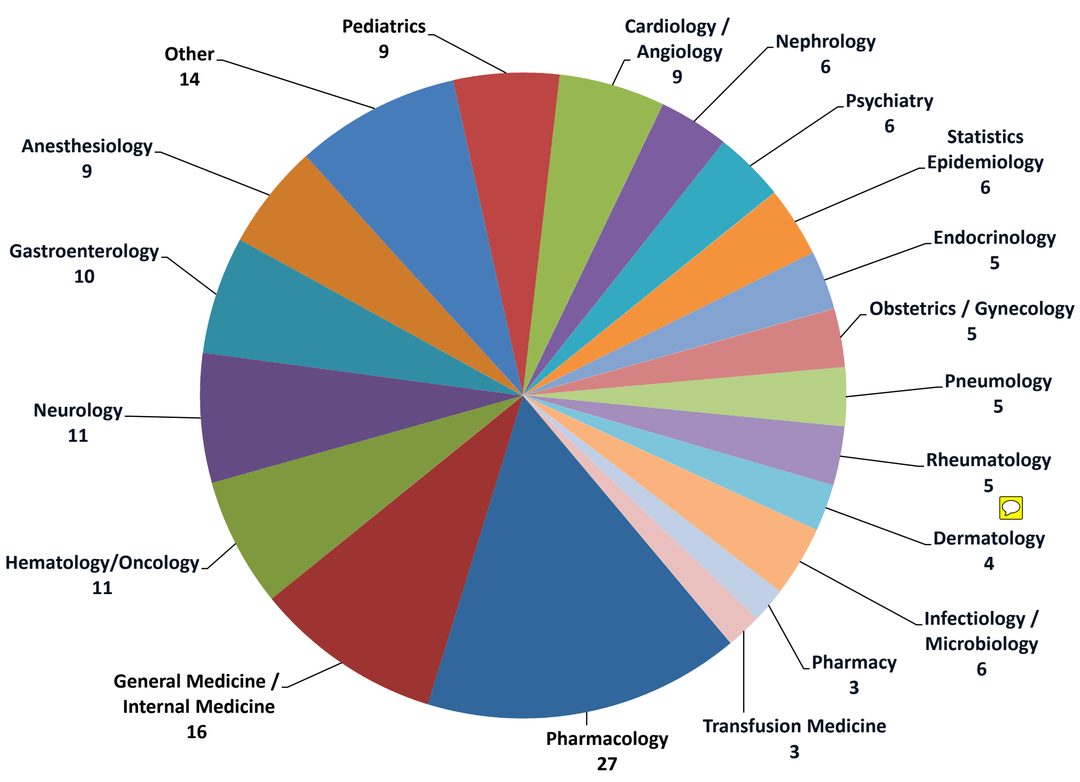

Figure 1: Medical specialties of the current members of the Drug Commission of the German Medical Association (n = 170).

The activities are organized and coordinated by the committee's offices in Berlin. The DCGMA has participated in the national spontaneous reporting system since the late 1950s and cooperates with the two national competent authorities (NCA) – the Federal Institute for Drugs and Medical Devices (BfArM) and the Paul Ehrlich Institute (PEI) – on a contractual basis. Individual case safety reports are exchanged between the institutions and experts of the DCGMA provide medical advice to the two NCAs in joint conferences (Figure 2).

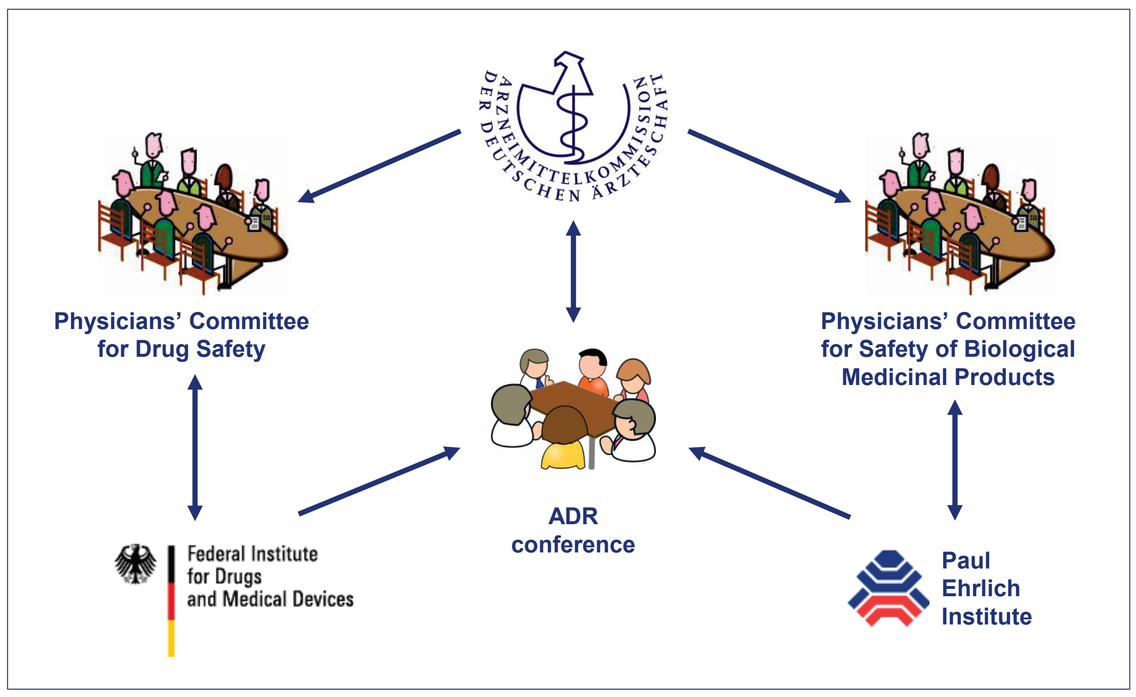

Figure 2: Cooperation of the DCGMA in pharmacovigilance with the German national competent authorities, BfArM and PEI

Incoming ADR reports are first assessed by medical specialists working in the DCGMA's central office. Cases are presented and discussed at weekly staff meetings. In complex cases, one or more committee members are asked to provide a scientific statement, including a detailed case assessment and recommendations on measures to be taken.

The pharmacovigilance forum of the DCGMA (ADR conference) is a subcommittee on adverse drug reactions that meets twice a year (Figure 3). The subcommittee consists of DCGMA members with special expertise in pharmacovigilance. Invited guests are representatives of the NCAs, a representative of the drug commission of pharmacists and a representative of the German poison information centers. In the meetings, complex cases are presented and discussed and a decision is made regarding further steps, e.g. publication of selected cases in the GMA's German Medical Journal (*Deutsches Ärzteblatt;* print circulation of 350,000) or the Journal of the DCGMA (available online). Discussions are held with representatives of the NCAs about whether or not regulatory measures would be appropriate for reducing risk.

In addition to the publications in these two journals, the DCGMA informs German physicians and the public about the assessment results and about other drug safety issues using an email service called Drug Safety Mail (about 14,000 subscribers).

Aim

To illustrate the role of the DCGMA in the German pharmacovigilance system and the outcome derived from the assessment of ADR reports submitted to the DCGMA.

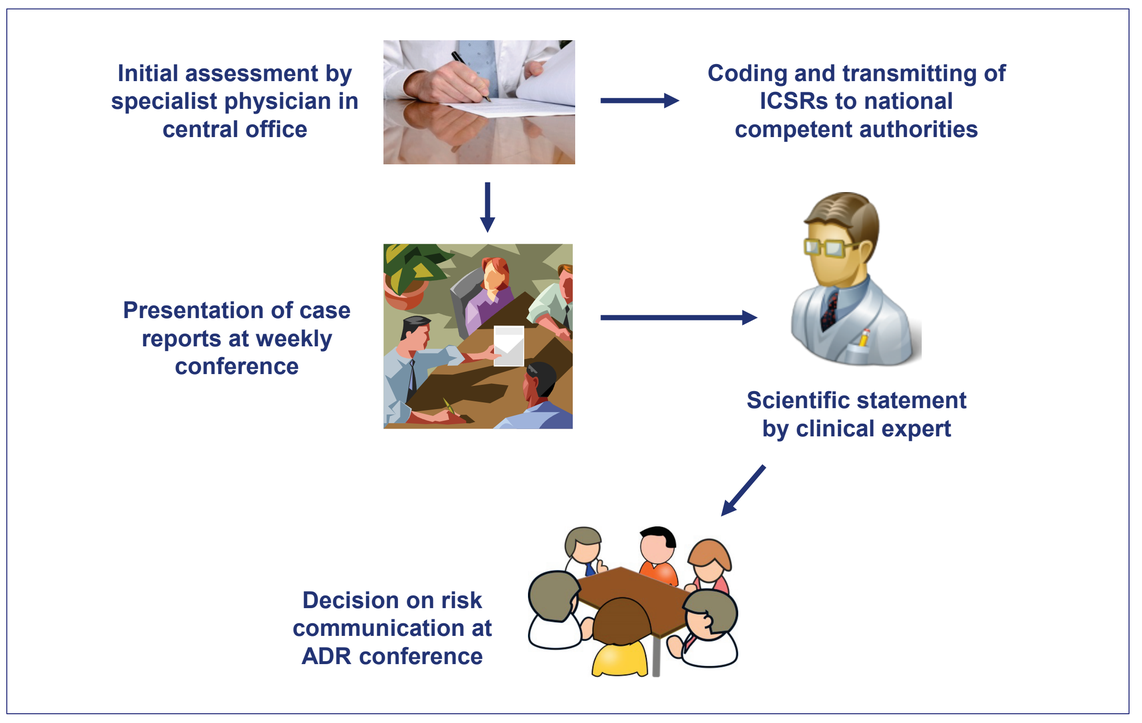

Figure 3: Assessment of ADR reports (individual case safety reports, ICSR) in the Drug Commission of the German Medical Association (DCGMA)

Methods

Data on pharmacovigilance activities from the ADR database, the archive and the website of the DCGMA from 2010 to 2014 were investigated.

Results

About 14,100 ADR reports were submitted to the DCGMA from 2010 to 2014. Two hundred six case reports were assessed in detail by clinical experts and 78 of these were discussed in the subcommittee. Thirty-five safety announcements were published in the German Medical Journal (*Deutsches Ärzteblatt*) and 259 Drug Safety Mails were sent out (Figure 4). Examples of published safety announcements are displayed in Table 1.

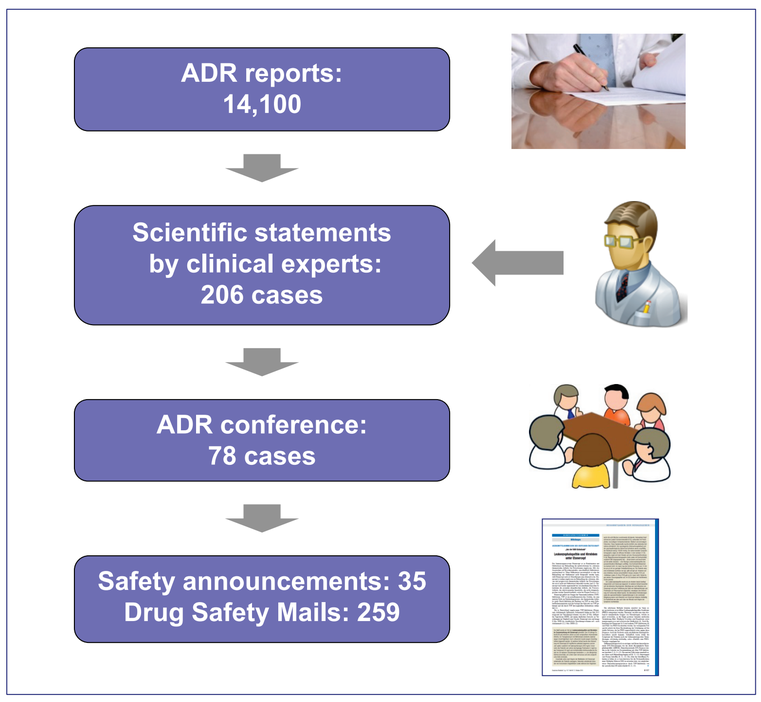

Figure 4: Processing and outcome of ADR reports submitted to the DCGMA, 2010–2014

Drug	Safety issue
Amygdalin / Laetrile	Cyanide poisoning in a child
Carboplatin	Coronary spasm
Combined hormonal contraceptives	Cerebral venous thrombosis
Exenatide	Pancreatic carcinoma
Fumaric acid	Acute renal failure Lymphopenia, Nocardiosis
Isotretinoin	Rhabdomyolysis Inflammatory bowel disease
Metamizole (Dipyrone)	Increase of reports of agranulocytosis
Metformin	Increase of reports of lactic acidosis
Pelargonium sidoides	Hepatitis
Phosphate-containing enema	Fatal hyperphospatemia in an infant
Pregabaline	Drug dependence
Temozolomide	Fatal hepatic failure Alveolitis
Zolmitriptan	Acute peripheral arterial occlusion

Table 1: Examples of topics derived from the ADR conference that were published in safety announcements in the German Medical Journal (*Deutsches Ärzteblatt*), 2010–2014

Conclusion

The DCGMA incorporates expert knowledge of medical doctors in the national pharmacovigilance system on different levels. Clinical experts are engaged in the assessment of single ADR reports. They also advise the NCAs on current drug safety issues. This concept of involving physicians and their clinical experience may serve as an efficient model for other countries as well.